Understanding how to recruit and retain participants to a Digital Health Intervention (DHI) for a unique service population

Shireen Patel, BSc, MSc.

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Abstract

Background

Health anxiety is a debilitating condition prevalent in primary and secondary care settings. Challenges to engaging individuals with health anxiety to cognitive behavioural therapy (CBT) led to the development of a remotely delivered Cognitive Behavioural Therapy (RCBT) randomised controlled trial (RCT) (the "Urgent Care trial") for the treatment of health anxiety for those accessing unscheduled care services. Whilst an RCT assesses overall effectiveness, the nested piece of qualitative research which forms this thesis is necessary to understand service provider and service user views of trial participation, given that recruitment and retention to trials remains a challenge.

Aims and objectives

The primary aim of this thesis was to understand factors influencing recruitment and retention to a Digital Health Intervention (DHI) trial from a service provider and service user perspective. The objectives of the thesis were:

1) To review the published literature on factors impacting recruitment and retention into depression, anxiety and somatoform DHI trials;

2) To explore service provider reasons for participating and referring patients to the Urgent Care trial, and

3) To understand service user reasons for participating and remaining or withdrawing from the Urgent Care trial.

Methods

This qualitative thesis comprises three work packages. In work package one a systematic review and meta-synthesis was conducted. Work package two consisted of interviews with 18 service providers from primary and secondary care services who had been invited to participate in the Urgent Care trial or who had been involved in referring or recruiting service user participants to

the trial. In work package three, 28 interviews were conducted with service users, randomised to one of two groups; Remotely Delivered Cognitive Behavioural Therapy (RCBT) and Treatment As Usual (TAU) in the Urgent Care trial. Data was collected using purposive sampling and analysed using Reflexive Thematic Analysis.

Results

The systematic review identified 15 studies. Three main themes were identified: 1) initial motivations and approaches to DHIs, 2) personalisation of treatment and 3) support to understand DHIs. Limitations of the review included no qualitative data on somatoform disorders being included, and the limited availability of research specifically focusing on recruitment to DHIs.
Analysis of the service provider interviews led to the identification of three main themes: 1) service provider understanding and perceived credibility of the trial over existing interventions**,** 2) perceived benefits and costs of trial participation, and 3) risk of the trial to the service provider-patient relationship.
Analysis of the service user data resulted in the identification of two main themes in relation to recruitment: 1) initial perceptions and its impact on motivation to participate, and 2) perceived credibility of the intervention over existing treatment pathways. Three main themes were evident in relation to retention: 1) research related aspects and its impact on therapy and questionnaire completion, 2) perceived change in circumstances because of study participation, and 3) DHI factors influencing retention to RCBT treatment sessions.
The findings from all three work packages indicated that the analytical themes could both be facilitators and barriers to recruitment and retention. The thesis offers a conceptual framework highlighting the contributions from existing theoretical models on innovation adoption (noting digital delivery of health interventions was considered an innovation at the time of data collection) and the additional novel contributions uncovered by this analysis. The major finding from this is the importance of personalisation and collaborative working when developing and delivering DHI trials.

Conclusions

By combining original, empirical qualitative data and existing knowledge on the reasons for innovation engagement and adoption, this thesis offers an original contribution in understanding the factors influencing recruitment and retention to a DHI trial for health anxiety, from both a service provider and service user perspective.

These results have implications for the future design of DHI trials to improve recruitment and retention rates in research studies. Future research should explore how the constructs identified from the theoretical models' impact recruitment and retention into DHI trials. This could involve exploring which aspects of a DHI trial are determined to be most influential in recruitment and retention, and if these are specific to DHI research, or research recruitment and engagement more generally. Further research on the unintended benefits of trial participation particularly when randomised to TAU also warrants further exploration.

Publications and presentations arising from this thesis

Peer Reviewed Publications

Patel S, Akhtar A, Malins S, Wright N, Rowley E, Young E, Sampson S, Morriss R. The Acceptability and Usability of Digital Health Interventions for Adults with Depression, Anxiety, and Somatoform Disorders: Qualitative Systematic Review and Meta-Synthesis. J Med Internet Res 2020;22(7):e16228 URL: https://www.jmir.org/2020/7/e16228. DOI: 10.2196/16228.

Malins S, Biswas S, **Patel S**, Levene J, Moghaddam N, Morriss R. Preventing relapse with personalized smart-messaging after cognitive behavioural therapy: a proof-of-concept evaluation. Br J Clin Psychol. 2020 Jun;59(2):241–59. https://doi.org/10.1111/bjc.12244.

Morriss R, **Patel S** Malins S, Guo B, Higton F, James M, Wu M, Brown P, Boycott N, Kaylor-Hughes C, Morris M, Rowley E, Simpson J, Smart D, Stubley M, Kai J, Tyrer H. Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat unscheduled care users with severe health anxiety: a multicentre randomised controlled trial. BMC Med. 2019 Jan 23; 17(1). https://www.ncbi.nlm.nih.gov/pubmed/30670044

Presentations

May 2019 – **Patel S**, Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat unscheduled care users with severe health anxiety. Oral presentation delivered at the Primary Care Mental Health Research Conference University of Manchester. Early Career prize winning abstract was selected to be presented as a plenary session.

May 2019, **Patel S**, Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat

unscheduled care users with severe health anxiety. Oral presentation IMH, University of Nottingham.

September 2019 – **Patel S**, Patient Experience of Remotely Delivered Cognitive Behavioural Therapy for Repeat Unscheduled Care Users with Health Anxiety. Oral presentation delivered as part of a symposium at the Annual BABCP Conference on patient experience of digital therapies, at University of Bath.

June 2018 – **Patel S**, Exploring the factors affecting recruitment and retention of service users and service providers in a remotely delivered Cognitive Behavioural Therapy (CBT) intervention for people with health anxiety. Oral presentation at the CLAHRC East Midlands Presentation Day.

May 2018 – **Patel S**, Bringing Health Research to Life: A Researcher Perspective. Oral presentation at the Community Partner's Orientation Event CLAHRC East Midlands.

June 2018 – **Patel S**, Helping Urgent Care Users Cope with Distress about Physical Complaints: A Randomised Controlled Trial. Study overview and findings. Oral presentation at the Network of Practice, presentation of findings dissemination event CLAHRC East Midlands.

March 2018 – **Patel S**, Helping Urgent Care Users Cope with Distress about Physical Complaints: A Randomised Controlled Trial. Oral presentation at a Research Seminar at Birmingham City University.

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I cannot believe that after 9.5 years I am finally submitting my PhD, it's been quite a journey! Getting married, turning forty, moving house three times, family deaths, new arrivals, Covid-19 pandemic, successfully managing two RCTs to completion -plenty of tears of both sadness and happiness!

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Chapter One: PhD Context and Aims

Introduction: Rationale for the thesis

In health services, unscheduled same-day care is defined as any unplanned contact with a health service by a person requiring or seeking help, care or advice (Huntley et al., 2014). Unscheduled same-day care is on the rise globally within both primary care and hospital settings, posing a significant challenge for health care systems (Van den Heede and Van de Voorde, 2016). One potential driver behind repeated instances of unscheduled care is severe health anxiety, defined as excessive preoccupations with health worries or a belief that one might have a serious physical illness (Salkovskis and Warwick, 1986)

Severe health anxiety is prevalent in health care settings, with lifetime occurrence rates of 8.5% in primary care and 24% in hospital clinics (Sunderland et al., 2013, Barrett et al., 2012). It can manifest in increased utilisation of unscheduled care for reassurance-seeking and medical investigations, or in delayed health care-seeking behaviours followed by emergency presentations due to anxiety-induced avoidance of medical attention. Moreover, it can exacerbate functional impairment, lead to extended sick leave, elevate the risk of cardiovascular disease and other chronic physical or mental health issues, and inflate health care costs (Barsky et al., 2001)

Although Cognitive Behavioural Therapy (CBT) is the recommended treatment for health anxiety, its uptake remains limited due to stigma, long waiting times and negative experiences with mental health services (Kirmayer and Looper, 2006, Tyrer et al., 2014). Remotely delivered CBT (RCBT) presents a potential solution to address these barriers, as it could improve accessibility, acceptability, and service capacity for individuals with health anxiety

The Helping Urgent Care Users Cope with Distress about Physical Complaints (Urgent Care) trial was a Randomised Control Trial (RCT) assessing the clinical and economic effectiveness of RCBT for the treatment

of health anxiety for repeat users of unscheduled care. The Urgent Care trial was considered a successful trial because the intervention showed clinical and cost effectiveness. However, the trial experienced delays in recruitment and a two-month extension were required to enable the trial to meet its recruitment target. Although 54 primary and secondary care services agreed to participate in the trial only 31 GP surgeries and four secondary care outpatient departments recruited service user participants. Furthermore, two participating GP surgeries accounted for 41% of the recruitment total. Out of the 524 service user participants referred to the Urgent Care trial 156 (30%) were eligible and randomised (Morriss et al., 2019). These findings suggest that recruitment to RCTs from a service provider and service user perspective is challenging and requires further exploration of the factors that may influence recruitment and retention to Digital Health Intervention (DHI) trials.

The thesis is divided into eight chapters.

The current chapter **(Chapter One)** provides an overview of the wider study context within which this PhD was conducted and outlines the aims and objectives of the thesis.

Chapter Two provides and overview of the literature pertaining to health anxiety, highlighting the challenges of defining health anxiety and the impact of health anxiety on wellbeing and associated economic costs. The treatment of health anxiety is considered and the potential for remotely delivered Cognitive Behavioural Therapy (RCBT) in overcoming barriers to accessing psychological therapy are presented.

Chapter Three critically reviews the literature exploring factors that influence recruitment and retention to Randomised Controlled Trials (RCTs). The theoretical models that could explain recruitment and retention to RCTs are presented along with the potential strengths and weaknesses.

Chapter Four includes a systematic review and meta-synthesis of the literature relating to the factors that facilitated and hindered service user recruitment and retention to Digital Health Interventions (DHIs) for depressive, anxiety and somatoform disorders.

Chapter Five describes the methodological approach used in the research and the tools used to collect data. The data collection process and methods of analysis are given in detail.

Chapter Six presents the data from interviews with service providers, their perceptions of the Urgent Care trial and the factors affecting their decisions to participate in the trial and refer patients are explored.

Chapter Seven illustrates the data from interviews with service users, their perceptions of the Urgent Care trial and the factors affecting their decisions to participate in the trial and remain in the trial are explore. Personal as well as contextual factors influencing their perceptions are explored.

Chapter Eight discusses and concludes the study and takes a reflexive look at the study process. The strengths and limitations of the study are described and recommendations for future work are also included.

Aims of the Thesis

Using qualitative methods, this PhD aimed to address the following overarching aim: To explore and understand the factors that affect recruitment and retention of service users who regularly accessed urgent same day health care services for health anxiety and service providers who were involved in their care into a DHI trial for health anxiety management.

The specific research questions (RQs) of the thesis were:

RQ1- What are the factors reported in previous research affecting the recruitment of participants into depression, anxiety and somatoform DHI trials?

RQ2- What are the factors influencing service providers decision to participate in the Urgent Care trial?

RQ3- What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?

RQ4- What are the factors influencing service user participants decisions to participate in the Urgent Care trial?

RQ5- What are the factors influencing service user participants the decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial?

The overall aim of the doctoral thesis was to contribute new knowledge towards the wider understanding of recruitment and retention in Digital DHI trials, and the potential strategies that could be implemented to address recruitment and retention challenges. This thesis seeks to explore and understand the factors that affect recruitment and retention into a RCT for service users who regularly accessed urgent same day health care services for health anxiety and service providers who were involved in their care within the context of the Urgent Care trial. As such, it is important to understand the design of the Urgent Care trial to understand the context in which the qualitative study (thesis) was conducted.

PhD Context- The 'Helping Urgent Care Users Cope with Distress about Physical Complaints (Urgent Care) Trial

The Helping Urgent Care Users Cope with Distress about Physical Complaints ("Urgent Care trial") was a three-year NIHR ARC East Midlands funded randomised controlled trial (RCT).

The Urgent Care trial set out to 1) assess the clinical and cost-effectiveness of Remotely delivered Cognitive Behavioural Therapy (RCBT) via videoconferencing or telephone to repeat users of unscheduled care with severe health anxiety compared to usual care and 2) explore the feasibility and usefulness of research on implementation processes by identifying the barriers and enablers to delivering such remote treatment and how such treatment might fit into a wider care pathway to enhance patient experience of care.

Urgent Care trial methods

In this section of the chapter, additional relevant detail about the design of the Urgent Care trial and the intervention is presented, before moving on to discussing in greater detail the unique contribution that this PhD research had in relation to the trial, and how this sits within the context of the Urgent Care trial.

Table 1 illustrates that determining the eligibility criteria of potential participants required a degree of clinical judgement by service providers prior to referring service users to the Urgent Care trial. Service providers were required to identify and then explain health anxiety to their patients. However, this necessitated a degree of familiarity and sensitivity, as health anxiety is infrequently recorded as a diagnosis in patient medical notes. Therefore, patients may not have previously been informed that their symptoms may be attributed to health anxiety.

Participant flow of the Urgent Care trial is detailed in Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) diagram outlines exclusions at the various stages of recruitment and the allocation ratio for the respective trial interventions.

To undertake the qualitative studies which formed part of the thesis, I wished to interview service users and service providers who were invited to take part in the Urgent Care trial to explore how they made the decision to accept or decline participation in a trial for health anxiety, and what aspects made them remain or withdraw from the trial and/or the intervention. Thus, the nested thesis includes a sub-sample of service users who were approached to participate in the Urgent Care trial. Table 1 details the trial's design using the PICOS framework.

Table 1 Trial design

Participants	**Inclusion criteria:** • Aged 18 years and over • Two or more unscheduled consultations with any health care provider in the last 12 months • Met criteria for clinical severity of health anxiety (a score of 18 or above on the 14-item Short Health Anxiety Inventory (SHAI) • Had sufficient understanding of English to engage with the intervention **Exclusion criteria:** • At immediate risk of harm to themselves or others • Had moderate to severe learning disability • Serious mental or physical illness, including substance use disorder
Intervention	Remotely delivered Cognitive Behavioural Therapy (RCBT)
Comparison	Treatment as Usual (TAU)
Outcomes	Primary outcome (collected at 6 months) Health anxiety severity recorded using the Short form version of the Health Anxiety Inventory (SHAI) Secondary outcomes (collected at 12 months) Health anxiety (*SHAI) Generalised anxiety GAD-7) Somatic symptoms (PHQ-15) Depression (PHQ-9) Work and social functioning (WSAS) Health related quality of life (EQ5D-5L, SF-36) Health care service use (CSRI)
Study Design	RCT

*SHAI = Short form Health Anxiety Inventory; PHQ-15 = Patient Health Questionnaire-15; PHQ9 = Patient Health Questionnaire-9; WSAS = Work and Social Adjustment Scale; CSRI = Client Service Receipt Inventory; EQ-5D = EuroQol-5D; GAD-7 = Generalised Anxiety Disorder; SF-36 = Short Form-36

Figure 1 shows, that between November 2014 and December 2016, of the 524 patients referred to the study and assessed for eligibility, 470 were eligible and 156 (33%) participants were recruited. Seventy-eight participants were allocated to each of the RCBT and TAU arms. Of the 368 referred who did not take part in the trial 15% did not meet the eligibility criteria and almost 50% declined participation or did not attend the baseline assessment. Despite numerous attempts to do so, the remainder were unable to be

contacted by the research team. These figures suggest that following referral, many service users decided not to participate in the Urgent Care trial. This warrants further exploration from both a service user and service provider perspective. Figure 1 also illustrates that the follow-up rates for both groups were comparable suggesting that despite not receiving the intervention service users still completed outcome assessments. These findings may be important to explore given that RCTs are the gold standard of research to determine effectiveness/efficacy, but they often face recruitment and retention challenges especially when evaluating mental health interventions (Liu et al., 2018).

Urgent Care trial intervention

An established CBT for health anxiety treatment protocol was adapted for remote delivery through collaboration between two Patient and Public Involvement and Engagement (PPI/E) representatives and a CBT therapist (Tyrer et al., 2011, Tyrer et al., 2014, Patel et al., 2016). Treatment included identification of key beliefs and assumptions about health and illness, followed by testing and evaluation of beliefs using behavioural experiments. Potentially problematic anxiety-maintaining cognitive and behavioural strategies, such as repeated reassurance-seeking or body checking, were collaboratively identified and reduced or stopped (Malins et al., 2020).

Between six and 12 sessions of CBT were offered, with up to three booster sessions if required. This was determined based on the trajectory of symptomatic improvement. If their symptoms were improving slowly but they had reached six sessions, further sessions were offered to continue progress up to a maximum of 12 sessions in the CBT course. At a booster session two further sessions were added if there were symptoms suggestive of a worsening of health anxiety to prevent relapse. The initial series of sessions included an initial ‘setup’ meeting, during which the methods used to adapt CBT to remote delivery were discussed and any concerns about this method were addressed. Participants were free to continue to consult their usual

health care providers, other than a CBT therapist, throughout the intervention delivery and after the treatment was completed.

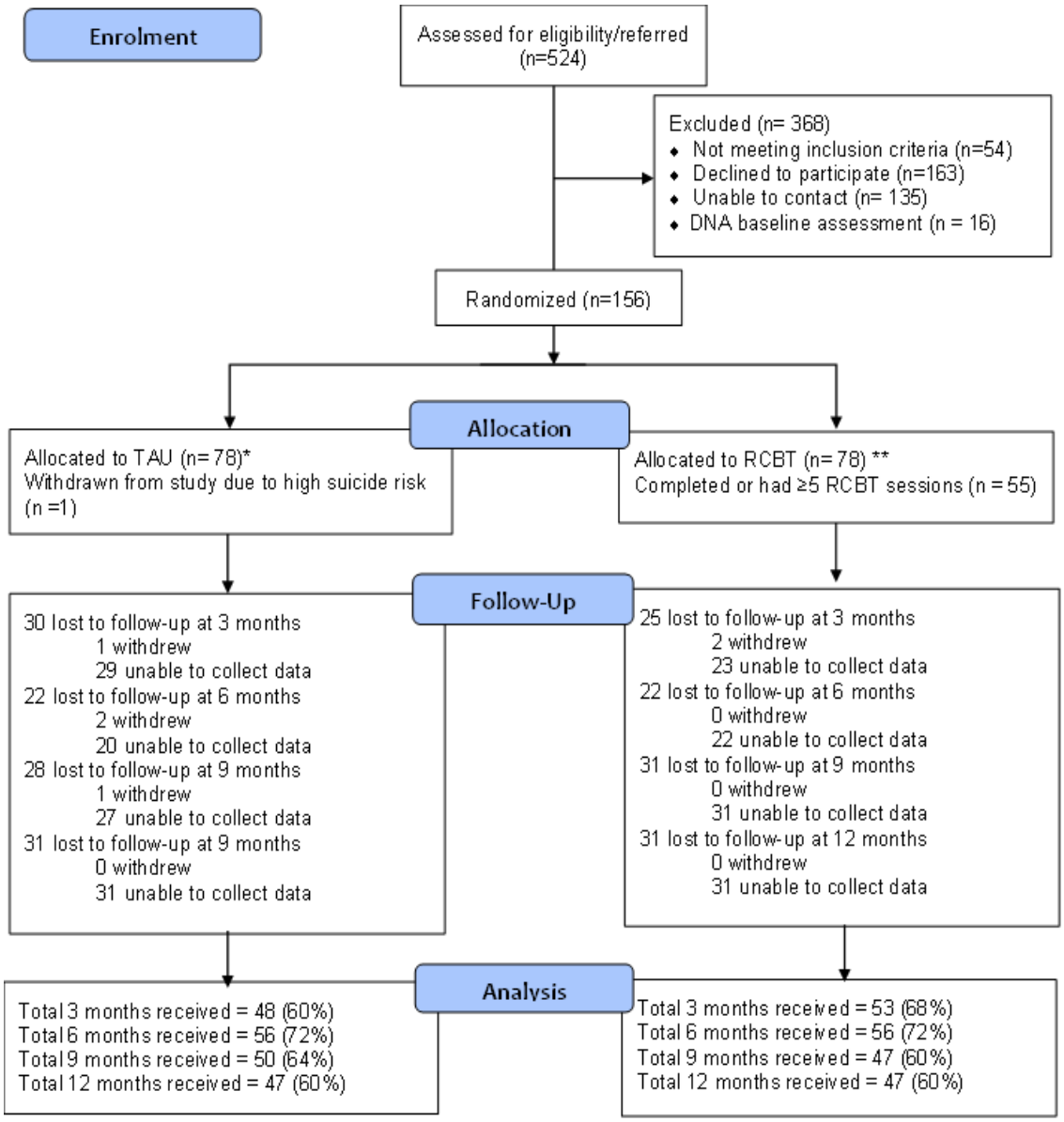

Figure 1 Consort diagram: participant flow into randomised controlled trial

*There was one randomisation protocol violation. One participant who was allocated into TAU by the randomisation system was accidentally sent the incorrect treatment allocation letter resulting in them receiving the remote CBT therapy. This error was identified following the completion of treatment. The participant completed outcome data only at 3 months.

** There was an enrolment protocol violation. Two participants in the RCBT group did not meet the criteria of ≥18 on the SHAI. This error was not identified until final analysis and as such both participants were included in the analysis.

RCBT was delivered via a videoconferencing system called WebEx or by telephone, depending on the participant's preference. It is important to note that the Urgent Care trial was conducted prior to the Covid-19 pandemic. Data was collected pre-Covid19 pandemic, when telehealth care delivered via videoconferencing was still in its infancy and not routinely adopted by NHS Trusts. It was at a time when remote health care consultations in mental health services were uncommon, not routinely offered and there were few videoconferencing platforms available with even less that met NHS information technology governance standards. Pre Covid-19 pandemic remotely delivered therapy was considered more as a fall-back - a second choice, and only to be offered in the absence of the availability of face-to-face therapy. Post Covid-19, most of the therapy offered by Improving Access to Psychological Therapies (IAPT), now known as NHS Talking Therapies is online using videoconferencing. Service providers and service users are more familiar and accustomed to using remote consultations in health care. There is also greater choice in terms of the videoconferencing platforms such as Microsoft Teams and Zoom, both of which are widely used by health care professionals, academics and service users.

WebEx was selected because of connection security and interactive utilities enabling an experience close to face-to-face CBT. At the time of assessment, compared to eight other piloted systems (see Table 2 below), WebEx was also comparatively cheaper, and thus more likely to have been adopted by NHS organisations, and passed NHS governance checks, which at the time, systems such as Skype, did not. Permission was sought to record audio/video treatment sessions. These recordings were accessible to participants after sessions, as a means of consolidating learning from each session.

Table 2 Comparison of videoconferencing systems

	Must have	Skype	Lync SP	Saypage	Vesee	Citrix Go to Webinar	Red Embedded SP	Polycom	WebEx
Functions: video recording, chat/IM, file sharing, apt reminder via email/text message	 Yes Yes Desirable	 ✓ ✓ X	 ✓ ✓ ?	 ✓ ✓ ✓	 ✓ ✓ X	 ✓ ✓ ?	 ? ? ?	 ✓ ✓ ?	 ✓ ✓ X
Platforms: mobile, tablet, PC,	 Yes Yes Yes	 ✓ ✓ ✓	 ✓ ✓ ✓	 ✓ ✓ ✓	 ✓ (I phone) ✓ (ipad) X	 ✓ ✓ ✓	 X X X	 ✓ ✓ ✓	 ✓ ✓ ✓
Session requirements: time/date recording, pausing, scheduling (meeting room/virtual waiting room), rescheduling	 Yes Yes Desirable	 ? (need App) X X	 ✓ X X	 ✓ ✓ ✓	 ? ✓ ✓	 ✓ X X	 ? ? ?	 ✓ ✓ ?	 ✓ ✓ ?
IG: Privacy, Data security, Data location, HIPAA as well as Data protection act?, ownership of data	 Yes Yes Yes ? Yes	 X X X X N/A	 ✓ ✓ ✓ ? ✓	 ✓ ✓ ✓ ✓ ✓	 ✓ ✓ ✓ ✓ ✓	 ✓ ✓ ✓ ? ✓	 ✓ ✓ ✓ ? ✓	 ✓ ✓ ✓ ✓ ✓	 ✓ ✓ ✓ ? ✓
Network: Broadband speed, N3 compatibility	 Desirable Yes	 ✓ X	 ✓ ?	 ✓ ✓	 ✓ ?	 ✓ ?	 ✓ ✓	 ✓ ✓	 ✓ ?
Usability: therapist, service user No software download	 Yes Yes Desirable	 ✓ ✓ X	 ✓ ✓ ✓	 ✓ ✓ ✓	 ✓ ✓ X	 ✓ ✓ ✓	 ✓ ✓ X installation of box	 ✓ ✓ X	 ✓ ✓ ✓
Costs: capital outlay, ongoing/subscription,	Desirable	Free	Free for UoN	Monthly	Monthly	Monthly	Monthly per pt	Bespoke (annual subscription)	Monthly

An established smart-messaging system was used to develop the post-treatment messaging intervention (http://www.simple.uk.net/). This smart-messaging system was already employed across several different health services to help people manage their health long term (Malins et al., 2020).

A relapse prevention plan was developed in the final two CBT sessions. This covered aspects such as using template worksheets participants and therapists first to identify characteristic patterns of responding for the individual patient when: (1) doing well, (2) experiencing early warning signs of relapse, and (3) experiencing full relapse. These included patterns of thought, behaviour, and characteristic emotional responses. Secondly, the participant was asked to imagine themselves in 3–6 months' time: (1) doing well, (2) experiencing early warning signs of relapse, and (3) experiencing full relapse. The participant was then asked what advice or actions they would suggest if they were able to send themselves a text message under each of these three circumstances. The patient and therapist then collaboratively developed a series of brief advice messages for each of the three levels using the learning gained from CBT sessions. Participants were asked if they wished to have elements of their relapse prevention plan sent to them in text messages after CBT sessions had finished.

My role in the Urgent Care trial

The Urgent Care trial commenced in January 2014. I was the Operational Lead Researcher, and my role involved the management and co-ordination of the trial, which consisted of obtaining approvals to commence the trial and setting up NHS sites. I also supported the recruitment and follow-up assessments of service user participants to the trial. At all times during data collection, I was blinded to treatment allocation. In October 2014, alongside the management of the trial I commenced a part-time PhD.

Urgent Care trial- Recruitment methods

Research participation in primary and secondary care can involve up to four stages:

1) Clinicians agreeing to participate in the research.
2) Clinicians recruiting or referring patients.
3) Patients agreeing to take part in the trial.
4) Patients remaining in the trial.

Before presenting a summary of the trial findings I will describe the methods utilised to recruit service providers and service users into the Urgent Care trial.

Service provider recruitment

Service providers became aware of the trial in several ways. Being the lead researcher for the trial, initially I contacted three sites via email to inform them about the study and asked if it was something they would be keen to be involved in. These sites were contacted because I had previously worked with them on other research projects. I contacted two GP surgeries and an Emergency Department (ED). All three sites expressed an interest in the trial and as such I arranged face-to-face meetings with the sites. I recognised the importance of setting up an initial face-to-face meeting with sites to introduce the trial and the study team. The meetings were attended by me, the lead Cognitive Behavioural Therapist and the Chief Investigator for the trial. GPs, Practice Managers, and receptionists attended the meeting at the GP surgeries, whilst the meeting was attended by two research nurses in the ED.

The trial was presented in the form of a PowerPoint presentation, providing an overview of the importance of the research and its clinical relevance, an explanation of the randomisation process and the potential benefits of the trial. We highlighted the benefits of participating in the research e.g. providing their service users with a remotely delivered form of psychological treatment for health anxiety. The meeting also highlighted the trial processes and the requirements from the service providers, clarifying all roles and responsibilities. Health care professionals were provided with the opportunity to ask questions and raise any queries. They were also informed that each participating site would receive £75 for each service user they recruited to the study. This was to reimburse recruiting sites for their time. GP surgeries

require financial incentives to participate in research as GPs are private providers contracted to the NHS. Staff time spent on research is costed in a similar way to time and resources spent on other clinical and non-clinical duties such as teaching. Therefore, money is paid to GP surgeries for recruitment into research. In hospitals, staff are employed directly by the NHS but the cost of staff time that might be used for research duties is costed and paid to the NHS organisation. In either case, the staff members do not get paid this incentive into their own salaries.

These meetings were held before ethical approval for the trial was sought. This was important as it enabled the Urgent Care trial research team to consult with the service providers with regards to their views on referral approaches, which ensured that the referral and recruitment approach was deemed to be appropriate by the service providers. The GP surgeries expressed that within their practice an opportunistic approach would be the most appropriate referral method. This approach was perceived to be straightforward and required minimal input from GPs, as they only had to obtain verbal consent from participants that they were happy to be contacted by the research team, and then share contact details with the study researchers.

The ED nurses consulted with their team at their research meeting where the difficulty in recruiting this group of patients was highlighted. Within ED it was identified that a direct face-to-face approach would be challenging because it implied that a diagnosis of nothing abnormal found would need to be given. In practice, within ED this was not common as most consultations would result in a diagnosis of some sort being given. Therefore, it was suggested that to identify patients in ED, a retrospective screening of patient records to identify potentially eligible participants would be the most suitable recruitment approach. Following identification of these patients, a letter of invitation, participant information sheet and a consent to contact form would be posted out. Those interested would be asked to complete the consent to contact form and return it in the pre-paid envelope provided. Research nurses would also follow-up all patients invited a week later via telephone.

The difference in preference for referral approaches highlighted the heterogeneity in practice across sites often experienced when conducting multi-site research, particularly where sites may be representing different sectors of health care (e.g. GP surgeries vs ED). This reinforces the need for researchers to understand the context into which they are working, and to be adaptive and offer some degree of flexibility in trial processes. Following alterations based on the feedback received from the practitioners, the study protocol and supporting documents were finalised and ethical approval for the Urgent Care trial obtained.

The Urgent Care trial was adopted onto the NIHR Clinical Research Network (CRN) portfolio. This meant that the CRN would support the research team in terms of releasing their staff to support the trial with the promotion or recruitment of participants. The trial was subsequently promoted on CRN study websites and GP surgeries were asked to express an interest in the trial. The Urgent Care trial researchers usually heard about GP surgeries expressing an interest in taking part in the trial via a member of staff from the CRN. Within the CRN, sites that are enrolled on the Research Sites Initiative scheme are provided with funding to establish and maintain their infrastructure to enable them to deliver NIHR portfolio adopted research. Practices can apply for three different levels of funding: Level 1 - £1,500, Level 2 - £4,000 and Sessional - £15,000. Based on the level of funding they apply for; GP surgeries are provided with a performance criteria that they must try and achieve. The CRN staff would inform me of any interested sites and provide their contact details, usually this would be an email address for the Practice Manager. I would contact the sites via email and try and arrange site initiation meetings with the GP surgeries. An introductory email was sent to all sites that expressed an interest in hearing more about the Urgent Care trial, consisting of a brief overview of the study and attempts were made to arrange a face-to-face site initiation visit. At these visits the study team would provide a rationale for the trial and advise on the level of commitment required for trial participation from a service provider and user perspective.

Where possible, a member of staff at each recruiting site was designated as the main point of contact who would liaise with the lead researcher via email

or telephone with referrals and any queries. We regularly obtained feedback from primary care staff with regards to any challenges experienced in referring patients. We sent out quarterly newsletters to participating sites updating them on recruitment progress and commending top recruiting sites. Towards the end of trial recruitment, a competition was held, in which the top three recruiting sites received a Christmas hamper.

The recruitment target for the Urgent Care trial was 144 participants with the trial expected to complete recruitment by 31st October 2016. However, by the end of September 2016, 105 participants had been recruited. Therefore, the research team requested a two-month extension which was granted. By 31st December 2016, 156 participants were recruited enabling the Urgent Care trial to meet the sample size target. Figure 2 describes the referral processes.

Service user recruitment

The initial approach to service users asking them to consider participating in the trial was from the referring clinicians (opportunistic or mail-out as described above). Upon receiving verbal or written consent to be contacted, the initial communication with interested participants by the researchers was in the form of a conversation over the telephone. The researcher explained that they (service user) had been referred to the study because they had been experiencing physical symptoms and associated distress, and that talking therapy via videoconferencing or telephone may help to manage this distress. Participants were informed that the study was an RCT, and what this meant for them i.e. they had a 1 in 2 chance of receiving the RCBT intervention and that the study was being offered as an additional source of support, rather than replacing or restricting their current health care use. At no point were participants advised that the study aimed to reduce service use. Potential participants were offered the opportunity to ask questions and express any initial concerns.

Potential participants expressing an interest in the trial were then asked if they were happy to complete the short form health anxiety questionnaire

over the phone to determine eligibility. If eligible, a time and place to conduct the baseline assessment was arranged. This was completed over the phone or in person. Verbal and written consent was received at this baseline assessment interview. Following assessment and confirmation of eligibility, participants were randomly allocated to one of two treatment arms: RCBT in addition to usual treatment, or treatment as usual (TAU).

The responsibilities of the study researchers included making initial contact with potential participants, determining eligibility, and conducting baseline and follow-up assessments. Therefore, they played a key role in participant recruitment and retention as they communicated with participants from initial contact to collection of the final assessment. All researchers had good knowledge of the trial. They individualised their communication style to the needs of the participants. Study researchers informed participants about the potential benefits and costs involved in taking part in the trial and highlighted that participation was voluntary and would not affect their usual care in any way. Study researchers dedicated additional time to speak to the participants and listen to their experiences.

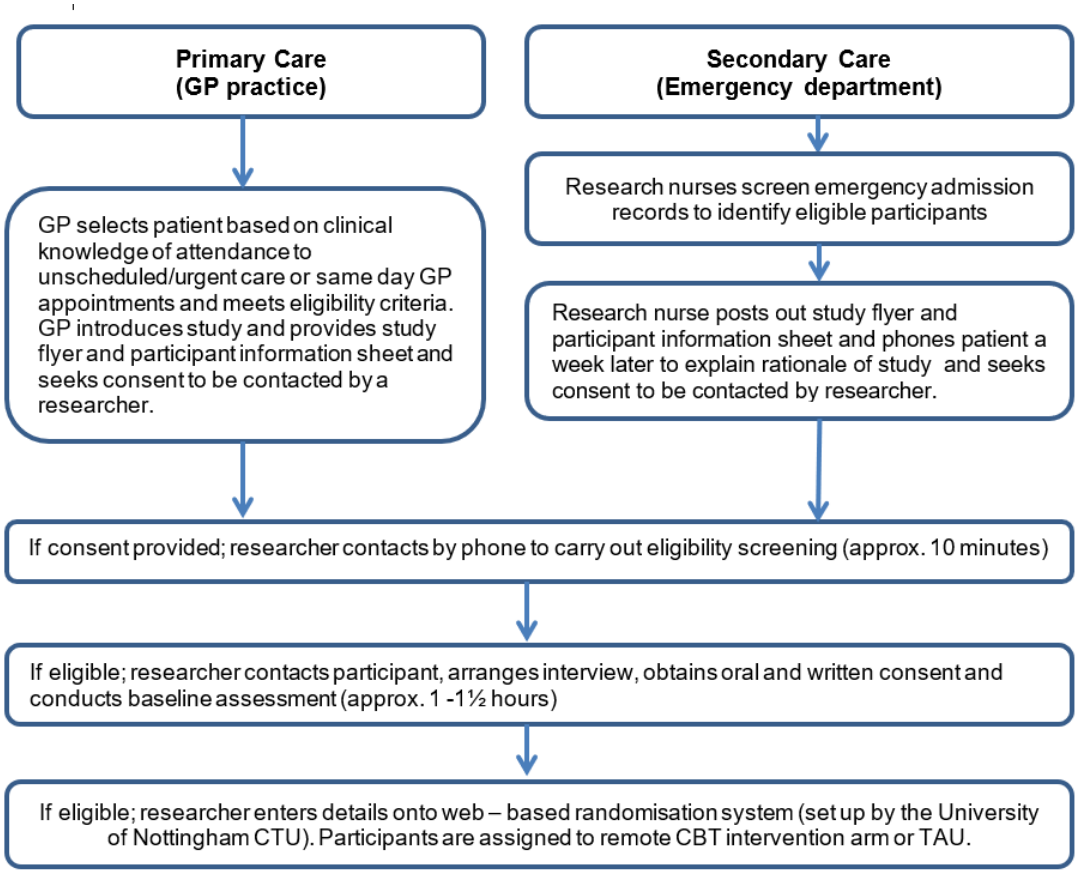

Figure 2 Urgent Care trial referral processes

Follow-up assessments were intended to be simple and concise, requiring minimal time commitment from participants. These were completed either with the researcher face-to-face, over the telephone, emailed or posted out to the participants depending on their preference. Study researchers were flexible, offering assessments outside of their working hours to accommodate participant needs. This included assessments in the evenings and occasional weekend working. Where possible, the same researcher conducted the baseline and follow-up assessments to ensure continuity. All participants were contacted via text message a week prior to their follow-up assessments being due to arrange a time for this. If participants did not respond, two reminder texts were sent out followed by a phone call if no response was received. Following completion of each assessment participants were posted out a £5 gift voucher for each assessment completed as a token of appreciation for their time.

Urgent Care trial- Patient and Public Involvement and Engagement (PPI/E)

The principles of co-production were utilised by developing a network of Patient and Public Involvement and Engagement (PPI/E) representatives, health practitioners and researchers contributing at all stages of the study including study design, recruitment, RCBT delivery methods and interpretation of results. PPI/E representatives were integral in helping to shape the study design and the development of the study. They attended all study team meetings and dissemination events and played an essential role in enabling the study to be meaningful and sensitive to the needs and views of its participants. PPI/E input was at all stages of the research, from proposal to dissemination.

Summary of Urgent Care trial results

The main trial findings are outlined below:

- At the 6-months follow-up time-point, participants in both arms showed a reduction in health anxiety, suggesting that there were benefits from taking part in the study for both treatment groups. Participants in the RCBT arm showed a significantly greater reduction in health anxiety symptoms (mean change difference at six months –2.81 95% CI –5.11 to –0.50; P = 0.017), showing a clinically and statistically significant difference between the two groups.
- The reduction in health anxiety and significant differences between the two groups was maintained at 9 and 12 months, suggesting the longer-term benefits of RCBT for the treatment of health anxiety.
- Participants in the RCBT arm also showed statistically significant greater reductions in generalised anxiety (GAD-7) at 6 and 12 months, depression (PHQ-9) at 12 months and improvements in overall health (VAS) at 12 months.
- No statistically significant differences were found in number of somatic symptoms (PHQ-15) or occupational and social functioning (WSAS)

between the two groups at any time point, but both groups showed an improvement on these measures over time.

- There were reductions in the overall contacts with health care services for participants in both groups, with a significant difference in the mean cost of inpatient hospital use (P = 0.031) between the two groups.
- The mean cost of providing RCBT was calculated at £531.80 (95% CI £466.80–£597.80). Including the cost of providing RCBT, the mean overall cost saving per patient over 12 months with RCBT, health care, medication, travel and informal care costs was £1,064 (95% CI –£845–£2973, P = 0.269).
- Participant completion of RCBT or attending 5 or more sessions was 71%. 47 (60%) received sessions via WebEx, 20 (25%) had sessions over telephone and 11 (14%) received no sessions.
- Overall, 72% of participants in both arms completed the 6-month follow-up primary outcome.
- The findings of the trial have been published and provides a more detailed account of the findings. This can be accessed via: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-019-1253-5.

Contribution of this PhD

Using a qualitative design, this thesis explores the barriers and facilitators to engaging service providers and service users into the Urgent Care trial. Table 3 summarises the additional contribution of this PhD research, compared to the research conducted as part of the Urgent Care trial.

This PhD consists of three component parts:

Firstly, I developed and conducted a systematic review and synthesis of the qualitative literature exploring the aspects that impact on service users' decision to participate (recruitment) and continue with (retention) digital health interventions (DHIs) for depressive, anxiety and somatoform disorders (Chapter Four).

Secondly, I conducted individual qualitative participant interviews (Chapter Six) with service providers to explore differences in clinician's decisions to participate in the trial intervention (recruitment) and explore factors facilitating or hindering referral of patients (retention).

Thirdly, I conducted individual qualitative participant interviews (Chapter Seven) with service users to explore individual variation in decisions to participate in the Urgent Care trial (recruitment), and individual disparity in treatment and/or trial completion or withdrawal (retention).

Table 3 Contribution of this PhD research to the wider Urgent Care trial

	Urgent Care Trial	**PhD study**
Aim	To evaluate the clinical and cost-effectiveness of RCBT for urgent care users with severe health anxiety.	To explore service provider and service user experiences and decision-making processes in trial participation. To understand how service providers and service users reached the decision to continue or discontinue participation in the trial.
Sample	156 service users with health anxiety.	18 service providers who were invited to be involved in the Urgent Care trial. 28 service users with health anxiety who participated in the Urgent Care trial.
Study design	RCT	Qualitative study
Data collection methods	Standardised questionnaires	Semi-structured interviews
Data Analysis	Multi-level modelling	Reflexive Thematic Analysis

Chapter Summary

RCBT offers a promising treatment option for health anxiety as it has the potential to improve accessibility. acceptability and service capacity for patients with severe health anxiety. The Urgent Care trial investigated the clinical and cost effectiveness of RCBT for repeated urgent care users with health anxiety. This PhD was conducted within the context of this large RCT and adopted a qualitative methods design.

The thesis set out to understand the experiences of service provider and service user decisions in participating in a DHI trial for the treatment of health anxiety. This is because the despite the importance of evaluating economic and clinical advantages of trials, there is a need to understand individual views in terms of facilitators and barriers to participating and remaining in trials. It is also important to understand these factors from a service provider and service user perspective because access to patient participation in health care trials is often determined by service providers who act as gatekeepers to patients accessing trial and other research information. These key aspects are addressed by the PhD.

The next chapter will outline the literature pertaining to health anxiety, highlighting the impact of health anxiety on wellbeing, and associated economic costs. It will also address the challenges to treating health anxiety and the potential for remotely delivered psychological therapy in overcoming these challenges.

Chapter Two: Introduction Health Anxiety

General introduction

Severe health anxiety is defined as a preoccupation with health worries or a belief that one might have a serious physical illness (Salkovskis and Warwick, 1986). The cognitive explanation for the development of health anxiety is based on the tendency to misinterpret bodily sensations and changes as evidence of underlying serious physical illness (Salkovskis and Warwick, 1986). Selective attention, safety seeking behaviours, physiological arousal and low mood leads to health anxiety persisting. According to Salkovskis and Warwick (1986), providing reassurances without an explanation only temporarily reduces these worries (less than 24 hours) and in fact over time maintains the worry. Severe health anxiety can lead to increased health care usage, including unscheduled same day care (Fink et al., 2010). Unscheduled same day care is defined as any unplanned contact with a health service by a person requiring or seeking help, care or advice (Huntley et al., 2014). Globally, unscheduled same day care utilisation is increasing across primary and hospital care settings, presenting a burgeoning challenge for health systems (Van den Heede and Van de Voorde, 2016, Finkelstein et al., 2016).

As described in Chapter One the Helping Urgent Care Users Cope with Distress about Physical Complaints ("Urgent Care trial") was a randomised controlled trial (RCT) evaluating the clinical and cost effectiveness of remotely delivered CBT (RCBT) for patients with severe health anxiety who frequently access urgent/unscheduled health care services. However, in addition to investigating whether the intervention is clinically and cost effective, it is important to understand the factors that may have impacted on service user and service provider willingness to participate in the trial and remain engaged with it. This PhD is concerned with the factors affecting willingness to participate and engage with the Urgent Care trial rather than the results of the trial, which I will refer to only when it provides context to the recruitment and retention to the trial.

This chapter provides an overview of health anxiety, as well as summarising the current treatment pathways in the English NHS and the challenges in treating health anxiety. The chapter concludes by highlighting why understanding the experiences of responders and non-responders to treatment for health anxiety is important, and why this is a topic that warrants further exploration.

Health anxiety as a psychosocial construct

Most people will experience worries about health at some stage in their life. Most often this is following a physical illness in the individual or a family/friend or media coverage of an illness (Deale, 2007). This anxiety is often short-lived and will subside following reassurance from a health care provider (Deale, 2007). However, when the anxiety persists and begins to impede on an individual's daily life, health anxiety can be considered as a disorder rather than normal adaptive coping (Newby et al., 2017).

Health anxiety includes an individual's worry about health, stemming from beliefs that the person's physical integrity is threatened. When it is mild and acute in relation to the changes in symptoms or signs possibly of illness, health anxiety can play a useful role even if it is distressing because it encourages people to prioritise their health over other concerns in their life and to seek help if necessary (Asmundson et al., 2010). Health anxiety is multifaceted and consists of distressing emotions (e.g. fear), physiological arousal (e.g. palpitations), thoughts and images of danger, and avoidant behaviours (Scarella et al., 2019). It is a psychological construct that ranges on a continuum from mild and transient to its extreme form which is severe and chronic and consists of excessive and maladaptive anxieties about health (Taylor and Asmundson, 2004). Often a chronic and debilitating psychiatric condition, severe health anxiety is characterised by an excessive and persistent fear or worry about serious illness perceived to be a threat to the person's own health (Sunderland et al., 2013, olde Hartman et al., 2009). Throughout the health care system (Tyrer et al., 2011) severe health anxiety

leads to excessive medical investigations and substantial societal costs (Sunderland et al., 2013).

Severe health anxiety – Definition and Diagnosis

The classification of mental disorders that are related to distress from somatic symptoms has been problematic. A term that has been used for many years is hypochondriasis, defined as a "non-delusional preoccupation with fears of having, or the idea that one has, a serious disease based on the misinterpretation of rather harmless and benign bodily symptoms" (Bailer et al., 2016 page 220). However, this term became pejorative due to the negative connotations of the term, suggesting the illness is factitious. Due to hypochondriasis being considered a stigmatising label, the term health anxiety was suggested (Fink et al., 2010) as a replacement and is used to reduce pejorative connotations. The term health anxiety has been used by Improving Access to Psychological Treatment services in the NHS (now known as NHS Talking Therapies). It was preferred to hypochondriasis by the patient and public involvement and engagement (PPI/E) representatives advising the Urgent Care trial and for this reason I will use this term in the thesis.

The definition of health anxiety and other related distress due to somatic symptoms have posed a problem in terms of definition. For this reason, I will briefly review the definitions considered standardised within the psychiatric field. The International Classification of Diseases (ICD) is the official world classification for psychiatric disorders whilst in the USA, the official classification for clinical diagnosis is the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) (American Psychiatric Association and Association, 2013). The main argument used by those who favour DSM is that it creates more accurate diagnosis (Tyrer, 2014). In the Diagnostic and Statistical Manual of Mental Disorder 4th edition (DSM-IV), the disorder was labelled hypochondriasis (Association, 2000). Hypochondriasis has been redefined in DSM-5 to Illness Anxiety Disorder (IAD) or somatic symptom disorder (SSD) (American Psychiatric Association and Association, 2013). In all these definitions, this problem is characterised by a preoccupation with

the belief that one has, or could acquire, a serious illness, emanating from 'anxiety about the meaning, significance or cause' of their symptoms. This is accompanied by high anxiety about health and excessive health-related behaviours or maladaptive avoidance. There were several reasons for replacing hypochondriasis in DSM-5 with IAD and SSD in DSM-5. The DSM-5 diagnosis of IAD focuses on the positive symptoms of the disorder (preoccupation and anxiety) in contrast to the DSM-IV categorisation, which focused more on medically unexplained symptoms (Chappell, 2018). Primarily, the emphasis on medically unexplained symptoms in the DSM-IV hypochondriasis diagnosis was questioned because of the difficulty in judging whether a somatic symptom is medically explained or not (American Psychiatric Association and Association, 2013). In diagnostic terms, health anxiety is classified as an SSD where distressing somatic symptoms are a central feature of the patient's reported behaviour, and IAD where they are not. Additionally, the DSM-IV hypochondriasis diagnosis required a misinterpretation of bodily sensations, even though many individuals can experience clinically relevant health anxiety without having marked somatic symptoms. (American Psychiatric Association & Association, 2013).

Given this complexity, for ease, in this thesis the term "health anxiety" will refer to individuals with an elevated and clinically significant level of worry about health or the presence of disease (severe health anxiety), regardless of the diagnostic criteria applied.

Nature and presentation of health anxiety

According to Scarella *et al*. (Scarella et al., 2019), health anxiety comprises three domains:

1) Disease conviction: a belief that one has a serious, terminal physical illness that doctors have failed to diagnose despite investigations and tests.

2) Disease fear: the worry of developing a serious illness, which leads to heightened distress when presented with any suggestion of the possibility of illness.
3) Bodily preoccupation: a heightened salience of physiologic functions, benign bodily sensations and sources of discomfort, and physical limitations. These are subjected to intense scrutiny with the goal of identifying the warning signs of illness.

People with health anxiety often (and repeatedly) seek medical intervention from primary or secondary care rather than a mental health care provider (Tyrer and Tyrer, 2018). For people with health anxiety, the fear of illness persists despite medical investigations and reassurances from health care providers ruling out illness (Scarella et al., 2019).

Health anxiety can also be co-morbid with a physical illness. A diagnosis of health anxiety is given if the worries are out of proportion to the medical illness (Chappell, 2018). Insight into the pathologic nature of the worry varies; some patients can acknowledge that their worry is excessive yet feel helpless to control it, whereas others are unable to be dissuaded from their fear of being ill (Scarella et al., 2019). More recently, there has been an increase in excessive use of searching health information on the internet. This is described in the literature as “Cyberchondria” (Fergus and Russell, 2016, Muse et al., 2012).

Severe health anxiety can be debilitating, it is associated with functional impairment, heightened health care consumption, and a marked increase in sick leave (Eilenberg et al., 2015, Barsky et al., 2001, Mykletun et al., 2009, Sunderland et al., 2013). It can result in frequent unscheduled same day attendance at primary care and secondary care settings, increased medical investigations or delayed health care attendance followed by catastrophic emergency presentation because of anxiety-related health care avoidance (Barsky et al., 2001). Most health anxiety does not persist; 6/7 people with moderate or severe health anxiety will return to normal within 12 months (Smits et al., 2009). Persistent severe health anxiety however, is associated with repeated medical consultation or phobic avoidance of medical contact

over a 12 month period, and is usually present for two years or more (Neal et al., 1998). Individuals with health anxiety overestimate the likelihood of serious medical conditions but tend to fear minor medical problems no more than the general population (Barsky et al., 2001, Schwind et al., 2016).

Is health anxiety distinct from other forms of anxiety disorder?

The classification of health anxiety is important because it has implications for treatment (Scarella et al., 2016). In DSM-5, IAD is classified in the Somatic Symptom and Related section. However, there has been a debate whether it is better classified as an anxiety disorder (Scarella et al., 2016) and if it is a separate disorder from other types of anxiety, depression, or somatic distress disorder. This distinction is important in relation to treatment because in some instances the treatment of depression or generalised anxiety disorder might sometimes improve health anxiety without the need for specific treatment of health anxiety. Although, severe anxiety about illness is a core feature of health anxiety it is not a specific feature unique to this disorder, which raises the question of whether health anxiety is an independent entity. Patients with anxiety disorders (as in generalised anxiety disorder or panic disorder (PD), obsessive-compulsive disorder (OCD) or mood disorders may experience distressing somatic sensations and feel intense anxiety about physical health. This non-specificity has led to debate as to whether health anxiety should be considered as its own entity or thought of as a secondary feature of other disorders (Scarella et al., 2016).

There is also the assumption that health anxiety might be more closely related to mood disorders and may in fact be a form of “masked” depression (Scarella et al., 2016). They found that health anxiety could be present in the absence of comorbidity, implying that health anxiety is a primary disorder that can exist independently of other psychiatric disorders; one-third of participants did not meet the criteria for any other disorders. The study also found that health anxiety was more closely related to anxiety symptoms and anxiety disorders than to depressive symptoms and depressive disorders. These findings suggests that health anxiety whether defined as hypochondriasis in DSM-IV or IAD in DSM-5, might be better classified as an

anxiety disorder rather than a somatoform disorder particularly given the low comorbidity rates of somatisation disorder (11.5%), pain disorder (6.7%), and body dysmorphic disorder (5.2%) (Scarella et al., 2016).

Three of the most widely used and psychometrically validated dimensional self-report instruments of health anxiety are the Whiteley Index (WI) (Pilowsky, 1967), the Illness Attitude Scales (IAS) (Kellner et al., 1987), and the Health Anxiety Inventory (HAI) (Salkovskis et al., 2002). The 14-item WI was designed to discriminate persons with severe health anxiety from those not having the disorder (Speckens et al., 1996). The IAS is comprised of 29 items forming nine subscales and was developed to assess psychopathology related to severe health anxiety (Kellner et al., 1987). The 64-item HAI was developed to improve the assessment of health anxiety and was designed to measure a broad range of health anxiety symptoms and to be sensitive to discriminate persons with elevated health anxiety from somatically ill persons without exaggerated health concerns (Salkovskis et al., 2002). A shortened version of the HAI (SHAI, 18 items) performs as well as the 64-itme HAI and is now widely used in both research and clinical practice e.g. NHS Talking Therapies. The HAI is based on a cognitive-behavioural model of health anxiety whereas the WI and IAS were developed using a descriptive approach. All three measures have been shown to have high reliability (Salkovskis et al., 2002, Pilowsky, 1967, Speckens et al., 1996).

Table 4 describes the standardised rating scales used for the assessment of health anxiety. Cut off scores indicate the score used to indicate significant health anxiety in studies. All scales listed are self-report and available for use in the public domain.

Table 4 standardised rating scales for assessing health anxiety

Scale	**Items**	**Cut off**
Whitely Index (Speckens et al., 1996, Pilowsky, 1967)	14	5-8
Illness Attitudes Scale (Kellner et al., 1987)	29	47

Health Anxiety Inventory (Salkovskis et al., 2002) Full Shortened	 64 18	 67 20

Prevalence of health anxiety

Severe health anxiety has an estimated lifetime prevalence of 5.7% in the general population (Sunderland et al., 2013). It common both in primary care (0.8 and 3.05%) and some secondary medical care settings (4.2 and 10%) (Seivewright et al., 2004, Barsky et al., 1990, Gureje et al., 1997, Escobar et al., 1998). There are widely differing estimates from study to study since many different definitions of health anxiety have been used, measured with different instruments and time durations for prevalence estimates (e.g. one month, one year, lifetime) number of different ways and in different populations e.g. community, primary care, secondary medical care. In a study carried out in 2006 in north Nottinghamshire with patients attending cardiology, respiratory medicine, gastroenterology, and endocrinology clinics, 15% had excessive health anxiety, but four years later in the same clinics this had risen to 20% (Tyrer et al., 2019). The prevalence levels varied by clinic with neurology having the highest prevalence (24.7%) followed by respiratory medicine (20.9%), gastroenterology (19.5%), cardiology (19.1%), and endocrinology (17.5%) (Tyrer et al., 2011). The heightened prevalence in medical practice may reflect the fact that health anxiety is also characterised by a strong “disease conviction” that persists despite appropriate medical evaluation. In a study conducted in Australia for treatment seeking patients it was estimated using the prevalence of DSM-III and DSM-IV that approximately a quarter of participants met the criteria for Illness Anxiety Disorder (Newby et al., 2017).

Factors that maintain health anxiety

Severe and persistent health anxiety appears to affect men and women equally, and onset can occur at any age (Newby et al., 2017). Once established it tends to become chronic and persists for many years. Childhood adversity appears to be a risk factor for adult hypochondriasis. This includes: serious illness or injury, parental illness, physical or sexual abuse, lack of parental care or over-protection (Deale, 2007). The age of onset of the illness seems to be in early to middle adulthood (American Psychiatric Association and Association, 2013). Few studies have measured the incidence of health anxiety through time in adults; one study that followed a cohort with hypochondriasis and a matched control population found that 3% of the control population had developed hypochondriasis in the 4 to 5 year follow-up period (Barsky et al., 1998). The disorder is often chronic; in adults, up to 70% of patients meeting criteria for hypochondriasis continue to meet criteria in long-term follow-up four years later (Barsky et al., 1998, Barsky et al., 2000, Fernández et al., 2005). In a more recent study using the newly defined criteria of health anxiety it was found that severe health anxiety was found to persist at the two year follow up assessment (Fink et al., 2010). Remission is associated with less disease conviction, fewer somatic symptoms, higher level of functioning, less disease fear, and fewer disability days at baseline. Presence of comorbid psychiatric illness has not been shown to be a significant factor in remission status (Barsky et al., 1998, Barsky et al., 2000, olde Hartman et al., 2009, Fink et al., 2010).

Multiple risk factors have been linked to the development of health anxiety. People with health anxiety may be uncomfortable experiencing normal sensations and may perceive subtle changes in the body as pathological (Newby et al., 2017). A person may be more likely to develop illness anxiety disorder if they have been raised in a family where health anxieties are discussed frequently or if parents had health anxiety (Alberts et al., 2016) or if a person experienced a serious illness in their childhood or someone from their family did (Scarella et al., 2019). People with underlying anxiety disorders such as GAD are at an increased risk of developing illness anxiety disorder (Chappell, 2018). A person who spends an excessive amount of

time reviewing health related information is at an increased risk (Newby et al., 2017).

Emotional impact of health anxiety

Severe health anxiety is highly prevalent in health care settings, associated with long-term disability, and an increased risk of developing major depression, which often becomes chronic if untreated (Hedman et al., 2014). It can have a significant impact on a person's personal life and relationships, impacting on their normal functioning (Chappell, 2018). A person with health anxiety may also take additional time off from work (Chappell, 2018). Additionally, they are at a high risk for the development of another psychiatric illness such as major depressive disorder, other anxiety disorders, or a personality disorder (Chappell, 2018). For both the individual and from a societal perspective, these conditions have serious consequences, as they are associated with reduced quality of life, functional disability and risk of developing somatic disorders such as coronary heart disease (Sunderland et al., 2013). It could be assumed that individuals with severe health anxiety might have better overall health than the general population because of intense health-checking behaviours and frequent contact with health care providers. However, several studies indicate a positive association of health anxiety with the development of medical illness (Berge et al., 2016) . This study in the Norwegian general population found that over 10 years, severe health anxiety doubled the risk of cardiovascular death when all other risk factors for cardiovascular health were controlled and people with cardiovascular disease were not included. Other studies in people who have had a myocardial infarction show that health anxiety increases the risk of further adverse cardiac events and death (Fink et al., 2010) implying that health anxiety increases the risk of mortality and does not necessarily lead to more positive health maintenance behaviours (Schwind et al., 2015).

Economic impact of health anxiety

Untreated health anxiety places a substantial burden on the health care system. Elevated health anxiety is associated with greater total outpatient costs, greater laboratory and procedure costs, higher numbers of visits to primary care and specialist physicians, higher number of specialists seen, increased inpatient medical hospitalisations, and increased presentations to emergency departments (Fink et al., 2010, Hedman et al., 2015). Primary care patients with health anxiety have been found to consume 41–78% more health care resource than primary care patients with a well-defined medical condition (Fink et al., 2010). A longitudinal study of hypochondriasis suggested that development of serious medical illness was associated with remission of hypochondriasis (Schwind et al., 2015). Patients with severe health anxiety report more days off work, increased functional impairment, and are more likely to be in receipt of disability benefits as compared to the general population and medical patients without health anxiety (Eilenberg et al., 2015).

The top 3% of attenders to primary care have been associated with 15% of overall appointments (Neal et al., 1996). Frequent attendance is associated with increased investigations, referrals, and hospital admissions (Stewart and O'Dowd, 2002). In a sample of adults with health anxiety recruited from secondary care medical clinics, average costs per participant were £2,796 over six months (range: £146–£25,200) (Barrett et al., 2012). The costs were highest for participants who had inpatient admissions and several diagnostic tests. The three factors identified to be significant independent predictors of higher total costs were: 1) self-reported poorer social functioning, 2) lower health-related quality of life and 3) lower levels of generalised anxiety. The relationship with social functioning suggests that individuals who function poorly access more services and receive more care than those who function well. This finding is supported by data that indicates that heath anxiety is associated with a greater degree of disability (Mykletun et al., 2009).

Current treatment pathways for people with health anxiety

The average patient with health anxiety has had the condition for many years before it is diagnosed (Hedman et al., 2011). This is one of the main reasons it can be under diagnosed. Treatment for people with health anxiety tends to focus on helping patients cope with their health anxieties. This shift in focus from negative to positive symptoms opens up new avenues for treatment where a lifestyle medicine approach including motivational interviewing and mindfulness training may be particularly effective (Chappell, 2018). Within the NHS, the two main treatment pathways for treating health anxiety are psychological treatment and medication.

Psychological treatment

Although many patients with health anxiety do respond to antidepressant medication (Louw et al., 2014), psychological treatment is the first line of treatment for health anxiety (Newby et al., 2017). The evidence for the use of talking therapies in health anxiety is more extensive than that for medications (see next section); in addition, it is cost-effective and preferred by patients over medications (Tyrer et al., 2014). Psychoanalytical and other psychodynamic psychotherapies, stress management, Cognitive Behavioural Therapy (CBT) mindfulness-focused therapy, and acceptance and commitment therapy have all been used in the treatment of health anxiety. Bibliotherapy has also been used as a supplement to formal psychological therapies (Tyrer and Tyrer, 2018). More recent “third-wave” iterations of CBT including small randomised control studies supporting use of group acceptance and commitment therapy (Eilenberg et al., 2016) and individual mindfulness-based cognitive therapy (McManus et al., 2012) have also been found to be effective. These therapies focus on mindful awareness of thoughts and changing an individual's relationship to their thoughts rather than changing their content. One RCT showed that short-term psychodynamic psychotherapy (STPP) did not improve symptoms of health anxiety compared with a wait-list control after 6 months of treatment. In the same study, CBT was found to be superior to the control group and superior to STPP (Sørensen et al., 2011). Other forms of psychotherapy with some

evidence to suggest benefit include behavioural stress management (Hedman et al., 2014). Although longitudinal studies have reported a reduction in heath anxiety symptoms on diagnostic tools, they have not shown consistent improvements in functional status, social activities, health-related quality of life, and days of lost work. (Eilenberg et al., 2015, Tyrer et al., 2014).

Cognitive–behavioural therapy for health anxiety

Cognitive–behavioural therapy (CBT) has the best evidence base for effectiveness for health anxiety (Olatunji et al., 2014, Cooper et al., 2017, Axelsson and Hedman-Lagerlöf, 2019). The CBT model suggests that dysfunctional beliefs about bodily symptoms and illness play a significant role in the development of health anxiety. These mistaken beliefs can lead to catastrophising thoughts when exposed to benign bodily symptoms or health-related information. According to the cognitive-behavioural model, the beliefs are maintained despite contradictory information and repeated reassurances from health care professionals. This approach also suggests that avoidance and health-related safety behaviours prevent dysfunctional beliefs from being disconfirmed, and thereby exacerbate excessive health anxiety symptoms (Warwick & Salkovskis, 2001). CBT focuses on treating the maladaptive cognitive beliefs using behavioural modification strategies. It addresses aspects such as excessive body checking and education about normal somatic sensations and their normal variations (Newby et al., 2017). CBT for health anxiety focuses on the misinterpretation of bodily symptoms, identification of maladaptive behavioural and cognitive patterns, and generation of alternative explanatory models for symptoms and psychologic distress (Salkovskis et al., 2003).

Three recent meta-analyses have shown the effectiveness of CBT for severe health anxiety, with large effect sizes (Hedge's g = 0.95 for individual CBT) (Olatunji et al., 2014, Cooper et al., 2017, Axelsson and Hedman-Lagerlöf, 2019). The most recent systematic review consisted of 19 RCTs and a total of 2,008 participants. The effects of CBT are maintained 7 to 24 months after treatment, although symptomatic improvement and remission tend to diminish over time (Salkovskis et al., 2003, Tyrer et al., 2014, Weck et al.,

2015). Tyrer et al (Tyrer et al., 2017) in a large RCT consisting of 444 participants found the benefits of CBT over usual care in terms of reduction in health anxiety to show effects 8 years post randomisation (Cooper et al., 2021) highlighting the potential of CBT for long-term improvement. Larger effect size is related to higher severity of pre-treatment symptoms, greater number of CBT sessions, and fewer depressive symptoms (Olatunji et al., 2014). One study found that participants with chronic lower back pain and health anxiety did not respond to CBT as compared with participants with health anxiety and no chronic lower back pain (Nakao et al., 2012), suggesting that burden of somatic symptoms may be a modifier of CBT efficacy. The demographic information highlighted in the reviews imply that there tends to be a larger percentage of female participants and of white ethnicity included in the trial, with the mean age of participants being around 40 years.

Challenges to CBT for health anxiety and the need for remotely delivered CBT

Despite extensive evidence identifying that CBT for health anxiety has large and lasting effects on the core symptoms of health anxiety, as well as therapeutic effects on secondary symptoms of depression and general anxiety (Olatunji et al., 2014, Cooper et al., 2017), the availability of CBT for health anxiety remains poor (Cooper et al., 2017). About 66% of patients respond to CBT (Axelsson and Hedman-Lagerlöf, 2019) but given the prevalence of health anxiety and scarcity of mental health professionals, the need for treatment far exceeds the availability of evidence-based, face-to-face therapy.

In addition to barriers related to accessibility, there is a low uptake of CBT for the treatment of health anxiety. This is attributed to the fact that most patients with health anxiety do not recognise it as a problem; they do not perceive their anxiety to be excessive and are convinced that they have a physical illness (Tyrer et al., 2011). Most health professionals are not familiar with diagnosing health anxiety and therefore may not provide the appropriate treatment or know how to explain health anxiety to their patients (Tyrer et al.,

2016). There is also often stigma around health anxiety. This is reflected in some of the labels often used for describing patients with health anxiety such as the worried well or frequent flyers (Spence, 2016). These pejorative terms can lead to patients feeling like their symptoms are being perceived as factitious, leading to conflict between the patient and health professional (Fink et al., 2010) and individuals not accepting treatment addressing health anxiety and continuing to require medical reassurance and investigations (Tyrer et al., 2016). In a previous study carried out with frequent attending patients in primary care, only 7% of potentially eligible patients participated in the study (Patel et al., 2015).

To address the issue of accessibility, remotely delivered CBT (RCBT) for the treatment of health anxiety delivered over the internet has emerged as a delivery option (Tyrer et al., 2016). There is no face-to-face contact provided. Where therapist contact is provided this typically consists of emails from therapists providing feedback regarding homework, granting access to subsequent modules, prompting participants to complete treatment and being a point of contact should the participant have any queries, although a response is usually within 24 hours and not immediately available. RCBT is advantageous because it is not restricted by geographical distance. This increases flexibility for participants in terms of how they can fit therapy into their daily life routines, and service efficiencies, as therapists can treat up to five times as many patients compared with face-to-face delivered CBT (Axelsson et al., 2020). Thus RCBT holds promise for increasing the reach of psychological treatment (Holmes et al., 2018).

There are several formats of RCBT, including therapist-guided internet CBT (G-ICBT), which is similar to an online self-help book with text-based therapist support (Hedman et al., 2012). Another format is unguided internet CBT (U-ICBT) where the treatment is provided over the internet with no therapist support. Third, there is cognitive behavioural bibliotherapy (BIB-CBT), where the treatment is delivered in book form. RCBT, in whatever form, requires less therapist time than CBT delivered face-to-face (Hedman et al., 2011).

RCBT has been shown to be effective in treating health anxiety including in patients with DSM-IV hypochondriasis, and DSM-5 IAD and SSD prior to the Covid-19 pandemic (Sharrock et al., 2021). These randomised controlled trials involving 377 participants have shown that RCBT for health anxiety leads to large and clinically significant improvements in health anxiety (within-group effect sizes > 1.30), as well as comorbid anxiety and depression, psychological distress and quality of life in treatment-seeking samples. RCBT outperforms a range of control groups, including waitlist, behavioural stress management, and psychoeducation controls (Hedman et al., 2014, Hedman et al., 2016). The most recent RCT including 204 participants with IAD or SSD showed that RCBT for health anxiety was non-inferior to face-to-face CBT with effects maintained up to 12 months following treatment. It also demonstrated lower societal costs to deliver the therapy (Axelsson et al., 2020) . RCBT has also shown to improve health anxiety symptoms in unguided and clinician-guided models of care in routine care settings, although treatment adherence and completion are typically lower in community and routine care settings compared to clinical trial settings (33% for self-guided RCBT, and 46% for guided RCBT) adherence in community/routine care (Newby et al., 2020) vs. 60% under RCT conditions (Newby et al., 2018).

A more recent systematic review investigated the clinical and cost effectiveness of CBT for the treatment of health anxiety which included subgroup analyses of face-to-face delivered CBT and RCBT (Axelsson & Hedman-Lagerlöf, 2019). This study investigated the clinical efficacy and cost-effectiveness of CBT for health anxiety and included 19 randomised controlled trials with post-treatment outcome data from 2,008 participants. The review highlighted that CBT leads to large reductions of health anxiety and small to moderate effects on depressive, general anxiety, and physical symptoms compared to waitlist controls as well as treatment as usual and other psychological treatments. They also found that the effects of CBT were maintained in the longer term. Furthermore, six studies, of which four tested RCBT, reported cost-effectiveness data suggesting that the treatment is likely to be cost-effective. However, only six studies reported health economic

outcomes, of which the three investigating the efficacy of RCBT were conducted by the same Swedish research group, and both studies that concerned face-to-face CBT were conducted by the same British research group. Thus, further health economic research is needed. In line with previous meta-analyses the pooled primary outcome effect size was large, with some factors moderating this effect. There was no significant effect difference between studies testing face-to-face treatment and those testing Internet-delivered treatment. The review recognised that future research needs to look more closely at non-responders to treatment (Axelsson and Hedman-Lagerlöf, 2019). There also needs to be an exploration of the factors important in determining the outcome of RCBT for health anxiety.

Medication

Medication is the second line treatment for health anxiety. Patients who respond to antidepressant therapy are recommended to receive maintenance treatment for at least 6 to 12 months. There is limited but promising evidence of the effectiveness of the use of medication for treating health anxiety (Scarella et al., 2019). Antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) have been shown to be effective (Scarella et al., 2019).

To date, there have been three trials of medication for health anxiety (Greeven et al., 2007, Fallon et al., 2008, Fallon et al., 2017). In a large RCT, 112 patients were randomly assigned to 16 weeks of CBT (n = 40), paroxetine (n = 37) or placebo (n = 35). In addition, participants in all groups were allowed to take benzodiazepines. The results showed that CBT and paroxetine were equally effective and more so than placebo, in reducing health anxiety symptoms and these improvements were maintained at 18 months (Greeven et al., 2009). However, due to the small sample size the trial was insufficiently powered to detect whether CBT was superior to paroxetine. In another study patients were enrolled to a comparative study of fluoxetine and paroxetine. 12 dropped out during the placebo run-in phase and so only 45 entered the acute treatment phase of 12 weeks. The mean dose of fluoxetine was relatively high (51.4 mg) and the improvement levels only just reached significance (Fallon et al., 2003).The findings of this RCT

were inconclusive since the sample size was too small to detect differences between active treatments. Furthermore, the dose of fluoxetine was much higher than used in clinical practice, possibly contributing to the high dropout rate.

The third trial consisted of 195 participants and compared CBT, fluoxetine, combined CBT and fluoxetine, and placebo. All the active treatments were superior to placebo at 24 weeks, with best results in the joint treatment group, but response rates overall were poor (Fallon et al., 2017). The trial was one of the largest treatment studies for health anxiety and was the first study to assess joint therapy. However, due to high attrition rates the findings of the study need to be treated with caution. In part this was a consequence of the study design as it removed participants from treatment if they were not at least minimally responsive at week 12. The final sample size of 195 fell short of the target sample size of 264. Therefore, the study was under-powered to detect smaller differences between the groups. However, this study also demonstrates that approximately 50% of patients continue to suffer with high health anxiety despite treatment, highlighting the limitations of both the pharmacologic and the cognitive behavioural approaches used in the trial.

The literature pertaining to the treatment of health anxiety recognises that CBT is a well-evidenced treatment for severe health anxiety, with benefits lasting at least eight years (Cooper et al., 2021). However, despite its effectiveness, uptake is typically low, which has been explained by perceptions of stigma and negative experiences of mental health services (Kirmayer & Looper, 2006; P. Tyrer et al., 2014). RCBT for health anxiety has been recommended (Andrews et al., 2018; Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlof, 2018) to overcome barriers such as lessening stigma and improving access for those with logistical barriers (Hollis et al., 2015).

Despite these recommendations, little is known about RCBT, which consists of patients talking directly to a CBT therapist using internet-based videoconferencing (L. F. Christensen, Moller, Hansen, Nielsen, & Gildberg,

2020; Patel et al., 2020; Thomas et al., 2021). Videoconferencing software may offer a compromise; it enables an experience closer to face-to-face clinical delivery than most computer-oriented therapy, whilst also offering the service efficiencies and public anonymity (not being seen entering a therapy centre, which some people report as stigmatising) that online interventions offer. Therapy delivered in this format may enhance accessibility, acceptability, and service capacity for patients with severe health anxiety (Matsumoto, Hamatani, & Shimizu, 2021). Therefore, the Urgent Care trial set out to test if RCBT for health anxiety would offer a solution to this problem. This rationale formed the basis for the Urgent Care trial, which provides the context in which this PhD study was embedded. It is important to acknowledge here that the Urgent Care trial was completed pre Covid-19 pandemic, when access to and utilisation of videoconferencing technology for routine patient care appointments was neither the norm nor universally accepted to the extent that it is at the time of writing. There was a rapid huge uptake in psychological therapy delivery using videoconferencing during the public health measures to tackle Covid-19 because of restrictions on face-to-face contact (Witteveen et al., 2022). Both the public and therapists became much more familiar with this technology and now it is still widely used to deliver psychological treatment because it allows patients to work with a more diverse range of therapists than offered by their immediate locality.

Chapter Summary

Health anxiety is a prevalent, debilitating, and often chronic long-term condition characterised by an excessive and persistent fear or worry about serious illness. It leads to increased use of health care services and has an impact on social, occupational and emotional functioning.

RCBT appears to be an accessible and effective treatment option for the treatment of health anxiety. This option may have become even more pertinent during Covid-19 pandemic when access to face-to-face services was restricted and there were increased anxieties about being exposed to the virus. RCBT might be especially useful when trying to engage people

with little understanding of health anxiety and high stigma who might be deterred from consulting a psychological therapist face-to- face.

However, despite RCBT showing promise for the treatment of health anxiety there is not sufficient evidence about uptake and treatment completion. Little is also known about the experiences of people with health anxiety who are offered RCBT. Greater understanding about the benefits of treatment for health anxiety are required to optimise benefits to participants. Future research efforts are needed to explore the factors which help health anxious individuals to decide to participate and remain engaged in RCBT trials to identify the benefits of RCBT in comparison to face-to-face CBT.

Thus, there is a need to look at factors impacting recruitment and retention to Digital Health Interventions (DHIs), especially in conditions where potential participants might not see the need yet are likely to show a benefit to both the patient and health service. The next chapter will address this, by defining recruitment and retention to DHI trials, before moving on to identify why these aspects are important and concluding with a consideration of theories and models related to recruitment and retention.

Chapter Three: Challenges of recruitment and retention to Digital Health Intervention (DHI)trials

Introduction

Research in health care is critical to evidence-based practice as it enables the establishment of early access to treatments and prevention strategies (Bower et al., 2009). There is currently a worldwide drive to enhance health, wellbeing, and wealth through effective research and dissemination. In the United Kingdom, the overarching vision of the National Institute for Health and Care Research (NIHR) is to see 'more patients and health professionals participating in health research' (Bower et al., 2014). Randomised Controlled Trials (RCTs) are widely regarded as the gold standard, and the most powerful and rigorous research design for the testing of interventions (Odgaard-Jensen et al., 2011). However, recruitment and retention to RCTs is often a challenge.

A review of 151 UK NIHR Health Technology Assessment (HTA) funded RCTs found that between 2004 - 2016, only 40% of RCTs recruited 100% of their original target; 63% recruited 80% of their original target with one-third of RCTs requiring an extension (Walters et al., 2017). Poor recruitment of research participants is also common in general practice-based trials (Foster et al., 2015, van der Gaag et al., 2017). A review of 34 general practice randomised trials in the United Kingdom reported that only a third of trials recruited to time (Bower et al., 2014). Another survey found that the top priorities of UK CTU directors for trials methodological research included 'research into methods to boost recruitment in trials'(considered the highest priority) and 'methods to minimise attrition' (Tudur Smith et al., 2014).

According to Keith (2001), there are two main aims for research: 1) to recruit a sample that adequately represents the target population, and 2) to recruit a sufficient number of participants to meet the sample size and power requirements of the study (Keith, 2001). Failures in recruitment can delay trials, leading to increased costs, delayed access to new treatments and the

inability to infer the effectiveness of a trial (Kasenda et al., 2020, Krzywinski and Altman, 2013). If high levels of participation (through recruitment to the study and longer-term retention) are not achieved, this has implications for statistical power, internal and external validity. Underpowered trials not meeting their recruitment target runs an increased risk of finding no statistically significant difference between two groups even if one exists raising ethical concerns about trial participation. Recruitment problems also have practical and financial impacts resulting in delays in trial completion or reducing its timely impact on patient health and wellbeing.

The importance of overcoming recruitment difficulties was identified as the top priority for methodological research in a Delphi survey of Clinical Research Collaborative registered Clinical Trials Units in the United Kingdom in 2011–2012 (Kearney et al., 2018). Recruitment and retention in health care trials can be complex. It involves the participation of service providers and service users. Service providers are required to inform potential participants about the trial and refer them to trials. According to Bower et al (2009), recruitment and retention in trials can involve up to four stages with aspects influencing recruitment and retention at all stages (Bower et al., 2009). In health care research, service providers are primarily responsible for approaching patients about RCTs (Rooshenas et al., 2016). Service users often only become aware of trials through contact with their service providers. Therefore, service user recruitment is often attributable to the trust and existing relationships they have with service providers (Houghton et al., 2020). A recent review (Farrar et al., 2022) synthesised the evidence concerning the experiences and viewpoints of recruiters in the context of healthcare professionals recruiting participants for RCTs. The review found overlapping themes associated with recruitment challenges, such as navigating a clinical environment, fostering enthusiasm for the RCT, making judgments regarding eligibility criteria, communication with potential participants, and the recruiters' dual/conflicting roles. This exploration sheds light on the difficulties and commonly observed issues in RCTs. However, only three studies were related to mental health conditions and none of them were digitally delivered.

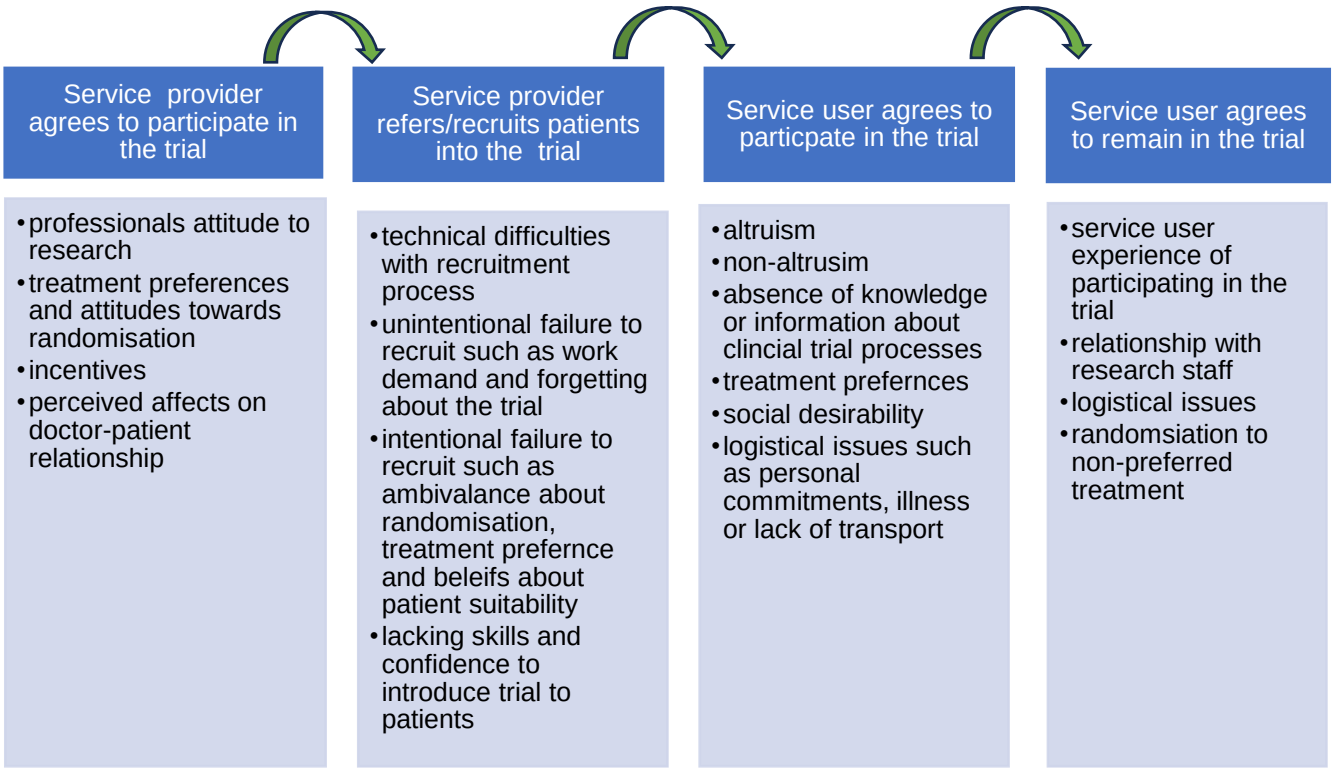

Figure 3 Stages of recruitment process and factors affecting recruitment and retention adapted from Bower et al (2009)

A meta-synthesis was conducted, examining factors affecting trial participation (Houghton et al., 2020). The initial theme centred on intrinsic aspects of the trials themselves, including factors like how trial information was communicated and components such as perceived burdens like time commitments. The second theme explored individual factors, considering how the influence of peers and personal perceptions of potential risks and benefits could influence decision-making. Finally, the decision to participate was shaped by perceived advantages, such as personal benefits like access to innovative treatments and the opportunity to contribute to the greater good by aiding others. It is noteworthy that that among the 29 studies included, only two were linked to mental health, and neither of them involved digitally delivered trials.

Ngune et al. reviewed 66 articles on improving recruitment in primary care research (Ngune et al., 2012). Patient level strategies included newspaper articles, mail-outs and incentives. Practitioner level strategies involved peer recruitment, opinion leaders, assigning research responsibility to researchers rather than practitioners, and recruiting practitioners interested in the

research topic. Finally, at the organisational level, the recruitment efforts were bolstered by supporting primary care services directly to optimise the effectiveness and efficiency of services, or by enlisting assistance from professional bodies whose role it is to support these services. Limitations of the review included their scope, whereby the effectiveness of recruitment strategies was part of standard reporting, rather than the focus of the study, confounding variables, dissimilar comparison groups, small sample sizes and limited attention given to cultural background or socio-economic status of patients or practitioners despite both being known to impact recruitment (Sheikh et al., 2009). The review highlighted the need to utilise key strategies to improve recruitment efforts at all three levels, especially at the professional level because in health care trials, practitioners are often the gatekeepers for providing access to services and patients.

Another study examined the barriers faced by GPs when introducing RCT participation to patients with depression during routine consultations (Mason et al., 2007). They identified three main themes: (1) concern about protecting vulnerable patients and the potential impact on the doctor–patient relationship; (2) the perceived lack of skill and confidence among GPs in introducing requests for research participation during sensitive consultations; and (3) the prioritisation of clinical and administrative issues over engagement in research participation. GPs noted that consultations regarding depression differed in content, style, and perceived difficulty compared to other types of consultations.

Interventions to improve recruitment to RCTs have been the focus for several systematic reviews. A Cochrane review collated randomised and quasi-randomised controlled trials of interventions to increase recruitment to trials, including non-health care studies and hypothetical studies (Treweek et al., 2018). Studies aiming to increase response rates to questionnaires or trial retention and those evaluating incentives and disincentives for clinicians to recruit participants were excluded. The review included 68 trials and over 74,000 participants. There were 63 studies involving interventions aimed directly at trial participants, and five studies evaluating interventions aimed at recruiting participants. All studies were in health care. The review found that

some interventions were effective in increasing recruitment, these included open trials rather than blinded, placebo trials and telephone reminders to non-respondents of postal invitations. However, contrary to popular wisdom about coproducing research with the intended audiences (Knowles et al., 2021), they found that using a bespoke, user-tested approach to developing participant information leaflets made little or no difference to recruitment. A substantial problem noted by Treweek et al. (2018) was the tendency for interventions to have variety but little depth making pooling data difficult. Of the 72 strategies tested only seven were utilised in more than one study. This resulted in a large pool of relatively unique recruitment interventions that had design flaws, were single studies, had uncertain results or were hypothetical trials. The review highlighted the need for more studies to understand if recruitment strategies worked or not. Furthermore, the 68 studies covered included disease areas such as antenatal care, cancer, home safety, hypertension, podiatry, smoking cessation and surgery but only three studies included mental health disorders. This omission is important because poor recruitment to RCTs is even more of an issue in mental health trials (Liu et al., 2018), this will be addressed later in the current chapter.

Barriers and facilitators to recruitment and retention in trials

The next section of the chapter identifies the barriers and facilitators to recruiting trial participants that have been reported in the literature.

An overview of systematic reviews conducted (Sheridan et al., 2020) aimed to identify psychosocial determinants of research participation and connect them to psychological theories and empirical recruitment research. The analysis involved 26 systematic reviews conducted between 1999-2019, encompassing 429 primary studies across various patient populations and health care settings. Perceived personal benefits, altruism and trust in health care staff emerged as key facilitators to trial participation. Conversely, the overview identified nine barriers, including fear of treatment risks, distrust in research, perceived stigma and practical difficulties, which varied depending on the study type. Two factors, participant information and social influences, were identified as both barriers and facilitators. The strengths of the overview

lie in its comprehensive compilation of evidence on health research participation across diverse settings and study designs, and the mapping of psychosocial determinants into a theoretical framework, offering original insights. However, a limitation of the overview is the overrepresentation of cancer, HIV, and other physical health conditions in the systematic reviews, with only two reviews focusing on mental health studies (Hughes-Morley et al., 2015, Woodall et al., 2010).

To date, there have been two reviews that have specifically investigated factors affecting recruitment into mental health trials (Hughes-Morley et al., 2015, Woodall et al., 2010). The most recent of these was a systematic review and meta-synthesis of published qualitative studies included data from service providers and users in terms of factors influencing their decision to participate in a depression trial (Hughes-Morley et al., 2015). The review included 15 studies, with 10 of the studies being conducted in primary care settings. Seven studies included the perspectives of service providers only, six studies focussed on patients with depression only and 2 studies included the perspectives of both service providers and service users. The review highlighted that the decision to participate in a depression trial are influenced by the service user's health state at the time of being approached to participate, this included aspects such as the impact of trial participation on their depressive symptoms. Trial participation was also influenced by attitude towards the research and trial interventions, which included aspects such as trial interventions offering an additional treatment option. Additional aspects here included randomisation as a potential barrier to trial participation and altruism being a facilitator. Finally, the decision to participate in a depression trial was also influenced by the extent to which participants become engaged with the trial. This focussed on the communication and relationships between service providers and their patients and included themes of stigma and mistrust. A key finding of the review was that the decision to participate by service users and service providers is largely influenced by weighing the risks and rewards of trial participation. The review identified the need to undertake further qualitative work to understand the process and priority of decision making for patients approached to participate in depression trials

and develop recruitment interventions that can be evaluated and implemented. Consistent with these findings, a review of 49 papers, identified barriers including practical difficulties such as transport or inconvenience, distrust of researchers, stigma of mental illness, acceptance and severity of illness and language difficulties as barriers to participation in mental health research (Woodall et al., 2010). Strategies to overcome these barriers included offering bilingual research staff, travel assistance, communicating study information using non stigmatising language and greater focus on education about the research area. There were very few evaluations of such strategies, but there was evidence that ethnically matching recruiters to potential participants did not improve recruitment rates. Educational strategies were helpful and increased recruitment.

Across these systematic reviews, there appear to be consistent, key recruitment barriers and facilitators in mental health trials relating to 1) service provider participation and service provider as a barrier to service user participation, and 2) service user participation. The following table summarises these.

Table 5 Barriers and facilitators to recruitment and retention

	Barriers	**Facilitators**
Service provider participation	Inadequate resources or capacity to carry out research related activities Inadequate skills/knowledge to introduce the study Concern for patient and the impact of trial participation on their well-being Impact of trial on service provider-service user relationship Difficulty understanding or carrying out trial processes	Relevance and importance of research Effective working relationships with the research team
Service user participation	Logistical issues Time commitment issues	Altruism

	Treatment preferences Research related aspects such as lengthy questionnaires or complex research process Mistrust and stigma towards research area and research team Severity and acceptance of illness	Access to treatment and perceived benefits of intervention Financial and non-monetary incentives Quality of information and support provided by the research team

Another challenge faced by RCTs is participant retention or keeping participants engaged in a trial and completing outcome assessments. Retention in trials is defined “as the strategy and tactics designed to keep participants enrolled in clinical trials, from discontinuing participation and dropping out” (Chaudhari et al., 2020 page 66). Literature around participant retention is limited, but this can be important too because it has implications on the success, validity and cost of RCTs (Watson, 2018). Like recruitment, participant retention to RCTs can be more challenging for participants with mental health conditions (Abshire et al., 2017). Recently there has been an increase in studies investigating effective retention strategies. Two systematic reviews conducted found the following retention strategies: (1) contact and scheduling methods, (2) visit characteristics, (3) study personnel, (4) nonfinancial incentives, (5) financial incentives, (6) reminders, (7) special tracking methods, (8) study description, (9) benefits of study, (10) reimbursement, (11) study identity, and (12) community involvement (Robinson et al., 2015, Robinson et al., 2007). The reviews concluded that studies using multiple retention strategies had higher retention rates. Limitations with these reviews was that the findings were limited to published papers and did not therefore allow for in-depth exploration of retention strategies and their implementation, potentially overlooking other retention strategies or themes that may have been effective but not reporting in existing research papers.

A review investigated retention strategies in longitudinal studies involving at least 200 participants, with reported retention rates of at least 80% over a minimum of one year (Abshire et al., 2017). Among the 19 studies analysed (comprising 13 cohorts, 5 randomised controlled trials, and 1 quasi-experimental study), effective strategies included implementing study reminders, optimising visit characteristics, emphasising benefits, and employing effective contact and scheduling methods. Studies with high retention rates tended to have well-trained, organised, and communicative research staff. Tailoring retention strategies based on participant needs, such as distributing newsletters, was found to positively influence retention rates. Whilst the study offers insights for maximising participant retention, limitations include the exclusion of mental health studies.

A systematic review on strategies for recruiting and retaining participants in mental health trials addressed this omission (Liu et al., 2018). Thirteen articles, including 5 RCTs and 8 observational comparisons, were analysed. One study involved recruitment to a preventive programme for depression, and one involved a relapse prevention trial in women with a history of post-partum depression. Two of the studies was conducted with people with severe mental illnesses. Five were carried out in a primary care setting. Except for one RCT which was a study of recruitment to a hypothetical trial, the studies involved recruitment to randomised trials involving a range of interventions including mindfulness cognitive behavioural therapy, health promotion via email, telehealth intervention, exercise, antidepressants, interpersonal therapy and psychoeducation. Recruitment strategies, such as leaflet invitations and multimedia, showed no significant differences from routine methods. Retention strategies, including pre-notification and financial incentives, had small positive effects on retention rates. Like others, the review highlights the need for further research in this area to enhance trial recruitment and retention. A strength of the review was that the recruitment studies included showed differences in strategies, clinical settings, mental health conditions and study design. However, it is difficult to assess the overall effectiveness of any recruitment strategy as some strategies that worked well for a particular population may not work as well for others.

Limitations of the review were that studies in which mental illness was comorbid with other physical medical conditions (e.g. cardiovascular disease) were excluded. Given the small number of randomised comparative studies identified, and the inconclusive results, this review suggests further research in this area may benefit trial recruitment and retention.

In recognition of the need to improve recruitment and retention to trials, The PRioRiTy (Prioritising Recruitment in Randomised Trials) collaborative study led by the Health Research Board – Trials Methodology Research Network (HRB-TMRN; https://www.hrb-tmrn.ie) in Ireland with the support of the James Lind Alliance (JLA) in the UK was set up (Healy et al., 2018). The PRioRiTy Study asked people across Ireland and the UK with experience of designing, conducting, or taking part in randomised trials to identify and prioritise a list of questions that could be researched, about how to improve the process of recruitment and retention of participants to clinical trials. Through a face-to-face workshop, the 10 highest-priority questions were ranked for recruitment and retention. These questions highlighted the need for a collective effort to normalise trials as a part of clinical care, improve communication, address barriers and facilitators to participation, and explore increased public involvement in the research process.

This overview of research on recruitment and retention to trials highlights, the importance of relationships in both recruitment (with the focus on relationships between the research team and service providers and service users) and retention (in terms of building and maintaining relationships with service users) is vital. These have implications for recruitment and retention in Digital Health Interventions (DHIs) trials, because due to their design, they tend to consist of reduced contact with research team or therapists and this could potentially exacerbate recruitment and retention challenges. An RCT exploring the effectiveness of an automated web-based peer support programme for managing depression and anxiety failed to recruit and retain sufficient participants to test the clinical effectiveness of this digital intervention. Of 1,510 eligible participants, 790 participants were randomised with only 131 (16.6%) completing the primary outcome assessment. Despite a considerable amount of effort in advertising the study, utilising various

recruitment strategies, recruitment and retention was poor. Feedback was obtained, which identified a lack of personal interaction with the research team, refusing those with severe depression and lack of technical support as barriers to participation and retention (Kaylor-Hughes et al., 2017).

I now turn to exploring why recruitment and retention is particularly pertinent within RCTs consisting of a DHI in mental health studies.

Recruitment and retention to Digital Health Interventions (DHIs)in mental health trials

As discussed in Chapter Two, remotely delivered psychological therapy can be effective in the treatment of health anxiety and warrants further research. Evidence relating to Digital Health Interventions (DHIs) suggests that despite the proven effectiveness of DHIs, high attrition rates and a lack of reporting on adverse effects are common issues (Mogoașe et al., 2017). Waller and Gilbody (Waller and Gilbody, 2009) found that only 38-56% of participants in computerised Cognitive Behavioural Therapy (cCBT) trials completed the intervention, attributing low engagement more to personal circumstances than technological aspects. Elsewhere, therapist supported DHIs show promise in improving completion rates and treatment effects (Andersson and Cuijpers, 2009, Christensen et al., 2009). The integration of face-to-face therapy with digital delivery aims to address reported engagement barriers (Erbe et al., 2017, Etzelmueller et al., 2018, Kaltenthaler et al., 2008). Furthermore, anarticle identified that the top 10 priorities for DHIs in mental health include considering how DHIs could be combined with human support to improve its effectiveness (Hollis et al., 2018).

Guided Cognitive Behavioural Therapy (CBT) appears more effective than unguided CBT, with studies emphasising the positive impact of therapist contact on effectiveness and adherence (Johansson et al., 2015, Andersson and Hedman, 2013). However, these conclusions are based on small studies, prompting a call for further research in clinical settings, particularly in primary care, and with a focus on the role of the supporter (Fairburn and

Patel, 2017, Wells et al., 2018). The need for more research into factors influencing negative aspects of treatments has also been emphasised (Richards and Richardson, 2012).

Qualitative reviews shed further light on barriers and facilitators in recruiting and retaining DHI participants. One review identified four themes affecting engagement: personal agency, personal life and values, recruitment approach, and DHI quality (O'Connor et al., 2016). Factors such as flexibility, anonymity, and endorsement by health care professionals facilitated engagement, while concerns about privacy and the lack of human interaction posed challenges. The authors proposed the DIgital Health EnGagement MOdel (DIEGO) to highlight key decision-making and operationalising processes, emphasising the complexity of engagement and recruitment. Another review stressed the importance of personalisation in digital therapy for depression and anxiety (Knowles et al., 2014). This involved tailoring and personalising DHIs to address individual needs, fostering a sense of connection and promoting collaboration.

Since the 1990s, there has been a rise in Digital Health Interventions (DHIs) for mental health trials, with a recent shift towards online recruitment strategies, targeting populations not usually accessing mental health services. Iflaifel et al. (2023), explored perspectives on online and offline recruitment in mental health, revealing online benefits such as improved accessibility. However, concerns about privacy and security, demographic preferences, and cultural differences were identified as challenges. The study recommended a combination of recruitment methods to optimise mental health trial recruitment, acknowledging the need for further research on effective strategies and reasons behind their success. Brogger et al. (2020), conducted a meta-analysis comparing online versus offline recruitment methods in clinical trials. They found online strategies had faster and more cost-effective participant recruitment, but offline methods yielded better conversion rates with regards to actual participants recruited. The study emphasises the effectiveness of online recruitment, particularly through social media. Frampton et al (2020) systematically reviewed research studies that had evaluated the effectiveness of digital tools for

improving recruitment and retention in RCTs. They found a lack of experimental studies on digital tools, especially for specific populations and health conditions, emphasising the need for more research to explore user attitudes and satisfaction with online recruitment and retention. They also highlighted that studies focussing on ethnic minority groups or under-served populations such as children and older people were limited. The review highlighted the need for more research exploring the efficiency of digital tools for recruitment and retention to RCTs (Frampton et al., 2020).

Theories and models relating to recruitment and retention

Despite RCTs remaining the gold standard for evaluating effectiveness of health care interventions, recruitment and retention to trials remains a challenge. Regardless of the widespread nature of recruitment and retention challenges and the negative impacts that failure to recruit or retain participants can have on research evidence generation, relatively little is known about which recruitment and retention strategies work best with service providers and service users, particularly in DHI mental health trials.

As the chapter has demonstrated, recruitment and retention to RCTs primarily requires individuals and organisations to change their normal behaviour to participate in the trial and the intervention. Facilitators and barriers to behaviour change can be complex and consist of a range of factors and at multiple levels. The current evidence is largely atheoretical and do not propose a theoretical lens through which recruitment and retention to RCTs might be understood. Looking beyond the barriers and facilitators reported in the literature to account for recruitment and retention, there are various theoretical models that offer potential value in informing the development and evaluation of future recruitment and retention approaches. Some of these focus upon the individual level, whilst others at an organisational level. Sociological models of engagement are targeted more towards explaining how innovations are implemented and adopted at an individual and organisational level. Psychological models tend to focus on individual factors deriving from the service user and service providers such

as motivations, behaviours, and attitudes of individuals and how these influence desire to participate in behaviour change. Table 6 provides an overview of the theoretical models that could be drawn on to understand recruitment and retention into trials from a service user and service provider perspective. The models covered are:

- Theoretical Domains Framework (TDF) (Michie et al., 2005, Cane et al., 2012)
- Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017)
- Diffusion of Innovation Theory (DOI) (Rogers, 2003)
- Normalisation Process Theory (NPT) (May et al., 2007, May et al., 2011)
- Non-adoption or Abandonment of technology by individuals and difficulties achieving Scale-up, Spread and Sustainability (NASSS) Framework (Abimbola et al., 2019, Greenhalgh et al., 2017)

Table 6 Overview of theoretical models

	Theoretical Domains Framework (TDF) (Michie et al., 2005, Cane et al., 2012)	**Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017)**	**Diffusion of Innovations Theory (DOI) (Rogers, 2003)**	**Normalisation Process Theory (NPT) (May et al., 2009, May et al., 2011)**	***N*on-adoption or *A*bandonment of technology by individuals and difficulties achieving *S*cale-up, *S*pread and *S*ustainability (NASSS) Framework (Abimbola et al., 2019, Greenhalgh et al., 2017)**
Aim	A comprehensive framework that synthesises psychological and organisational theories to understand and address behavioural barriers to implementation of evidence-based practices.	Provides a lens through which to understand and assess the factors that influence the acceptance or perceived acceptability of a particular intervention, process, or strategy.	Focuses on how new ideas, innovations, or technologies diffuse (spread) and are adopted within a social system	A framework designed to understand the implementation, embedding, and integration of new practices within health care settings.	A conceptual framework designed to analyse and understand the complexity of health care technology implementation.

Brief description	Consists of 84 constructs sorted into 14 domains. Domains include: 1. Knowledge, 2. Skills, 3. Social/professional role and identity, 4, Beliefs about capabilities, 5. Optimism, 6. Beliefs about consequences, 7. Reinforcement, 8. Intentions, 9. Goals, 10. Memory, attention and decision processes, 11. Environmental context and resources, 12. Social influences, 13. Emotion, and 14. Behavioural regulation	Represented by 7 component constructs: 1. affective attitude, 2. burden, 3. perceived effectiveness, 4. ethicality, 5. intervention coherence, 6. opportunity costs, and 7. self-efficacy	DOI theory integrates three major components: adopter characteristics, characteristics of an innovation, and the innovation decision process. DOI theory categorizes individuals into adopter types (innovators, early adopters, early majority, late majority, and laggards) based on their readiness to adopt innovations. The success of diffusion depends on factors such as the relative advantage, compatibility, complexity, trialability, and observability of the innovation. There are five main steps in the	There are 4 main components to NPT. 1. Coherence (sense making), 2. Cognitive participation (engaging), 3. Collective action (enacting), 4. Reflexive monitoring (evaluating)	It consists of 7 domains, which may be simple (few components, predictable), complicated (many components but still largely predictable), or complex (many components interacting in a dynamic and unpredictable way). Domain 1. illness or condition. Domain 2. technology. Domain. value proposition. Domain 4. adopter system. Domain 5. organisation(s). Domain 6. wider system. Domain 7. embedding and adapting over time.

			innovation-decision process. 1. Knowledge, 2. persuasion, 3. decision, 4. implementation, 5. confirmation.		
Strengths	It is a validated framework used to identify implementation problems and professional behaviours. It has been used to inform data collection tools (Francis et al., 2012). The TDF is flexible and adaptable to different settings, populations, and behaviours. It can be applied to a wide range of behaviours and health-related issues, making it a versatile tool for	It can be applied within a process evaluation to assess anticipated and experienced acceptability of the intervention to people receiving and/or delivering the health care intervention at different stages of intervention delivery. By understanding the factors that contribute to or hinder acceptability, researchers can tailor interventions to enhance their acceptability.	DOI theory has been widely applied across various fields, including communication, agriculture, public health, criminal justice, social work, and marketing, to understand and accelerate the adoption of new ideas or behaviours. DOI is both descriptive and predictive, offering a framework that not only explains how innovations are adopted but also predicts the rate and patterns of adoption within a social system.	NPT recognises that any trial in health care is a collective activity requiring a multitude of interactions between service providers, service users and others and therefore considers wider system issues at the individual and organisational level (Murray et al., 2010). NPT offers a framework for tackling implementation challenges but also proves helpful in guiding the development and refinement of complex interventions.	NASSS takes a holistic approach, recognising that the implementation of health technologies is a complex and dynamic process involving multiple factors. It accounts for the entire life cycle of a technology, from adoption to sustainability. The framework considers multiple levels of analysis, including individual, organisational, social, and technological factors. This multilevel perspective helps in

	behaviour change research. The TDF provides a structured and organised framework, making it easier for researchers and practitioners to systematically identify relevant determinants of behaviour change. While the TDF primarily identifies determinants of behaviour, it can be used as a starting point for developing interventions. By understanding the factors influencing behaviour, researchers can design targeted and effective interventions. The TDF is not only a theoretical framework but has practical	The TFA can also be applied to assess patient engagement in the implementation phase when an intervention is scaled-up and offered as part of routine care. The TFA is flexible and applicable across various contexts, interventions, and populations. It can be applied to diverse fields such as health care, education, and technology, making it a versatile framework. TFA emphasises the importance of considering the perspectives of patients and	DOI takes a social systems perspective, considering the influence of social networks and interpersonal relationships on the diffusion process. This perspective is valuable for understanding the social context in which innovations are adopted. The theory has been successfully applied across different cultures and contexts, demonstrating its global applicability. This cross-cultural adaptability adds to its versatility. DOI helps identify barriers and facilitators to adoption, providing insights into factors that can impede or promote the uptake of	NPT is applicable across a wide range of health care interventions, making it versatile for studying various innovations and practices. It is not limited to specific types of interventions or settings. NPT can be applied both prospectively and retrospectively. It can help in planning and designing interventions by anticipating normalisation processes, as well as in evaluating and understanding the normalisation of practices that have already been implemented. NPT draws on sociological and psychological insights	understanding the intricate interactions influencing technology implementation. NASSS recognises the importance of social interactions, networks, and relationships in shaping the implementation of health technologies. The framework is adaptable and applicable to a wide range of health technologies, including digital health tools, medical devices, and interventions. NASSS emphasises the experiences of patients and clinicians in the implementation process. It recognises that user perspectives and experiences are crucial

	applications. It has been used in diverse fields, including health care, public health, and organisational behaviour, demonstrating its utility in real-world settings.	stakeholders in assessing acceptability. TFA takes into account both emotional and practical elements of acceptability.	innovations. This information is valuable for developing targeted interventions.	and recognises the social and cognitive aspects of implementation. NPT considers the concept of reflexive monitoring, encouraging stakeholders to reflect on the implementation process and make adjustments based on feedback. This reflexivity enhances the adaptability and improvement of interventions over time.	determinants of successful technology adoption. NASSS integrates insights from existing theories and frameworks, contributing to a more comprehensive understanding of technology implementation. It draws on concepts from fields such as sociology, psychology, and innovation studies.
Limitations	TDF does not attempt to explain causality (Atkins et al., 2017). No formal guidance exists on how to apply the TDF. The TDF is often used in conjunction with other frameworks or models. Combining it	TFA may not provide explicit guidance on how to intervene or design strategies to improve acceptability. TFA emphasises the importance of understanding stakeholder perspectives, but it	Most of the evidence for this theory, including the adopter categories, did not originate in public health and it was not developed to explicitly apply to adoption of new behaviours or health innovations.	NPT primarily focuses on the stages of normalisation and may not capture the dynamic nature of implementation processes over time. NPT provides a descriptive framework rather than a	NASSS is more focused on understanding the complexities rather than providing explicit guidance on intervention design of offering strategies for addressing identified challenges. The framework may not provide an in-depth

	with other frameworks may provide a more comprehensive understanding. The TDF may not explicitly explore cultural influences on behaviour change. Cultural factors can significantly impact the effectiveness of interventions, and their role may need to be considered separately.	may not offer comprehensive guidance on how to actively engage stakeholders in the process of assessing and improving acceptability.	The DOI is better at explaining adoption of behaviours rather than cessation or prevention of behaviours. DOI assumes a homogenous population, treating individuals as if they share the same characteristics and attitudes. While DOI recognises the influence of social systems, it may not delve deeply into the complexities of social and cultural factors that can significantly impact the diffusion of innovations.	prescriptive one. It helps in understanding what is happening during implementation but does not provide explicit guidance on how to intervene or improve implementation. NPT may not fully address the influence of power and politics in shaping the implementation process. It may not capture the full complexity of the organizational and social context in which the implementation occurs.	exploration of cultural and social factors that can influence technology adoption and implementation. It relies on retrospective analysis, therefore there is a potential for recall bias.

This Chapter highlights the barriers and facilitators impacting on recruitment and retention to trials and more specifically DHI mental health trials. Barriers and facilitators to recruitment and retention exist at both the service provider and service user levels. The chapter emphasises that the existing evidence lacks a theoretical foundation, making it challenging to steer the development of interventions. When examining the influences on recruitment and retention in RCTs, it is crucial to consider the foundational theoretical frameworks. The mentioned models could be utilised to shape the creation of strategies for recruitment and retention and warrants further exploration.

Chapter Summary

Conducting research in health care is crucial for generating evidence-based practice, offering early access to treatments and prevention methods. While RCTs are highly valued, recruiting into them remains a significant challenge, with just over half of trials meeting 80% of their target recruitment. This issue is especially prominent in mental health trials, leading to delayed trials, increased costs, and hindered assessment of trial effectiveness. Existing theoretical models provide insights for trialists to enhance recruitment and retention to RCTs, but further research, particularly concerning mental health trial utilising Digital Health Interventions (DHIs), is needed to identify barriers and facilitators for recruitment and retention.

Significantly, none of the reviews explored in this chapter on recruitment or recruitment included health anxiety trials. Given the contested nature of, and complexities in identifying and managing health anxiety outlined in Chapter Two, understanding these factors is crucial for developing effective strategies to improve recruitment and retention in research trials that explore not just mental health digitally delivered interventions, but also ones that focus on the management of health anxiety.

The next chapter (Chapter Four) outlines the methods and findings of a qualitative systematic review exploring the factors affecting recruitment and

retention of service users to Digital Health Interventions (DHIs) for depressive, anxiety and somatoform disorders.

Chapter Four – Systematic Review of Factors affecting Recruitment and Retention into depression, anxiety and somatoform Digital Health Intervention (DHI) trials

Chapter Three introduced the challenges faced in recruitment and retention to RCTs generally and to Digital Health Intervention (DHI) trials for people with mental health conditions. It also introduced the potential of DHIs for the treatment of health anxiety, and theoretical frameworks that may help to understand recruitment and retention to trials which includes identifying what helps (facilitators) and what impedes (barriers) the likelihood of taking part in a trial consisting of a DHI (recruitment) and continuing to engage in the DHI trial (retention).

This chapter focuses on research question 1 of the thesis:

RQ1. What are the factors reported in previous research affecting the recruitment and retention of participants into depression, anxiety and somatoform DHI trials?

This chapter presents a systematic review and synthesis of the qualitative literature exploring the aspects that impact on service users' decision to participate (recruitment) and continue with (retention) digital health interventions (DHIs) for depressive, anxiety and somatoform disorders.

This chapter discusses the aims, methods and results of a systematic review and meta-synthesis, which highlights the barriers and facilitators to taking part in a DHI trial and using the DHI for people with depressive, anxiety and somatoform disorders within the context of research. The review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) in July 2018. An updated systematic review titled 'Acceptability and Usability of Digital Health Interventions for Adults with Depressive, Anxiety and Somatoform Disorders: A Qualitative Systematic

Review and Meta-synthesis' was published in Journal of Medical Internet Research (JMIR) (Patel et al., 2020).

Introduction

According to the Joanna Briggs Institute (JBI), "systematic reviews aim to provide a comprehensive, unbiased synthesis of many relevant studies in a single document using rigorous and transparent methods". A systematic review aims to synthesise and summarise existing knowledge. It attempts to uncover all relevant evidence related to a particular question (Aromataris and Munn, 2020).

To improve outcomes for people with health anxiety and improve recruitment and retention research it is important to understand the factors that could influence recruitment and retention in trials. These factors could both facilitate and hinder trial participation and continuation.

There is an increased acknowledgment that qualitative systematic reviews exploring the experiences of those who provide and receive interventions can be extremely valuable. They can help to develop an understanding of experiences and facilitate the development of policies (Popay et al., 2006, Lisy and Porritt, 2016). Qualitative synthesis can explore questions addressing the barriers and facilitators to an intervention and participant experience of the intervention (Flemming and Noyes, 2021). Given the rise in prevalence of depressive, anxiety and somatoform disorders and advances in development of DHIs, but low uptake and completion rates, it was deemed important to conduct a systematic review exploring the already known perceived barriers and facilitators to recruitment and retention in DHIs. A systematic review of the qualitative literature may provide further explanation and a synthesis of factors that may facilitate adherence and outcome of DHI trials for co-morbid mental health conditions.

If academic researchers and clinicians can understand barriers and facilitators to trial recruitment and retention, then trials could be designed to improve uptake and completion rates. As discussed in Chapter Two there is

limited qualitative research exploring the barriers and facilitators to recruitment and retention to mental health trials, and more specifically to mental health trials with a DHI including health anxiety. Studies exploring DHIs have tended to tend to focus on intervention effectiveness and more data is required on barriers to uptake and retention to DHIs (Waller and Gilbody, 2009).

A preliminary search conducted in PROSPERO, the Cochrane Database of Systematic Reviews, and the Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports indicated that there were no systematic reviews in progress or already published on recruitment or retention to DHIs in mental health trials. Two related systematic reviews had explored similar areas. One review investigated the factors affecting patient and public engagement and recruitment to DHIs (O'Connor et al., 2016), whilst the other explored user experience of low-intensity digital interventions delivered with minimal or no professional support for depression and anxiety. (Knowles et al., 2014). Both reviews recommended future research was needed to explore if their findings could be extrapolated to other health conditions, delivery formats and treatment modalities.

Aims and objectives

The aims of the systematic review were to synthesise existing qualitative evidence regarding participant views and experience of using DHIs for the treatment of depression, anxiety and somatoform disorders with a view to identify the potential facilitators and barriers to recruitment and retention. Specific objectives were to systematically identify, appraise, and meta-synthesize available qualitative literature that explored the following:

- Identify the barriers and facilitators to recruitment to DHIs for adults with depressive, anxiety and somatoform disorders.
- Identify the barriers and facilitators to retention to DHIs for adults with depressive, anxiety and somatoform disorders.
- Identify gaps in reporting of barriers and facilitators in recruitment and retention to DHIs for depressive, anxiety and somatoform disorders.

The findings will also be useful to health care providers, commissioners, and clinicians in informing future clinical developments in trial recruitment and retention and the delivery of care.

Methods

Systematic literature search

The systematic review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and meta-analyses (PRISMA) statement checklist and Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) guidelines (Tong et al., 2012).

This review investigated all published articles of factors affecting the recruitment and retention of adults into DHI trials for depressive, anxiety and somatoform disorders. Any studies (including those using mixed methods) that reported qualitative empirical findings were included. Only articles looking at the views of service users were included, not service providers or carers.

Search terms related to depression, anxiety and somatoform disorders, and digital health interventions are shown (see table 7). A scoping search was conducted to identify key papers and associated search terms to inform the design of the search strategy. Disorders were selected based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria (American Psychiatric Association, 2013). Qualitative search filters were also applied. Recruitment and retention search terms were not specifically used because the initial scoping review indicated that 'recruitment' and 'retention' terms were poorly indexed. A combination of free terms and controlled vocabulary terms was used to ensure that all relevant studies were identified. Search terms were split into 2 categories: DHIs and mental health conditions (depression, anxiety, and or somatoform disorders). Qualitative search filters identified by the InterTASC Information Specialists Sub-Group were also applied.

The following search terms were used.

Table 7 Search terms used for systematic review

Search domains	Search terms
Sample	Depression Anxiety Somatoform disorders and associated search terms as classified in ICD 10 and DSM-IV and 5.
Phenomenon of interest	Digital Health Interventions – associated search terms were identified from a scoping search.
Design	Qualitative filters identified by InterTASC Information Specialists SubGroup (ISSG) (Glanville et al., 2008) were applied.
Limits	English

An initial limited scoping search of MEDLINE was undertaken to identify relevant articles. The text words contained in the titles and abstracts of relevant articles, and the index and Medical Subject Headings (MeSH) terms describing the articles were used to develop a full search strategy, which was then tailored for each included information source (see Appendix 1 for full search strategy). The search strategy was guided by similar qualitative reviews exploring DHIs (Knowles et al., 2014, O'Connor et al., 2016).

Seven electronic databases including Medline, PsycINFO, Cumulative Index for Nursing and Allied Health Professionals (CINAHL), EMBASE, ISI Web of Science, Scopus and the Cochrane Library were searched. Electronic databases for eligible studies from the databases were searched from their inception to 31st December 2015. The reference lists of all studies selected for critical appraisal were also screened to check for any additional studies that may have been missed in the main search.

Inclusion and exclusion criteria

Table 8 and 9 describe the inclusion and exclusion criteria.

Only publications available in English were included due to resource constraints. Articles were excluded if they consisted of primarily quantitative data only or had insufficient qualitative data or analysis. Studies where the primary focus was not on depressive, anxiety or somatoform disorders, or

that had a lack of data on the experience of using a DHI were also excluded. Articles were also excluded if 50% or more of the participants were aged under 18 and if data included was regarding carers of people with depression, anxiety or somatoform disorders.

Table 8 Inclusion criteria for systematic review

1) English language.
2) Community, Primary and Secondary Care.
3) Original qualitative studies, studies involving secondary analysis of qualitative data or qualitative studies that are part of a mixed methods study (e.g. the study also has a quantitative component but the major component is qualitative and a qualitative methodology is described). Studies must include a substantial amount of qualitative methods including interviews, observations and open-ended evaluation forms. Free text boxes on evaluation forms were included if there was richness in the data provided i.e. sufficient quotes to support the analysis.
4) Papers must include some form of qualitative data analysis such as thematic or inductive analysis.
5) Papers reporting on participants who had experienced the use of DHIs (also called “Internet interventions” or “eHealth interventions”), where the DHI was primarily used to treat depressive, anxiety and/or somatoform disorders. This included interventions that provided information and support (emotional, decisional and/or behavioural) via a technological or digital platform (website, computer, mobile phone app, SMS, email, videoconferencing, wearable device, patient portals or personal health records or VR).

Table 9 Exclusion criteria for systematic review

1) Grey literature/not published in a peer reviewed journal.
2) Dissertation/theses.
3) Published abstracts or conference proceedings.
4) Any type of literature review, systematic review and meta-synthesis.
5) Experience of health care professionals or parents/carers.
6) Studies where the primary DHI is telephone-based with no additional technological function (e.g. telephone counselling or triaging service); internet-based health tools that are not defined as interventions (e.g. internet health searching) or an implantable device that is remotely monitored.
7) Interventions to improve adherence to medication, improve assessment or diagnosis or where digital interventions are not the major constituent of the intervention.

8) Peer-to-peer networks and DHIs of social support via the internet, use of social media, online support groups or DHIs consisting of group therapy.
9) Data collected during the testing of the usability and design of DHIs.
10) Males and females aged <18. Studies were included if ≥50% of the sample were aged ≥18.

Data screening

Search results were uploaded and stored using Endnote version X7. Duplicated studies were removed in Endnote before screening and the remaining articles were exported into a Microsoft Excel document for screening. Titles and abstracts were screened for relevance by me, 10% of retrievals were reviewed by a second reviewer (AA). The double screening approach is an international standard and recommended by well-established handbooks, which mostly refer only to the study by Edwards (2002) as the evidence base for this recommendation. The double-screening approach offers the following advantages: it ensures that the study inclusion criteria are applied consistently, thus avoiding systematic errors, and the reliability of the decision process is increased if all papers are independently assessed by more than one researcher (Waffenschmidt et al., 2019).

Full-text retrievals were assessed by two reviewers (myself and AA). Where it was unclear whether to include or exclude a paper, the full text was obtained and discussed between the two reviewers. Disagreements were dealt with via discussion. Qualitative results from the same overall study that were split across different publications were not removed until full-text screening. Papers were removed if they reported the same qualitative findings otherwise, they were included.

Data extraction

Data were extracted from papers included in the systematic review using a data extraction form informed by an earlier review (Wood et al., 2017). The data extraction form was adapted and piloted by the review team. The primary focus of data extraction was the identification of specific qualitative findings—reported themes and subthemes related to the phenomena of interest, which were subsequently synthesised as described below. All text

from the papers labelled as results or findings were entered into a Microsoft Word document. Additionally, descriptive data, including details about DHIs, study aims, methods and analysis, country of research, and demographics of participants were extracted. The form was initially piloted on three papers by both reviewers. The second reviewer completed data extraction for 30% of articles to confirm congruence. Data extraction forms were compared to ensure data accuracy and comprehensiveness. Any disagreements were resolved through discussion until consensus was reached. Primary authors of the original papers were contacted for any missing data or to clarify any anomalies.

Quality Appraisal

Quality assessment of papers included in the meta-synthesis was undertaken using the Critical Appraisal Skills Programme (CASP) criteria (Casp, 2018). The tool is not used to provide an absolute score of quality but enables a consideration of aspects such as how clearly defined the aims were, suitability of study design, recruitment methods, design and data collection. It also facilitates consideration of researcher reflexivity, ethics and clarity of findings (McPherson et al., 2020). This tool has been used in other reviews of qualitative evidence synthesis (Glenton et al., 2013, Munabi-Babigumira et al., 2017, McPherson et al., 2020) The CASP checklist consists of the following questions:

Q1 Was there a clear statement of the aims of the research?

Q2 Is a qualitative methodology appropriate?

Q3 Was the research design appropriate to address the aims of the research?

Q4 Was the recruitment strategy appropriate to the aims of the research?

Q5 Was the data collected in a way that addressed the research issue.

Q6 Has the relationship between researcher and participants been adequately considered?

Q7 Have ethical issues been taken into consideration?

Q8 Was the data analysis sufficiently rigorous?

Q9 Is there a clear statement of findings?

Q10 How valuable is the research?

Each question is answered as yes, no or unsure/can't tell.

It is recognised that studies deemed to be of a low quality may still provide new insights (Dixon-Woods et al., 2005). Papers were excluded if they did not contain a substantial amount of qualitative data or did not include qualitative analysis such as thematic analysis. Since the doctoral researcher was more concerned about including papers which might provide valuable information regarding participant experience of DHIs studies, papers were not excluded based on appraisal of quality. All included articles were deemed to be of sufficient quality to contribute to the meta-synthesis. All papers reported a clear statement of the aims of the research and were deemed to contribute to the themes. Question 6 of the CASP referring to the relationship between the researcher and participants was acknowledged in 9 papers. Kuhn (Kuhn et al., 2014) contributed the least to the meta-synthesis because the paper provided minimal information regarding the data analysis method and how themes were derived. It was still included however, as it provided information on aspects related to participant experience of a DHI. Papers were included if they collected data through semi-structured interviews and through open response text if there was richness in the data provided.

Meta-synthesis

A meta-synthesis approach was used to organise and interpret data. Meta-synthesis is a technique for analysing qualitative research and consists of integrating findings from qualitative studies (Lachal et al., 2017). A meta-synthesis goes beyond a systematic approach to collecting, analysing, and interpreting results and involves developing an overarching interpretation of the qualitative studies included in the synthesis (Barnett-Page and Thomas, 2009, Lee et al., 2014) The findings of included studies were synthesised using methods proposed by Noblit and Hare (Noblit and Hare, 1988). Papers were read and re-read by both reviewers and first and second order

constructs from the results and discussion sections were extracted using a Microsoft Word template form. First order constructs were defined as direct participant quotes reported in the papers. Second order constructs were defined as the authors' interpretations of participants' quotes expressed as themes, extracted from both the results and findings sections of papers. Based on these first and second order constructs, third order constructs or interpretations were developed to generate a conceptual framework (Noblit and Hare, 1988, Britten et al., 2002). Both reviewers independently sifted the second order constructs, compiling new third order constructs that summarised and encompassed the various themes across studies. Third order constructs refer to synthesised constructs that emerge from the analysis of first and second order constructs. Constructs were reviewed to see how the themes were similar when compared across papers to make sense of the variability in participant experience of DHIs. A draft summary of the analytical themes was written up and shared with the doctoral supervisors. Themes were refined until consensus was reached. Table 10 shows an example of first, second and third order constructs and sub-themes and contrasting positive and negative participant experiences.

Table 10 Examples of first, second and third order constructs and sub-themes contrasting positive and negative participant experiences

First order construct	**Second order construct**	**Sub-theme**	**Third order construct – synthesis of findings**
Positive *"You could go back on yourself, you could go back and forward as much as you want, you could see what you'd put and what you were working towards, and that you could stop at any time if you wanted to and*	Flexibility and being able to refer back was perceived positively by some.	**Flexibility and autonomy**	**Personalisation of treatment** The flexible and accessible nature of DHIs makes it easier for participants to choose when and how to complete the sessions.

come back at a later time." (Knowles et al., 2015) Negative *"When you've got your off days it's easier to not bother with the computer whereas, you know, if you've got a face-to-face it's not, to me, I think it's not polite to not turn up. So I think yeah it's definitely going to work, you know, against it being so flexible."* (Knowles et al., 2015)	The flexibility of computerised therapy made it easier to avoid.	**Flexibility and autonomy**	**Personalisation of treatment** The flexible and autonomous nature of DHIs made it easier for participants to choose not to complete sessions, there was no sense of obligation when participants were feeling less positive.
Positive *"I felt like I was just chatting away, that was the good thing, I was talking to someone who was listening to me . . . I was talking to a person. I wasn't typing on a machine."* (Beattie et al., 2009) Negative	Participants were able to establish a good rapport with the therapist and expressed that it felt like a face-to-face interaction.	**Support to develop a virtual therapeutic relationship**	**The value of receiving personal support in DHIs.** Participants were able to develop a therapeutic relationship with the therapist via written communication. They felt listened to, it did not feel mechanical. It paralleled a face-to-face session.

"*Are they concentrating on what you're saying? Are they focusing really on what you're saying or are they doing something else . . . are they on the telephone, having a cigarette, maybe not taking me seriously"* (Beattie et al., 2009)	Absence of face-to-face contact led to speculation about whether the therapist was 'multi-tasking' during therapy.	**Support to develop a virtual therapeutic relationship**	**The value of receiving personal support in DHIs.** Absence of face-to-face contact led to uncertainty about the therapist's commitment.

Findings

Summary of search results

A total of 6,153 titles and abstracts were retrieved. Titles and abstracts were initially screened against the eligibility criteria by the doctoral researcher (screening phase n = 6,088 ineligible). Subsequently, 10% (n = 615 titles and abstracts) were then screened against the eligibility criteria by a second independent reviewer (AA). Inter-rater agreement for full-text screening was 99.4%; disagreements concerning eligibility were resolved through group discussion and recorded. Following discussion between the assessors, the full text of 65 papers was obtained for analysis and coding. One additional paper included in a key systematic review paper (Knowles et al., 2014) but not identified in the search was included (Farzanfar et al., 2007). One paper was identified and included through backward citation (Purves and Dutton, 2013). Sixteen papers met the eligibility criteria and were included in the meta-synthesis. These were amalgamated into 15 studies because one of the included studies reported data in two papers. Both papers were included because their study aims were different, yet the findings of both papers were pertinent to the systematic review aims. One paper specifically focussed on motivation to persist with the DHI, whilst the other paper focused on patient

experience and implementation of digitally delivered CBT (Lillevoll et al., 2013, Wilhelmsen et al., 2013).

Figure 4 shows the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow chart (Moher et al., 2009) The PRISMA diagram illustrates the flow of study identification and selection. The main reasons for exclusion included no qualitative analysis or data, primarily quantitative data, primary focus not being depression, anxiety or somatoform disorders and lacking data on the experience of using a DHI.

The majority of the 16 eligible papers were nested within a randomised controlled trial (RCT) (n=11). The included studies were published between 2007 and 2015. Most of the studies were carried out in European countries, primarily in England and Sweden (n=8). Eleven studies looked at all types of depressive disorder, including major depression and dysthymic disorder, postpartum depression and studies where depression was co-morbid with cardiovascular disease and multiple sclerosis (MS). Three studies looked at anxiety disorders which consisted of panic disorder, post-traumatic stress disorder (PTSD), and generalised anxiety disorder (GAD). One study looked at depression and/or anxiety. No qualitative studies were identified that explored the experience of using a DHI for the treatment of somatoform disorders. Most of the participants were recruited from the community or primary care; one study recruited participants from a multiple sclerosis out-patient clinic. Seven papers reported the ethnicity of participants. The participants in the studies were primarily of white ethnic background and younger or middle-aged. Most of the studies collected data via interviews and two studies collected data via open-ended questionnaires. Thirteen studies were purely qualitative studies, and 2 studies were mixed methods studies. Table 11 provides a summary of the included studies.

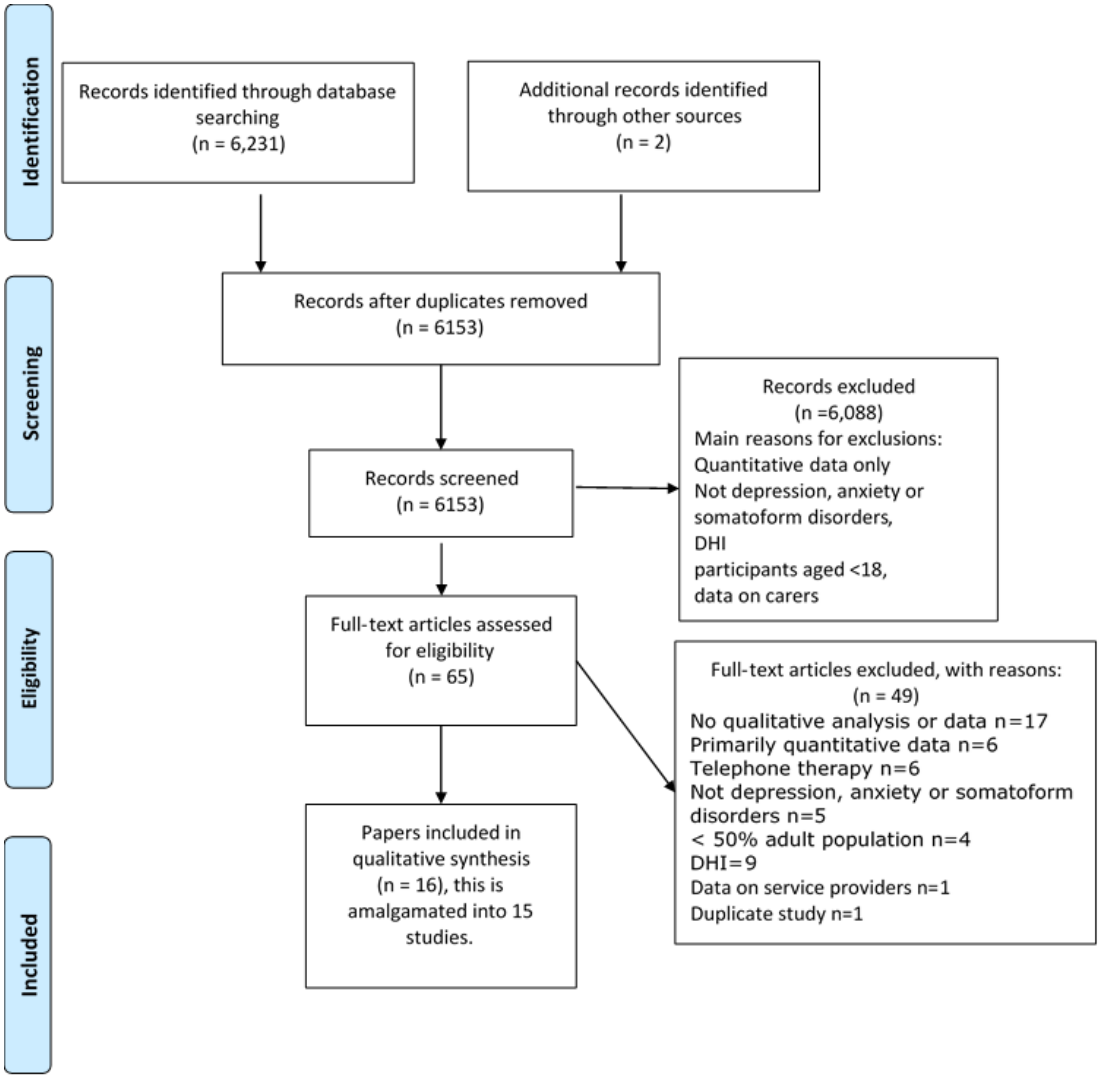

Figure 4 Flow diagram of study identification and selection adapted from preferred reporting items for systematic review and meta-analysis (PRISMA)

Sample characteristics of included studies are described in Table 12. The studies varied in types and formats of DHIs. Of the 15 studies the majority provided additional support via email, telephone calls or text messages, and four studies included some form of face-to-face support. In relation to the DHI platforms, the majority were delivered via a desk-based computer. One study included the use of a computer telephony system designed to monitor and support self-care. In terms of treatment approach, most studies were based on CBT principles.

Table 11 Summary of included studies

	No of studies (%)
Country	
England	5 (33)
Sweden	3 (20)
Norway	1 (7)
Netherlands	1 (7)
Australia	2 (13)
United States	2 (13)
Canada	1 (7)
Setting	
Community	6 (40)
Primary Care	5 (33)
Psychiatric Services	3 (20)
Medical Clinics	1 (7)
Condition	
Depressive disorders	8 (53)
Postpartum depression	1 (7)
Comorbid cardiovascular and depression	1 (7)
Comorbid multiple sclerosis and depression	1 (7)
Panic disorder	1 (7)
Generalised anxiety disorder	1 (7)
Post-Traumatic Stress Disorder	1 (7)
Depression or (mixed depression and anxiety)	1 (7)
Data Collection	
Individual interviews	12 (80)
Focus groups	1 (7)

Individual interviews and written based free text responses	1 (7)
Free text responses	1 (7)
Additional support provided	
None	4 (27)
Email/phone/text	8 (53)
Face-to-face	3 (20)
DHI Platform	12 (80)
Desktop based computer	1 (7)
Smart phone application	1 (7)
Mobile phone and web based	1 (7)
Computer telephony system	13 (87)
Treatment approach	
CBT principles	
Behavioural activation	1 (7)
Medication adherence and self-care training	1 (7)

Table 12 Sample characteristics of included studies

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
Advocat 2010	Explore experiences of internet delivered CBT	2 M, 8 F, Age range 20-66 years 9 Anglo-Australia, 1 Chinese-Australian	Community Australia	Panic Disorder	Internet delivered CBT for Panic Disorder	Yes, email support	Trial completion	Face-to-face in depth interviews	Open coding using a two-step model	Yes
Beattie 2009	Explore expectations and experiences of online CBT	17 F, 7 M Age range 24-66 Ethnicity not stated	Primary Care England	Depression	Live CBT delivered via the internet	Yes, psychologist via instant messaging	Before and after treatment	Repeated semi-structured interviews	Thematic approach drawing on constant comparative method	No in parallel
Bendelin 2011	Explore views of internet guided self-help treatment	6 F, 6M Age range 20-62 years, mean age 36 3 All	Community Sweden	Depression	Internet based CBT Guided self-help and email therapy	Yes, via email	Within 8-10 months of treatment completion	In depth face-to-face interviews	Thematic analysis and grounded theory	Yes

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
		Native Swedes								
Donkin 2012	Explore the motivators that influence persistence to continue online therapies	14 adults aged over 45 with physical health morbidities No other information provided	Community Australia	Co-morbid cardiovascular and depressive symptoms	12 week fully automated online CBT intervention for depression	Some, reminder email sent. If module not complete telephone call made with scripted reminder, No therapy provided	6-12 month follow up stage	10 phone and two f2f semi-structured interviews	Grounded theory approach using theoretical coding	Yes
** **Farzanfar 2007**	Explore attitudes of patients using an automated telephony system	9 F, 6M, 2 Hispanics, 5 Blacks and 8 Whites Age range 20-60	Psychiatric Clinics America	Depression	Telephone Linked Communications (TLC) for Depression An automated telephony system that asks questions and provides information and counselling	Yes, psychiatric Clinic Appointments	After each week of using the system	Three weekly depth interviews	Thematic analysis	Before RCT

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
Gega 2013	Explore patient experiences of computerised CBT compared to therapist delivered CBT	2 F, 3M Age range 19-33 years Ethnicity not stated	Primary Care England	Depression or mixed depression and anxiety	Beating the Blues computerised CBT and therapist assisted CBT (f2f)	Yes when receiving therapist assisted CBT Ccbt – minimal therapist input f2f to provide technical help and progress review after each session	Trial completion or drop out from both modalities	Repeated semi-structured interviews	Thematic analysis using an inductive approach	No repeat case series
Gerhards 2011	Explore patient experiences with online self-help cCBT and explanations for low treatment adherence and effectiveness	9M, 9 F Mean age 43 6 ethnicity not stated	Primary Care Netherlands	Depression	8 weekly sessions of an online multimedia interactive program “Colour your Life” (CYL) for depression	No	Treatment completion or withdrawal	Semi-structured interviews	Inductive content analysis in line with grounded theory approach	

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
Hind 2010	Investigated the acceptability of cCBT	4 M, 13 F Median age 46 (30-61) years Ethnicity not stated	England MS Clinic	Depression in people with MS	CCBT - 8 weekly sessions of Beating the Blues or 5 weekly sessions of Mood Gym	No	Written feedback after sessions Interviews after first session, and withdrawal/ completion	Semi-structured interviews and written feedback	Framework analysis	Yes
Johansson 2015	Explore patients' experience of non-adherence to ICBT	6 F, 1M Mean age 39 3 years, range (21-69) Ethnicity not stated	Psychiatric setting Sweden	GAD	8 modules of Self-help internet delivered CBT	Yes, email based weekly support from a Clinical Psychologist Phone reminders made for non-completion of weekly modules	Completion of at least one and no more than 7 treatment modules	Semi-structured interviews	Grounded theory using constant comparative process	Yes
Knowles 2015	Explore patient experience of cCBT	26 F, 10M 34 (94%) White British Mean age 51 (29-69) years. 34 (94%)	Primary Care England	Depression	CCBT – 6-8 weeks of Mood Gym or Beating the Blues	Yes, minimal, technical and general support via phone calls on a weekly basis. Psychological therapy not provided	After completion of 4 months trial follow up	Semi-structured interviews	Inductive and deductive approaches using the constant comparative method. Fragmenting and connecting	Yes

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
		White British, 2 other White								
Kuhn 2014	Explore user perspectives if a smart phone app	34 M (75 6%), 11 women. Mean age 45 25 years 46 7% Caucasian	Residential PTSD programmes America	PTSD IN Veterans	PTSD Coach, a smart phone app based on CBT Principles	No	After using the app for several days	Focus groups	Grounded theory approach. Data related to use of the app extracted from notes taken	No
*__Lillevoll 2013__ *__Wilhelmson 2013__	Explore pts experiences of being in ICBT	5M, 9 F (64%) Age range 22-61 years Ethnicity not stated	Primary Care Norway	Depression	Guided internet-based treatment - Five sessions of Mood Gym	Yes, weekly f2f consultations with a therapist over a minimum of 7 weeks	Treatment completion and withdrawal	Semi-structured interviews	A phenomenological-hermeneutical analysis	Yes

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
Ly 2015	Explore participant's views of smartphone based behavioural activation treatment for depression	6 F, 6 M, Age range 21-59 years Ethnicity not stated	Community Sweden	Depression	Guided behavioural activation self-help web – based treatment administered via a smart phone	Yes, minimal therapist contact (max time 20 minutes per week) via email or SMS like messages sent via the platform	6 months after trial involvement	In depth phone interviews 5 had a positive experience, 3 negative and 4 neutral	Thematic analysis	Yes
Pugh 2015	Gain an understanding of patients' experiences of therapist assisted internet based cognitive therapy Age not stated	24 (100%) F, 22 (92%) Caucasian	Community Canada	Postpartum depression	Therapy assisted internet based cognitive therapy (TAIBCT)	Yes, one e-mail a week from assigned internet therapist	Program completion	10 open ended survey questions on a secure internet survey site	Thematic analysis	Yes
[**]Purvez 2013	Explore the experience of self-help cCBT to alleviate psychological distress	6f and 1m Age range 30-57 years	Community England	Depression	Self-help Ccbt program called Blues Begone Program sent on a DVD to be installed on a computer	No	After program completion	Semi-structured interviews	Interpretative Phenomenological Analysis (IPA)	No

Reference	Aims	Sample (age, gender, ethnicity)	Study setting	Condition	Type of DHI	Support provided	Data collection point	Data collection	Data analysis	RCT
					Interacts with pts through animated talking heads					

16 papers included (* duplicate studies) amalgamated into 15 studies

2 paper identified through other sources (**)

Results of Meta-synthesis

Three major themes and nine subthemes were identified through the meta-synthesis in relation to the systematic review questions. These sub-themes were both “facilitators to recruitment and retention” and “barriers to recruitment and retention” in depressive, anxiety and somatoform disorder DHI trials.

The first theme: ***Initial motivations and approaches*** to DHIs had two subthemes:

a) Initial motivations: hope, accessibility and cynicism
b) Participant approaches to engaging with a DHI: active versus passive.

The second theme: ***Personalisation of treatment*** had three sub-themes:

a) Flexibility and autonomy
b) Stigma and privacy
c) Functionality, content and interface

The third theme: ***The value of receiving personal support in DHIs*** had four subthemes:

a) Support to understand DHIs
b) Support to enhance commitment and motivation
c) Suitability and the desire for additional support
d) Support to develop a virtual therapeutic relationship

Theme 1: Initial motivations and approaches to DHIs

The papers only identified one sub-theme that specifically related to recruitment. This subtheme was Initial motivations: hope, accessibility and cynicism and was within the main theme of *Initial motivations and approaches to DHIs.*

Participants’ initial motivations and approaches to participating in the DHIs had a significant impact on their perception of the DHI and this influenced how they engaged with the DHI. Those who approached the DHI with a sense of hope that it might be helpful and had an active, committed approach

to see the treatment through had more positive experiences of treatment and reported greater benefits than those who were initially more cynical and utilised a passive approach in their engagement with DHIs. Thus, participant approach to DHIs impacted on recruitment and retention. This began from when participants contemplated participating in the study (recruitment) and continued throughout their engagement with the DHI (retention). This is explored further in the following subthemes.

Initial motivations: hope, accessibility and cynicism

Ten papers reported on participant expectations of participating in a DHI trial (Purves and Dutton, 2013, Lillevoll et al., 2013, Wilhelmsen et al., 2013, Kuhn et al., 2014, Advocat and Lindsay, 2010, Beattie et al., 2009, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Pugh et al., 2015, Gerhards et al., 2011). Participants initially decided to participate in a DHI for several reasons. These included hope for recovery and the desire to improve health and reduce distressing symptoms through self-management. The prospect of using DHIs encouraged participants to feel empowered and manage their health by taking responsibility. Participants highlighted that participating in a DHI trial would enable them to develop coping strategies to manage their difficulties and increase their self-efficacy. DHIs provided a sense of agency, enabling patients to move from a passive to an active role in managing their condition.

> *"My expectation was clearly to find a tool that would help stop the depression from reappearing in the future. Both finding a tool that will help me recognise when a depression is on its way, and a tool that can quickly be a way out of it so that I won't have to end up being as deeply depressed"* (Ly et al., 2015).

DHIs were also viewed as novel approaches to treatment, which provided accessible approaches to receive help. DHIs were perceived to be more easily available because they increased flexibility and choice in accessing therapy.

> *"I loved that I could access the program anytime. It fit into my schedule in a way that traditional therapy could not have, as my baby is demanding and my husband works out of town"* (Pugh et al., 2015).

There were some negative expectations about DHIs, including scepticism about its helpfulness and concerns about whether a therapeutic relationship could be established remotely. However, in some cases the ambivalence was overturned once participants commenced treatment and there was surprise at how quickly a clinical relationship could be established remotely.

> *"I probably did come into it with lost heart, because I assumed from the start that I didn't think the computer programme was going to be for me, and maybe I sort of convinced myself"* (Gega et al., 2013).

> *"I was surprised, I felt as though it was flowing quite well, which I didn't think it would. And I warmed to him [psychologist], you know, straight away, you can do that over the internet . . . I think you could build up a good relationship over the Internet, I was quite surprised"* (Beattie et al., 2009).

In summary, participants initial motivations, hope, accessibility and cynicism influenced their decision to participate in the DHIs. The subtheme highlights that participants' decided to participate in a DHI because they desired an improvement in their health and to feel empowered and develop tools to self-manage their health conditions. DHIs were also perceived to be more accessible as they could be scheduled at times more suitable for the participant. Those who were sceptical about DHIs questioned whether DHIs were for them and were unsure if a therapeutic relationship could be built remotely. For some this scepticism/negative expectation could not be overturned, resulting in discontinuation of treatment and highlighting that DHIs were not a suitable treatment for everyone. However, others were pleasantly surprised at how quickly a therapeutic relationship could be built remotely. This sub-theme suggests that individuals' initial attitudes and feelings about DHIs impacted on willingness to participate in the trial.

Participant approaches to engaging with a DHI: Active versus passive

Participation in DHIs requires for participants to have a sense of agency and autonomy particularly where DHIs are self-directed. It can be perceived to require more effort because it relies on the individual allocating time and effort to use the DHI. It is different to having face-to-face therapy because in face-to-face treatment the therapist and client will arrange a time for when

the session will take place. The individual is expected to attend the session at the allocated time and complete any homework beforehand which is reviewed in the session. The review found that participants' approach to DHIs and technology in general impacted on their willingness to participate in the research and on their motivation to continue engaging with DHIs. This was reported in 15 papers (Purves and Dutton, 2013, Lillevoll et al., 2013, Wilhelmsen et al., 2013, Kuhn et al., 2014, Beattie et al., 2009, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Advocat and Lindsay, 2010, Bendelin et al., 2011, Gerhards et al., 2011, Hind et al., 2010, Knowles et al., 2015, Donkin and Glozier, 2012, Pugh et al., 2015). Participants who took a more active approach could see the unique benefits of DHIs compared to medication or face-to-face therapy.

> "*Rather than just saying well here's your pills or sit there and talk to somebody for 35 minutes…actually felt like I was doing something to help myself*" (Knowles et al., 2015).

Participants with an active approach embraced independent working. This involved actively processing information received (e.g. taking time to reflect on the sessions), educating themselves about their condition and applying the learning to their daily living.

> *"I felt it [working with the modules] took a long time because I was sitting reading and trying to interact…interact with what I read…It was not that I struggled with the homework or with understanding what it said, but I chose to spend time on it"* (Lillevoll et al., 2013).

> *"You could sit there and just actually take your time to do it. You know you could really think. Whereas when you're talking to somebody and you've got an hour or three-quarters of an hour or something, you really kind of you know . . . so time to me is the important thing"* (Donkin and Glozier, 2012).

Engaging with the DHI gave participants a sense of empowerment, understanding and awareness about their condition and its triggers which encouraged them to utilise the tools for self-management. It gave participants a sense of accomplishment and provided greater understanding and control over their lives. Accessing treatment online enabled participants

to choose how much time they wanted to spend on the sessions and facilitated greater control.

> *"I knew that I had a programme that I could utilise, so I did when I had time, and when I had…was in my doing mode… I felt that I wanted to take some control of the process, now I'm… I feel inspired to take more control"* (Wilhelmsen et al., 2013).

This theme was strongly represented in Bendelin et al (Bendelin et al., 2011) who highlighted that an active, self-reliant approach to treatment was related to more positive outcomes. However, participants who had a passive style of working struggled to apply the treatment and were more likely to discontinue treatment.

> *"I think I've realised that I'm kind of, I realised that I'm kind of lazy, by nature, one likes to take shortcuts, and perhaps not do the things you really ought to do. It might feel difficult or you can easily put these must-remember thoughts aside. I have realized that it's really easy to do that. If you got an assignment that made it clear that one should do so and so, then it might feel difficult, it was interesting though . . . .but still, it felt difficult"* (Bendelin et al., 2011).

Regarding completing therapy, participants with an active approach felt a sense of obligation or personal commitment to complete the therapy because they had agreed to participate in the DHI and owed it to the researcher or research team to complete the treatment. Others reported that they completed sessions because they valued the importance of research.

> *"I am thinking of the fact that I have committed. Commitment is all I can think of. And I am thinking that the person I have committed to is relying on my support. And um . . . it would be very unfair to let them down. I know that I am only one of many people, but if everybody would drop out . . . where would we be"* (Donkin and Glozier, 2012).

Participants with a more passive approach, however, struggled to maintain motivation. They found the nature of DHIs to be isolating and lacking relevance. They preferred face-to-face sessions and felt that this was an essential component of personalised practical and emotional support.

> *"Actually, the treatment program could have made a larger impact than it did, but I guess that's because I was too scared to work with it, I didn't use the material enough"* (Bendelin et al., 2011).

> *"At the end of the day, you still had to try and come up with the problems yourself and that's quite difficult and I found it quite stressful . . . I mean, it's hard doing it yourself, in isolation"* (Hind et al., 2010).

To summarise, participant approaches to DHIs impacted on motivation to complete treatment. Participants with an active approach embraced independent working and were able to relate the sessions to their daily lives. They valued that remote working allowed them to be able to spend more time on the modules and facilitated self-reflection. However, some participants struggled to work on the modules independently and found it isolating and stressful completing sessions on their own. Participants with an active engagement approach perceived DHIs to be more favourable compared to face-to-face therapy and were more likely to actively engage with DHIs by reflecting on and applying session content to their daily lives. Subsequently, these participants were more likely to complete treatment compared to participants who found DHIs isolating.

In summary, this theme highlights that participants initially decide to participate in a DHI for several reasons. These included hope for recovery and the desire to improve health and reduce symptoms through self-management. The prospect of using DHIs encouraged participants to feel empowered and manage their health by taking responsibility. Participants highlighted that participating in a DHI would enable them to develop coping strategies to manage their difficulties and increase their self-efficacy. DHIs provided a sense of agency to move from a passive to an active role in managing their condition. DHIs were also viewed as novel approaches to treatment, which provided an alternative more accessible opportunity to receive help.

Theme 2: Personalisation of treatment

The degree and ways in which DHIs were personalised to participants' situations and health status was deemed to impact the value of the treatment. The flexibility and convenience of DHIs had differential effects. For some participants this made it more accessible and possible for them to engage in treatment in a way that traditional approaches could not. However, for others the lack of structure, protected time and accountability present in more formal face-to-face therapy, meant that they forgot to complete sessions or disengaged from DHIs. Stigma and privacy were also a double-edged sword: for some the anonymity of DHIs helped them to trust the process and engage. For others the lack of a separate, private space to engage with difficult issues felt unsafe. There was broad agreement that DHIs with a simple interface and succinct content was preferred. There was also consensus that reminders, feedback on progress and acknowledgement of achievements helped to support engagement.

Flexibility and autonomy of DHIs

Flexibility and autonomy offered by the DHI in terms of health care delivery was emphasised in the majority of papers. Twelve papers reported about the flexible and autonomous nature of DHIs (Lillevoll et al., 2013, Wilhelmsen et al., 2013, Kuhn et al., 2014, Advocat and Lindsay, 2010, Beattie et al., 2009, Johansson et al., 2015, Ly et al., 2015, Bendelin et al., 2011, Hind et al., 2010, Knowles et al., 2015, Pugh et al., 2015, Gega et al., 2013). Some participants perceived DHIs to be more accessible and flexible, enabling more treatment choice. They used DHIs more responsively when they needed it, and this positively impacted on treatment completion.

> *"For me it was not a problem working on the computer. You could do it in your own pace, relax and sit comfortably. In that way I found it to be good. The only thing was a few questions or words I didn't understand so you sit there alone and think… but luckily, I have Google to help me"* (Wilhelmsen et al., 2013).

> *"It's some kind of security, because you can look at it whenever you want and so on. Because I'm the kind of person who always uses his/her phone so it felt good being able to bring it everywhere instead of other things. I think it was convenient"* (Ly et al., 2015).

Conversely, for some participants DHIs lacked the structure and protected treatment time they wanted, which subsequently impacted on their motivation to the complete treatment. Where interventions were self-guided and did not include monitoring, participants felt less obligated to complete sessions.

> *"If it was a person and if I didn't do something, I would feel guilty when I turned up, so I would be more inclined to do it"* (Gega et al., 2013).

In summary, DHIs were positively perceived by participants who found DHIs to be accessible and tailored to individual needs. Participants liked that they could access treatment at a time which was more convenient and appropriate for those who would otherwise not access treatment. The flexible and accessible nature of DHIs made it easier for participants to choose when to complete the sessions. However, for some participants, the autonomous nature of DHIs made it easier to prioritise other tasks and disengage from treatment because the sense of commitment to treatment was reduced. The flexible and autonomous nature of DHIs made it easier for participants to choose not to complete sessions as there was no sense of obligation, particularly when participants were feeling less positive.

Stigma and privacy

DHIs appealed to some participants because the remote delivery of the treatment was perceived to reduce the stigma and anxiety associated with seeking face-to-face psychological help for mental health conditions. This was reported in six papers (Beattie et al., 2009, Gega et al., 2013, Bendelin et al., 2011, Gerhards et al., 2011, Hind et al., 2010, Pugh et al., 2015).

> *"When my maternal depression was really bad, there was no way I would have left my house to speak with a therapist—I was so weepy, shaky and terrified. The online program was a perfect program for me"* (Pugh et al., 2015).

For participants who had not fully admitted their condition or felt afraid to express their thoughts, DHIs provided a safe platform from the comfort of their own home to access support. Participants felt less judged, more comfortable, and safer expressing their feelings on a computer rather than sharing it with somebody face-to-face.

> *"You can sort of say what you want without being judged … it's just you and the computer … just the two of you and whatever you put in is not known by anyone else"* (Gega et al., 2013).

However, some participants had concerns with security and privacy of accessing treatment remotely, particularly if they were not living alone.

> *"I often argue with my wife. We have a computer and that's in the living room. Everything that I do she can see, and I don't like that. So I could only do that program when she was gone*" (Gerhards et al., 2011)

In summary, for some participants DHIs were perceived to be more appealing because they reduced the stigma and anxiety associated with accessing treatment in person. The findings suggest that that for some, DHIs were seen as less personal which made it easier for individuals to express how they were feeling because it felt more private and comfortable. However, for others, DHIs raised privacy issues and accessing treatment from home was not always convenient especially for those who were not living alone.

Functionality, content and interface

There was great variability in the DHIs reported in terms of different interventions and varying levels and forms of support. Themes related to DHI functionality, content and interface were highlighted in 12 papers (Purves and Dutton, 2013, Lillevoll et al., 2013, Wilhelmsen et al., 2013, Kuhn et al., 2014, Beattie et al., 2009, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Donkin and Glozier, 2012, Gerhards et al., 2011, Hind et al., 2010, Pugh et al., 2015). Participants reported that content simplicity, reminders and progress monitoring were very important aspects of functionality, the absence of which impacted on treatment completion and satisfaction. This is because it influenced user identification with the material and provided feedback.

> *"It was good, but I did especially appreciate the reminder because sometimes it came through at a busy time, um, I didn't mean to forget about it but it happens. And I was thankful for the reminder"* (Donkin and Glozier, 2012).

Accessibility on a range of platforms, content relevance, ease of navigation, readability and inclusion of interactive elements impacted user acceptability and engagement with DHIs.

> *"I thought that it was too much to read, and I cannot read anything at all that I need to remember or learn. It goes in here and out there [pointing at the ears]"* (Johansson et al., 2015).

> *"It is very closed, there's no breaking away from the system, there is three buttons you can press and if you don't like any of the buttons that is it"* (Gega et al., 2013).

To summarise, this subtheme relates to DHI specific characteristics and how these impacted on the experiences of participants. A simple interface and succinct content with reminders, feedback on progress and acknowledgement of achievements was perceived positively and helped to support completion of therapy. The functionality of DHIs was perceived to facilitate or hinder engagement. DHIs that were easily accessible and interactive were viewed as more beneficial than DHIs that were harder to navigate and inaccessible from a range of platforms. DHIs consisting of smart phones applications were perceived to be easily accessible.

In summary, this theme relates to DHI specific characteristics and the impact these had on treatment completion and satisfaction. The flexibility and autonomous nature of DHIs made it easier for individuals to choose when to access treatment. However, others felt that the autonomous nature of DHIs lacked structure which made it harder to complete sessions. Being able to access treatment from participants homes was perceived to be more comfortable and accessible as it facilitated more openness and trust. However, others were dubious about the security of DHIs and found it difficult to find a private space away from those they were living making it difficult to access treatment privately. In terms of the functionality of DHIs there was a preference for interactive, simple interface as opposed to lengthy session content or reduced ability to navigate sessions.

Theme 3: The value of responsive personal support

This theme was identified in 15 of the 16 papers. Only Kuhn (Kuhn et al., 2014) did not report this. Participants were able to seek treatment to help them self-manage their symptoms via the use of DHIs, but they still valued some form of human, responsive, personal support even if it was not communicated in a face-to-face manner. The key elements of additional support valued by participants were support that was personal/human and support that was rapidly responsive to their emotional state, personal difficulties and achievements. Participants identified that additional support in DHIs helped them to better understand DHIs, increase commitment and motivation, and helped form more therapeutic engagement with the interventions. The rapidly responsive contact with a supporting person/therapist seemed to be missing from those who had poorer experiences of DHI. The presence and value of the provision of some form of personal support was identified as integral in the majority of studies and forms the most influential theme.

Support to understand DHIs

Incorporating some form of support in DHIs aided participants' in understanding the purpose of the intervention. This was particularly pertinent where participants were ambivalent about participating in a DHI or were unsure about the need or value of receiving psychological support. This was emphasised in 10 papers (Lillevoll et al., 2013, Wilhelmsen et al., 2013, Advocat and Lindsay, 2010, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Gerhards et al., 2011, Hind et al., 2010, Knowles et al., 2015, Pugh et al., 2015). Where support was not provided, participants misunderstood the difference between a research trial and the DHI and would often assume that trial participation was part of therapy.

> *"I thought that the computer program was the questionnaire, and the doctor. So however, I read it I thought computer program and doctor. That was it for me: questionnaire and doctor"* (Gerhards et al., 2011).

Guided support provided participants with direction about the interpretation of the treatment session content and made therapy more personally relevant.

> *"The book wasn't completely useless, but if I'd have just had the book without the therapist I don't think I would have made the improvements that I did do… when I talked about it with him, even thought it was basically common sense what he was telling me, because I'd never thought about it because that was my life the way it was, it was helpful the fact that he was putting everything into context for me"* (Johansson et al., 2015).

To summarise, this highlights the significance of the provision of some form of human support even if this was offered remotely. Support facilitated understanding of the relevance of research trials.

Support to enhance commitment and motivation

Incorporating some form of support to enhance commitment and motivation was highlighted in 13 papers (Lillevoll et al., 2013, Wilhelmsen et al., 2013, Beattie et al., 2009, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Bendelin et al., 2011, Donkin and Glozier, 2012, Gerhards et al., 2011, Advocat and Lindsay, 2010, Pugh et al., 2015, Purves and Dutton, 2013, Hind et al., 2010). Due to the autonomous nature of DHIs, participants reported forgetting or feeling less obligated to engage in treatment compared to face-to-forms of therapy as highlighted in the previous theme. Without additional support they struggled to relate to and apply the therapy content to their own condition leading to disengagement from the DHI.

> *"Because I just thought it was something on the computer and there was always going to be someone at the other end, I was a bit slack about it towards the end"* (Advocat and Lindsay, 2010).

> *"The therapist helped me to find my motivation every now and then, and then I was on top of it for about a week or so, and eventually the application sort of became a part of my everyday life. Then it was pretty obvious that I would use it and then I didn't even think about whether it was hard to use it, I just did it"* (Lillevoll et al., 2013).

Receiving feedback from a therapist/others allowed participants to monitor their progress, prevented forgetfulness and encouraged participants to continue with therapy.

> *"You haven't really got someone or something forcing you … I really need that. I either put it off or I just don't look at it … If you're in a bad mood then you really don't feel like it. Yes, that is motivation. Someone should say to me "you have to do it"* (Gerhards et al., 2011).

In summary, some form of communication was helpful and was achieved via several mediums including the provision of support face-to-face, but also remotely via emails, phone calls and text messages. Thus, receiving support facilitated understanding of symptoms, reminded participants to complete modules and provided encouragement to overcome challenges and reduce isolation. Participants who received self-guided DHIs expressed dissatisfaction with the lack of human interaction and expressed that it was required to increase commitment as it enabled personal support and feedback. Participants who received face-to-face contact as part of the DHI expressed that incorporating interpersonal features such as the provision of support was central because it personalised therapy. Personalised support facilitated an understanding of therapy, increased commitment and motivation to continue treatment, and helped form a more therapeutic engagement with DHIs. Similarly, participants in DHIs consisting of email or phone support reiterated that the presence of a supporter personalised therapy. However, they also expressed a desire for more contact with a supporter. Participants in the 2 studies that provided no therapy and only technical support or reminders (Donkin and Glozier, 2012, Knowles et al., 2015) expressed a need for personalisation in the form of feedback and emotional support. Disengagement from a DHI was more likely in the absence of support as it reduced commitment and motivation to complete therapy.

Suitability and the desire for additional support

Questions over the suitability of DHIs for some problems were raised in eight papers, alongside some patients' desire for additional responsive support when DHIs became challenging or unsuitable (Purves and Dutton, 2013, Johansson et al., 2015, Ly et al., 2015, Donkin and Glozier, 2012, Gerhards et al., 2011, Hind et al., 2010, Knowles et al., 2015, Pugh et al., 2015).

Treatment delivered remotely could be physically and mentally exhausting and exacerbated symptoms of low mood and anxiety for some participants.

> *"If you're mildly depressed, or if you've turned the corner, then I think that's when it's appropriate. But I think if you were deeply depressed, and still struggling, then it would be much harder …I think you probably would fail and that would make you feel worse. Because the last thing you need is another failure when you're feeling really down"* (Knowles et al., 2015).

Therefore, some participants wanted additional support to manage these negative feelings.

> "*I would have liked to have more of a personal contact, it became a little distant everything, to do this on the Internet, because it is so heavy stuff, it's nice to meet a real person when you're working with heavy things like this"* (Johansson et al., 2015).

Where support was not provided, participants decided to discontinue treatment.

> *"I just thought: I'm just torturing myself, I've had enough, I don't want this anymore … To write this feeling down and then at the end of the day to think about how I felt. It made me even more depressed so I just let it go"* (Gerhards et al., 2011).

The absence of support made module completion overwhelming for some participants, leading them to prioritise other commitments.

> *"I get anxious, and then I begin to think to myself that "I've got to do this" and "I've got to do that," and "I can't do my [program] now, I'll do it later," and really there is nothing that can't wait. Nothing at all. I have a set routine. I'm retired. But I get myself into such a state of anxiety that I can't relax and do my [program]. So, I leave it and go and do my silly little things such as taking my dog for a walk and doing my shopping. All sorts of, you know, mundane things that are not important, well they are important, but I could give myself the time to relax and do it" (Don*kin and Glozier, 2012).

One study (Hind et al., 2010) focusing on DHIs for people with depression and physical comorbidities, found that completion of DHI sessions placed

physical demands on participants such as having to sit up for long periods of time at a desk.

> *"Typing increases discomfort in my dominant right hand. It's a bit tiring sitting there clicking away . . . because I have a bit of a problem with my right hand and I sort of, you know you're click, click, click"* (Hind et al., 2010).

This theme was not highlighted by any of the papers that included face-to-face support (Lillevoll et al., 2013, Wilhelmsen et al., 2013, Farzanfar et al., 2007, Gega et al., 2013). Where support was not provided, some form of support was recommended to overcome feelings of isolation and enable emotional expression (Gerhards et al., 2011, Hind et al., 2010, Purves and Dutton, 2013).

> *"With MS you can become very isolated because of your disability . . . So, I think when working with something that is a computer programme it makes you feel even more like you're not speaking to someone face-to-face. You don't get the empathy there"* (Hind et al., 2010).

In summary, this theme highlights that the suitability of DHIs can be influenced by symptom severity. DHIs were not viewed to be suitable for those reporting severe symptoms of anxiety. Continuing with sessions without the presence of additional support was perceived to increase anxiety/depressive symptoms leading to a discontinuation of therapy.

Support to develop a virtual therapeutic relationship

The interpersonal and relational aspects remained an essential ingredient of therapy even if it was delivered as a DHI. This sub-theme was reported in 12 papers (Purves and Dutton, 2013, Lillevoll et al., 2013, Wilhelmsen et al., 2013, Beattie et al., 2009, Gega et al., 2013, Johansson et al., 2015, Ly et al., 2015, Donkin and Glozier, 2012, Gerhards et al., 2011, Knowles et al., 2015, Pugh et al., 2015, Farzanfar et al., 2007). Participants who engaged with DHIs reported feeling surprised at how quickly a relationship could be formed remotely with a person despite not being able to see them. They valued expressing feelings in written form, because it enabled self-reflection and communication of emotion without interruptions. Attributes associated

with developing a therapeutic relationship face-to-face were also identified in DHIs. This included building a trusting relationship and feeling supported.

> *"I thought it [the relationship with the therapist] was really good! She didn't make me feel judged in any way. She was very accommodating. Almost as if she understood what I was talking about. She sometimes was ahead of me about things I was going to say, in a way. She understood very well what it was like*" (Lillevoll et al., 2013).

Participants who disengaged from DHIs found them to be impersonal and expressed a preference for face-to-face psychological therapy. The absence of visual cues such as eye contact and gestures was perceived to reduce emotional closeness and made participants question whether the therapist was giving them their undivided attention.

> *"If you're feeling like that, then a computer telling you something isn't going to make any difference. Whereas somebody seeing you and seeing the state that you're in can make a big difference…, the verbal cuddle, which is what you need" (Knowles et al., 2015).*

> *"I'm not sure there was a relationship. And that, because of that, part of the reason for that was the lacking the face-to-face, it's like having a telephone conversation, isn't it? You don't have the same closeness as you would meeting somebody round a table, it's inevitable. And that, that's got to impact on the benefit of the therapy…I didn't build a relationship with him*." (*Beattie et al., 2009)*

The use of written communication methods and associated time delay between responses were seen as barriers to developing a therapeutic relationship. The absence of face-to-face contact resulted in DHIs lacking empathy and being machine-like which negatively impacted on the therapeutic relationship.

> *"That thing doesn't talk back, … I haven't got any contact with it. Whereas when I talk to you, then you react, and then you straightaway reach a much deeper level than with the computer" (*Johansson et al., 2015).

> *"I think the difference is when you're typing on to a computer you have to shorten what you want to type . . . .I mean, you could sit here and tell someone how you're feeling . . . and it could take you five minutes . . . but on*

a computer you haven't got the time or space . . . you haven't got the time to type out everything on how you're feeling" (Beattie et al., 2009).

To summarise, some participants were able to develop a therapeutic relationship with the therapist via written communication. They felt listened to, it did not feel mechanical. It paralleled a face-to-face session. However, in DHIs, body language is limited compared to face-to-face. For others therefore, the loss of body language and eye contact affected the therapeutic relationship.

This theme highlighted that incorporating interpersonal features in DHIs such as the provision of some form of support was central because it personalised therapy. Personalised support facilitated an understanding of therapy, increased commitment, and motivation to continue treatment, and helped form a more therapeutic engagement with DHIs.

Discussion

The aim of the systematic review was to understand the factors affecting recruitment and retention of service users who had been invited to participate in DHI trials for depressive, anxiety and somatoform disorders.

The meta-syntheses found that initial perceptions of can be positive or negative depending on individual expectations, preferences, and approaches to DHIs. Table 13 demonstrates the facilitators and barriers within each theme.

Table 13 Facilitators and barriers to recruitment and retention to DHIs

	Facilitators	**Barriers**
Theme 1 **Initial motivations and approaches to DHIs**		
Subtheme 1: Initial motivations: hope, accessibility and cynicism	Reasons for participating in a trial consisting of a DHI	Scepticism about the helpfulness of a DHI and whether therapeutic

	included hope for recovery and improved accessibility.	relationships could be formed online.
Subtheme 2: Participant approaches to engaging with a DHI: active versus passive	DHIs facilitated independent working and allowed more time for reflection and application.	The autonomous nature of DHIs could be perceived to be challenging and stressful.
Theme 2 **Personalisation of treatment**		
Subtheme 1: Flexibility and autonomy	The flexible and accessible nature of DHIs makes it easier for participants to choose when to complete the sessions.	The flexible and autonomous nature of DHIs made it easier for participants to choose not to complete sessions, there was no sense of obligation when participants were feeling less positive.
Subtheme 2: Stigma and privacy	DHIs were perceived to be more appealing because it reduced the stigma of accessing treatment for psychological problems.	Face-to-face contact was perceived to be essential in overcoming the stigma.
Subtheme 3: Functionality, content and interface	Functionality of DHIs such as being able to monitor and reflect on progress was perceive positively.	Lengthy sessions impacted on retaining focus.
Theme 3 **The value of receiving personal support in DHIs**		
Subtheme 1: Support to understand DHIs		

	Access to a therapist in addition to computerised sessions facilitated improvement and outcome.	Without additional support participants struggled to distinguish between the research and therapy.
Subtheme 2: Support to enhance commitment and motivation	Therapist contact encouraged motivation to complete tasks.	Lack of therapist contact impact discouraged participant willingness to continue with therapy.
Subtheme 3: Suitability and the desire for additional support		The decision to discontinue with the DHI was because continuing with sessions was perceived to increase anxiety symptoms.
Subtheme 4: Support to develop a virtual therapeutic relationship	Participants were able to develop a therapeutic relationship with the therapist via written communication. They felt listened to, it did not feel mechanical. It paralleled a face-to-face session.	In DHIs, body language is limited compared to face-to-face. The loss of body language and eye contact affected the therapeutic relationship.

The review highlights that therapeutic work in DHIs is a dynamic process and is perceived positively or negatively depending on how well the DHI is adapted to the participants' preferences. The personalisation of DHIs was an overarching theme, implying that DHIs need to consider individual preferences, circumstances and needs to improve DHI uptake and completion.

The themes emerging from the meta-synthesis highlight that that personalised support was valued across studies irrespective of DHI type, format, or health condition. Some form of human interaction was valued

because it personalised therapy and increased motivation to complete therapy. This supports the transferability of this finding, given that participants reported similar themes from a range of DHIs.

This meta-synthesis illustrates the different requirements of support that can potentially be provided in several ways. Thus, based on participant preferences and needs DHIs could be tailored to meet individual presentations. DHI functions and level of support likely to be required could be determined by initially assessing participant expectations and needs, as opposed to uniformly offering DHIs as an all or nothing option.

This meta-synthesis emphasises the significance of receiving personal support in DHIs and is consistent with the findings of O'Connor et al (O'Connor et al., 2016) and Knowles et al (Knowles et al., 2014); both reviews highlighted the need for personalisation and availability of support in DHIs. The meta-synthesis also informs some of the research priorities identified by Hollis et al (Hollis et al., 2018). This review highlights that the suitability of DHIs is based on differing needs and that DHIs could be optimised by incorporating additional support. This systematic review extends the previous findings of Knowles et al by demonstrating that personalised support was valued across studies, irrespective of DHI type, format or disorder (Knowles et al., 2014). The functionality of DHIs was perceived to both facilitate and hinder engagement. DHIs that were easily accessible and interactive were viewed as more beneficial than DHIs that were harder to navigate and inaccessible on a range of platforms. DHIs consisting of smartphone apps were perceived to be easily accessible. A simple interface and succinct content with reminders, feedback on progress, and acknowledgment of achievements also helped to support the completion of therapy.

Strengths

This was the first meta-synthesis that looked at the factors affecting recruitment and retention of DHIs for depressive, anxiety and somatoform disorders across different types and formats and across a range of depressive and anxiety disorders. This systematic review included all DHIs

regardless of the delivery method (i.e. text-based, automated, blended therapy). It compared very different experiences to consider whether therapies involving digital aspects shared common issues and if consistent themes were found across different formats and modes of delivery. The review aimed to build on previous literature to explore the diverse nature of DHIs and explore whether potential facilitators and barriers are consistent across different types and formats of DHIs. It also explores if there were specific issues relevant to integration of support compared to self-guided DHIs and explore whether varying levels of support, intensity and delivery formats influenced participant decision to participate and complete a DHI.

Limitations

A limitation of including a range of different interventions is that some comparisons may have been incompatible or inappropriate across these rather different technologies. However, given the broad inclusion criteria, it is particularly important that personal support was still highlighted as a theme across studies and gives greater weight to its importance. The review excluded peer-to-peer networks and DHIs of social support via the internet, use of social media, online support groups or DHIs consisting of group therapy, future research could explore whether participant experience of these delivery formats differ or are similar to our findings. It is worth highlighting that technological competence was only identified by two studies (Gerhards et al., 2011, Beattie et al., 2009) as a potential barrier to engaging with a DHI. Although this could be because the views captured in the papers are mainly of participants who chose to engage in a DHI and does not capture the experiences of participants who decided not to participate in a DHI or a research study. The majority of the DHIs were CBT-based despite including a broad range of mental health conditions, treatment settings and types of DHIs. Recommended therapies such as interpersonal therapy for depression were notably absent from studies included (NICE Guidelines 2019). In terms of DHI variability, the use of videoconferencing to provide therapy was not included in any studies. Furthermore, majority of studies were for the treatment of depression, and there were no studies on the use of DHIs for the treatment of somatoform disorders (including health anxiety).

This systematic review was not carried out using double screening, with only 30% of data being extracted by two reviewers due to resource constraints. However, the high level of congruence found for the subset sample implied that the screening methods were rigorous. The systematic review only included papers published in English, which may reflect the fact that the majority of the studies were conducted in European and American countries. However, major sources of technology production are found in non-English speaking countries e.g. China, Japan and India. Additionally, unpublished data were not included in the search strategy, and this may have impacted the results of this review. Nevertheless, this approach was also seen as a further strength by ensuring that only peer-reviewed interventions were included.

Implications for research

Based the findings from the meta-synthesis the following implications are proposed in relation to recruitment and retention to DHIs:

1. The first aim of the review was to identify the barriers and facilitators to recruitment to DHIs for adults with depressive, anxiety and somatoform disorders. The review acknowledged that expectations and pre-existing beliefs about DHIs and their effectiveness can have an impact on patient willingness to participate in a DHI and impact on overall participant experience and treatment completion levels. The perceived advantages and barriers at the recruitment phase determine trial participation and is influenced by the perceived usefulness of the intervention which determines intention to participate in a trial consisting of a DHI which then impacts on actual use of DHI. Therefore, addressing these attitudes and expectations prior to beginning a DHI and ensuring understanding of the research aims and objectives or building this into the initial stages of DHIs would help manage any misconceptions and address early barriers to recruitment. Initial assessment might also include addressing patient preferences in terms of autonomy, level of support and medium of

communication. This would help identify whether additional support is needed and if so, the level required. Identifying these needs would improve participant perceptions about and improve retention rates. Responsiveness to any potential barriers could improve recruitment and retentions to DHIs.

2. The second aim of the review was to identify the barriers and facilitators to retention to DHIs for adults with depressive, anxiety, and somatoform disorders. There was a clear and consistent theme of a preference for the provision of additional support particularly where the person was passive or indifferent in their willingness to engage with a DHI. Additional support should be personalised, incorporate some form of human interaction and be rapidly responsive. This support can be both technical and emotional support. Support provides clarification of the intervention's purpose, personalises therapy and increases self-discipline and motivation to engage with DHIs. Thus, retention rates to DHIs can be improved by including personal reminders for therapeutic activities and giving participants' individualised feedback on their progress with therapeutic tasks. Ensuring that the interface and content is succinct and easy to navigate around would also likely reduce DHI attrition. Thus, future DHIs need to consider how feedback and reminders could be incorporated and presented to improve treatment completion rates.
3. The third and final aim of the review was to identify gaps in reporting of barriers and facilitators in recruitment and retention to DHIs for depressive, anxiety, and somatoform disorders. Most studies included in the review were for the treatment of depressive and anxiety symptoms and there were no studies on the experience of DHIs for the treatment of somatoform disorders. This highlights the need to explore the experiences of this group of patients. In addition, none of the studies in the review used videoconferencing as a treatment modality. Videoconferencing has the potential to provide real-time face-to-face therapy remotely, thus improving accessibility but also increasing the level of personalised support. The findings from the Urgent Care trial showed treatment completion rates to be

substantially higher than other DHI studies (Morriss et al., 2019) thereby implying that offering therapy via videoconferencing where the visual cues are not missing and the communication is synchronous might be a more appropriate form of DHI format. Furthermore, only two studies specifically addressed recruitment and patient expectations prior to participation in a DHI (Beattie 2009 and Ly 2015), the remainder of the papers focussed more on participant experience of using or discontinuing with DHIs. Given that recruitment to health care trials primarily relies on being referred by clinicians, factors influencing service provider decisions to participate and refer patient to DHI trials and organisational factors also warrants further exploration.

Chapter summary

This review indicates that addressing service users' initial expectations of DHIs could help improve recruitment to DHIs. Furthermore, the addition of rapid, responsive personal/human support albeit offered remotely could improve participant completion and retention to DHIs. The recommendations offered by this review suggest that there needs to be an investigation into the factors influencing recruitment and retention to DHIs for people with health anxiety. Further exploration specifically focussing on participant perceptions and experiences of participating in and remaining in a trial consisting of a DHI is also required, as is the perspective of service providers who are often the gatekeepers to patients being offered the opportunity to participate in a DHI.

The next chapter outlines the aims of the qualitative study and the justification for adopting a qualitative approach. The methods used to collect and analyse the qualitative data are also described.

Chapter Five: Methodology and Methods

Introduction

This chapter will provide an overview of the study methodology and methods. The chapter begins with an explanation of the research questions and discusses the paradigmatic, ontological, and epistemological position of the doctoral researcher. A detailed account of the study design, outlining how the use of qualitative methods most suitably addresses the research questions is provided. The chapter then describes the data collection methods, participant recruitment processes and data analysis methods. The data concludes with the ethical implications arising from the study design and how these were addressed.

Research Aims and Objectives

In Chapters One and Two the background to this study was provided. Chapter One set the scene for this doctoral study that was nested within the Urgent Care trial. Chapter Two provided an overview of the literature pertaining to health anxiety, outlining the prevalence and treatment of health anxiety and the potential for treatment to be offered remotely. Chapter Three discussed the significance of recruitment and retention in research trials and outlined some of the factors influencing recruitment and retention of Digital Health Intervention (DHI) trials. It also explored some of the theoretical models that could explain recruitment and retention. Chapter Four was a systematic review and meta-synthesis which addressed Research Question (RQ1) of the doctoral study.

The main aims of the empirical data are to explore service user and service provider perceptions of being invited to participate in the Urgent Care trial and their experiences of participating in it. As such, the original empirical data addresses the following research questions:

RQ2- What are the factors influencing service providers decision to participate in the Urgent Care trial?

RQ3- What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?

RQ4- What are the factors influencing service user participants decisions to participate in the Urgent Care trial?

RQ5- What are the factors influencing service user participants the decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial (retention).

I wished to explore key aspects of recruitment and retention to the Urgent Care trial from the perspectives of service providers and service users. I wanted to explore the decision-making processes of service providers and service users when considering whether to participate and remain in the trial. I also wanted to explore commonalities and differences in the service-provider service-user relationship within secondary and primary care. I wanted to explore what aspects require further efforts to improve recruitment and retention to DHI trial, and I also wished to reflect on the data generated through the doctoral study to explore if it could inform future health care studies consisting of DHIs in improving trial uptake and retention.

Methodological Orientation

The research paradigm

The following sections of this chapter focus on the theoretical foundations of the study and justifies the use of a qualitative approach to data collection and analysis.

Within health care research there are two methodological approaches, quantitative and qualitative. Hammersley (Hammersley, 2002) states that although researchers are influenced by their epistemological and methodological beliefs, the choice of methodology largely depends on the topic being investigated and the research question(s) being posed. The chosen methodology influences the methods selected (Brewer and Crano, 2000)

According to Lincoln and Guba (1985), researchers begin their research by being clear about the paradigm that has guided and informed their approach. A research paradigm is defined as '*the world view that is accepted by members of a particular scientific discipline which guides the subject of the research, the activity of the research and the nature of the research outputs'* (Pickard, 2013 page 18).

Health care research, like any research endeavour, requires a philosophical position to be taken regarding the way in which the world is to be viewed, as this influences the researcher's decisions and chosen methodology (Mertens, 2023). This includes the researcher's views and understanding regarding the nature of the "knowable" or of 'reality' (ontology) and how 'reality' is understood (epistemology). The methodological question asks how can the researcher go about obtaining the desired knowledge and understanding (Pouliot, 2007).

Quantitative methodology is based on a positivist approach, and assumes that there is only one truth, an objective reality that exists independent of the researcher's perception (Willig, 2013). Epistemologically the researcher and the subject of research are independent, the research question is studied without being influenced by the researcher, hence the research is value free. Quantitative research consists of numerical values, often statistical analysis, and the testing of hypotheses (Creswell and Creswell, 2018).

In contrast, qualitative research focuses on the processes, meanings, experiences and understanding that the participants of the research have on the chosen area of focus (Mertens, 2023, Braun and Clarke, 2021). One particular qualitative approach referred to as interpretivism assumes that multiple realities exist, with reality being a social construct upon which participants and researchers bring their world view to depending on context (Creswell and Creswell, 2018). Epistemologically, there is no reality independent of our minds: the researcher and the participants are interactively linked, and findings are subjective and sensitive to social context. The qualitative researcher aims to explore social constructions of

meaning and knowledge through trying to understand the lived experiences of people (Mertens, 2023, Schwandt et al., 2007).

When exploring recruitment and retention in healthcare trials qualitative research is important because it can help to identify the concerns and priorities of patients and health care professionals and elicit what participants involved in a process consider as being important and significant. Furthermore, qualitative research can assist with the development and evaluation of theories, tools and interventions, as well as assist with translation and implementation into clinical practice (Renjith et al., 2021).

Table 14 highlights the most prominent paradigms in health services research and their ontological, epistemological and methodological assumptions (Guba and Lincoln, 1994).

Table 14 Paradigms in health service research

Paradigm	**Ontology**	**epistemology**	**Methodology**
Interpretivism	Reality is created by individuals and groups (Interpretivist)	All scientific inquiry is related to the values of the observer including choice of research question, paradigm selection, methods, analysis, and interpretation (Subjectivist)	Qualitative approaches
Positivism	Reality is 'knowable' and driven by natural laws (Realist)	The biases and values of the researcher must not influence outcomes. (Objectivist)	Experimental; quantitative approaches

An interpretivist paradigm focuses on understanding the way people interpret and make sense of their experiences and the world in which they live, and in doing so, utilises qualitative methodological approaches (Creswell and Creswell, 2018). This is because the concept of multiple realities and the

social construction of reality, which then necessitates that the perceptions of a range of individuals must be sought. Interpretivism can be characterised by a commitment to gain a better insight into the perceptions of those being investigated. In terms of ontology, an interpretive paradigm implies that no one reality exists, but that multiple realities exist, including those of the study participants and researchers. With regards to epistemology, from an interpretivist perspective, knowledge is derived from the subjective experiences of individuals. Taken together, in terms of methodology, in interpretive research the tools utilised to research a topic area are primarily inductive methods and acknowledge the role of the researcher in shaping the study (Rowlands, 2005). The benefits of an interpretivist approach to health research include understanding patients' use of services, and the meaning that they make of symptoms in relation to their broader lives (Green and Thorogood, 2018). They suggest that this can provide insight into how patients interact with (and comply with) care and suggested treatments. An interpretivist paradigm is more inductive rather than deductive and assumes that analytical themes are developed based on the data collected. Given that the aim of this doctoral thesis was to gain an understanding of experiences, meaning and decision-making processes of individuals', a qualitative approach was deemed to be most appropriate. Therefore, the epistemological stance taken in the thesis was an interpretivist approach. This is because the nature of the doctoral study and the research questions focused on exploring experiences, and understanding decision-making processes. As it is not possible to objectively measure or quantify experiences, a quantitative approach would have been inappropriate for this study.

The doctoral study required a qualitative approach, enabling the focus of the research to be on exploring and understanding the barriers and facilitators to recruitment and retention into a trial for a DHI from the perspective and experiences of service providers and service users. It was important to explore the multiple perspectives of service users and service providers to deepen an understanding of their experiences and reasons for participating in a DHI trial. From a service provider perspective, I wanted to learn about

the philosophy of their practices: how they delivered services and how they engaged in research. I also wanted to explore how the organisation operated as a whole and who were the key members of staff that promoted the research at the sites. I wanted to explore service provider attitudes about health anxiety and how this impacted on their practice. I also wanted to investigate their attitudes about research in general, and of their first impressions of the Urgent Care trial. Furthermore, I wanted to hear their thoughts on how they felt the study had progressed at their site and what the facilitators and barriers to referring patients to the trial were. From a service user perspective, I wished to explore the various stages of study participation: recruitment and non-recruitment to the trial, completion and non-completion of the treatment and completion and non-completion of outcome measures. This would allow a better understanding of the perceptions and experiences of service users who were invited to participate in a trial. It would enable an exploration of factors that influenced an individual's decision to take part and remain part of the study, as well as the aspects participants found helpful and unhelpful with regards to the trial in general and specifically the DHI. It would also enable me to explore the experiences of those who were allocated to the treatment us usual (TAU) arm and individuals who declined or withdrew from the trial or treatment, and the factors that influenced their decision-making processes.

Consideration of other methods of data collection

Alternative qualitative methodologies, such as Interpretative Phenomenological Analysis (IPA), Discourse analysis and Grounded theory were considered as methodological approaches for the current research. IPA was not selected because this methodological approach focusses on individual narratives (Griffin and May, 2012). Furthermore, as the research question is not idiographic or based around language, discourse analysis was not selected. Initially I did consider a grounded theory approach. However, it was not possible to use grounded theory because I had substantial prior knowledge and involvement in the Urgent Care trial. Therefore, an interpretivist approach was selected.

The use of qualitative interviews

Qualitative research is informed by one of a range of methodologies or broad theoretical and philosophical frameworks. It is not constrained to a particular tradition, framework or approach (Ravitch and Carl, 2019). Because the main aim of qualitative research is to gain rich, in-depth understanding it tends to consist of smaller numbers of participants than in quantitative research (Smith, 2015).

Techniques used in qualitative studies include in-depth semi-structured interviews and focus groups. Interviews are considered the backbone of qualitative research and are the most commonly used qualitative approach in social health research (Adhabi and Anozie, 2017). In qualitative research, data are commonly collected through in-depth interviews to gain insights into the experiences of the participants and explore to a phenomenon in-depth. Interviews are social interactions that take place between two or more individuals during which information is negotiated and exchanged. Qualitative interviews are seen as offering the possibility of exploring the way in which respondents themselves define the experiences and practices which are the object of the research (Paget, 1983, Merriam, 1988, Jensen, 1989, Britten, 1995). In contrast to quantitative research, which can be seen as pre-defining the topic and consisting of a set of pre-defined questions, qualitative approaches to interviewing are believed to offer respondents the opportunity to define the problem in their own terms and to challenge the researcher's pre-conceptions about what is important or significant about the matter at hand (Gray, 2021). Qualitative interviewing is advocated as a means of understanding the "insider's perspective"(Jensen, 1989), "how research participants understand their world" (Secker et al., 1995) and "what is on someone's mind" (Merriam, 1988).

Patton (Patton, 1980) argues that interviews are used when the researcher wants to find out something which cannot be directly observed. We cannot observe feelings, thoughts, and intentions. We cannot observe behaviours that took place at some previous point in time. We cannot observe situations that preclude the presence of an observer. We cannot observe how people

have organised the world and the meanings they attach to what goes on in the world and we must ask people questions about those things. The purpose of interviewing, then, is to allow us to enter the other person's perspective. Silverman (Silverman, 2015) states that the aim of interviews is to generate data which grants authentic insights into individual experiences.

One of the main reasons for the popularity of interviews is their flexibility and ability to access people's experiences, their attitudes, perceptions, feelings, and realities. They also help elicit participants' interpretations of their experiences with the explored phenomenon and give the researcher the opportunity to capture rich data (Britten, 1995, Creswell et al., 2007). Interviews provide study participants with the freedom to talk about their experience and express their feelings and viewpoints in their own words. The aim of an in-depth interview is to achieve rich data, that can provide breadth and depth in relation to the topic of enquiry. An interview is a "conversation with a purpose" (Lincoln and Guba, 1985) they are used as a data collection method to gain the participant perspectives and explore meanings placed by individuals about a phenomenon. Dingwall and Miller argue that, however informal, an interview is, it is not the same as a conversation because the interviewer determines what will be the key areas to discuss. (Dingwall and Miller, 1997). It is a deliberately created opportunity to talk about something which the interviewer is interested in, which may or may not be of interest to the respondent. According to Mishler (1991), an interview is a form of discourse shaped and organised by asking questions, it is a joint product resulting from the interaction between interviewers and interviewees.

Consideration of other methods of data collection

An observational approach involves the systematic observation of participants' behaviour and narratives in their natural settings (Mays and Pope, 1995) the researcher remains at a distance to avoid biasing participants' behaviour (Flick, 2009). This method was not suitable considering the aim of the doctoral study, which was to elicit users' experiences of deciding to participate in a trial (recruitment) and their experiences of participating in the trial which influenced whether they

completed the study processes (retention). Furthermore, an observational approach was not considered to be practical because of logistical challenges.

Focus groups are a popular method of data collection in qualitative research. This approach consists of interviewing participants together in small groups, making use of the interaction between research participants to collect data not only in response to the research questions but spontaneously generated through group discussion and dynamics (McLeod, 2001). Focus groups were not suitable in the context of this study for several reasons: Firstly, only a limited number of questions can be posed to a focus group in comparison to individual interviews, to accommodate greater inner-group discussion. Secondly, individuals with health anxiety may not feel comfortable discussing their thoughts within a group setting due to the stigma and perceptions about their health anxiety. Thirdly, an individual interview setting may be more suitable to explore interpersonal variation in the context of participating in a trial. Focus groups do not provide the environment to pursue everyone's understandings in particular depth, but rather to allow a group discussion to emerge. One criticism of this method is that following this more collaborative approach, an individual may be reluctant to express their views if they are not congruent with those of the group (Sim and Waterfield, 2019).

Types of interviews

The following sections discuss different types of interviews in qualitative research and limitations to this data collection tool.

All qualitative interviews contain the same basic elements of discussion, detail, and description. However, they vary according to the degree of control the interviewer imposes on the responses of the informants. Therefore, based on the degree of structuring, interviews can be divided into three categories: structured interviews, semi-structured interviews and unstructured interviews (Fontana and Frey, 2005). Structured interviews are composed of a set of predefined questions that are carefully and fully worded. These questions are asked to each interviewee in the same way, order and with the same probes. This standardisation is intended to minimise

the effects of the instrument and the interviewer on the research results. Thus, structured interviews allow a cross-comparison of responses over time. They are also suitable for studying the views of a large sample of participants on well-known or previously explored topics through open questions interviews. However, a weakness of this approach is that it limits the researcher from exploring topics that may emerge during the interview. In qualitative research most interviews tend to be less structured and controlled, structured interviews are more likely to be used in quantitative research to maximise reliability and validity of the measurement of variables.

Semi-structured interviews are less controlled than structured interviews and thus more flexible. A topic guide, consisting of closed and open questions, is developed. In semi-structured interviews, a minimal number of broad, data-generating questions are asked to initiate the interview process. Probes are used as needed to clarify the meaning of responses and encourage in-depth descriptions. The researcher prepares a short list of flexible questions as a starting framework for discussion with the participant and then further questions can be asked to allow participants to clarify and elaborate on their response (Howitt, 2016, Dicicco-Bloom and Crabtree, 2006). Howitt (2016) described semi structured interviewing as a commonly used technique in gathering qualitative data which can be applied with varying levels of flexibility and rigor.

Unstructured interviews can be an approach useful for exploring new topics or those that are not well known or understood. Because of their high degree of flexibility, respondents can express their views freely with minimum control from the interviewer. Although the interviewer needs to be aware of the areas to be covered during the interview and may be equipped with a checklist, the interview commences with a single question, after which the respondent is able to respond in any way. Interviewers only probe or respond to points raised to encourage and stimulate the respondents to express their views.

In keeping with the qualitative research design and exploratory purpose of the current research, semi-structured interviews were chosen as the method of data collection. Semi-structured interviews were chosen as a data

collection tool for the thesis because they allowed participants to express their views and perceptions about trial participation and enabled the researcher the flexibility to amend and change the interview guide to allow further exploration of emerging themes. Semi-structured interviews allowed interviewees to respond with as much detail as they wanted to share their experiences of living with health anxiety and their experiences of trial participation. The nature of semi-structured interviews also allowed for follow-up questions or prompts to gain a deeper understanding into participant responses (Howitt, 2016). At the end of all interviews, participants were given the opportunity to ask any further questions and were given the main researchers email address if they had any follow-up thoughts that did not arise within the interviews.

As with any data collection technique, there are strengths and limitations to using semi structured interviews in qualitative research. The following section highlights some of the limitations of in-depth interviews and its implications regarding the study scope and setting. As discussed above, a semi-structured interview is thought to be advantageous for exploratory research as it provides the researcher flexibility and control and helps to give participants the opportunity to provide detailed responses and descriptions, therefore giving a rich data set for analysis (Howitt, 2016, Dicicco-Bloom and Crabtree, 2006). However, semi-structured interviews are highly individual and have been critiqued due to concerns regarding their generalisability (Diefenbach, 2009). Potter & Hepburn highlight that internal and unconscious bias may impact on the interview process influencing both the data collection and analysis phase (Potter and Hepburn, 2005). Smith et al (Smith, 2015) propose semi-structured interviews produces data which varies in quality as it relies on the relationship between the researcher and participant. Being the lead researcher on the Urgent Care trial I had previously communicated with most of the participants when completing baseline and follow-up assessments and it is thus possible that this existing relationship may have influenced the responses provided.

Furthermore, when participants are asked to talk about their experience of a particular event, they need to recall the event and interpret it, before

formulating their description and discussing it during the interview. This may result in the generation of multiple valid accounts because responses may be influenced by what they have noticed during the event, what they remember, how they interpret what they observed or experienced and what they consider worthy of reporting or of importance to them or to the researcher. (Murphy, 2017). However, this does not mean that participants' responses during the research interview are false or invalid but that consideration must be given to the purpose of the explanations given and the influence of the context on participants' accounts (Murphy, 2017). It is important therefore to consider how the interview context may influence the participant's responses during analysis of interview data to ensure that bias is identified where possible.

The discussion in Chapter Eight (page 283) provides further information on methodological limitations.

Interview topic guides

The purpose of the interview topic guide is to offer a framework around the key areas to be covered during the semi-structured interview, based on the research aims of the qualitative study (Willig, 2013). Each interview would cover specific themes were discussed, but with the flexibility to access views in-depth, and pursue additional strands of interest if they emerge. A topic guide rather than an interview schedule was developed because I wanted to keep the interview questions broad whilst still identifying some topics to explore in the interviews. Developing a topic guide would facilitate exploration of topic areas of interest and enable more new ideas to emerge. The topic guide enabled an interaction with participants whilst ensuring that the interviews were focused and relevant to the research questions. This supported Robson & McCartan's suggestion that although the researcher can use questions to guide the interview, these may need to be modified as deemed necessary throughout the interview, allowing more flexibility for the participants' responses (Robson and McCartan, 2016). This was found to be applicable during the interviews because it allowed me to include additional questions as new ideas emerged from the interviews. I sought to develop questions that took both a narrative and descriptive approach, that were

open-ended and expansive. Questions were carefully phrased to avoid leading responses (Smith, 2015). A balance was sought between structured and unstructured approaches to questions to both focus the research around identified gaps in the literature but also to allow participants knowledge to fill these gaps. Open-ended, non-judgmental questions are best suited for qualitative research investigation as they invite and encourage participants to give a detailed description of the topic explored allowing unforeseen declarations and stories to emerge (Britten, 1995, Smith, 2015).

The topic guides were developed through an iterative process, to address the research aims whilst ensuring that they were appropriate for participants. The service provider topic guides were developed in collaboration with Patient and Public Involvement and Engagement (PPI/E) representatives and the supervisory team and amended in line with their feedback. Additionally, a GP was also asked to comment on the service provider topic guides (Appendix 2). The service provider interviews aimed at eliciting information about their attitude to research studies in general, why they became involved in the Urgent Care trial, their experience of referring patients to the trial, and factors that they believe influenced recruitment from a service provider and service user perspective. Service providers were purposively selected from primary and secondary care services that were approached or had been involved in the Urgent Care trial.

The topic guides for service users were drafted and underwent revision from the same team as above. All suggestions were considered, and a subsequent draft of the interview guide was later re-circulated to ensure that the questions addressed the research questions. The topic guide for service users focused on aspects such as what informed their decision to participate in or decline to take part in the wider trial, and what they hoped to get out of the trial. To ease service user participants into the interview process and reduce any initial anxiety, the opening section of the topic guide consisted of general questions about participants' health anxiety and its impact. Subsequent questions explored reasons for completion or non-completion of the follow up questionnaires and experiences of receiving remotely delivered

CBT for those allocated to the RCBT group (see Appendix 3 service user topic guides).

Piloting the topic guides

A practice interview was conducted with a PPI/E representative. Piloting of the interview guide enabled adjustment and paraphrasing of questions to simplify enquiry and remove ambiguity. Co-producing interview guides provided a framework that covered participant's experiences of participant recruitment and retention, and perceptions of the barriers and facilitators to trial participation.

During the data collection phase, bimonthly meetings with the PhD supervisors were conducted to discuss the interviews and potential themes identified. These regular discussions helped highlight new areas that were worthy of further exploration. This also helped in the alteration of the topic guide to include these areas of questioning and investigate such factors with subsequent participants.

Ethical considerations

The nature of the research (i.e., including service users with health anxiety) meant that consideration of key ethical guidance pertaining to informed consent, right to withdraw, confidentiality and anonymity, minimising harm and payment of service user participants was required; these will now be discussed in turn.

Ethical approval for this study was obtained alongside the wider Urgent Care trial application NHS HRA NRES London-Riverside Committee (reference 14/LO/1102) and the Research and Development (R&D) departments at each of the data collection sites. Approvals for the Urgent Care trial was obtained in July 2014. In May 2015, a substantial amendment was submitted detailing a proposal to carry out the qualitative doctoral study. Ethical approval was received in June 2015. The approval letters are included in Appendix 4.

Informed Consent

An integral part of the research process is to inform participants of the purpose of the study and detailed information regarding their participation, benefits and potential disadvantages (Miller and Bell, 2002). Service provider participants were provided with a Staff Participant Information Sheet (Appendix 5) and staff consent form (Appendix 6).

As part of the Urgent Care trial, service user participants provided written consent to be contacted and invited to participate in an additional interview for this study. Service user participants opting-in to be interviewed as part of the doctoral study were called by me. Participants who consented to be interviewed received a Participation Information Sheet (PIS) that included the aims and objectives of the doctoral study and the benefits and disadvantages of taking part in the interviews (Appendix 7). A minimum of 24 hours was provided for participants to consider involvement. Prior to the interview being conducted participants were given the opportunity to ask questions regarding the consent or information sheet, which were all answered and clarified before the interview began. All service user participants provided verbal informed consent before the interview commenced. Formal written consent was not required for the semi-structured service user interviews, as participants were only contacted if they had already provided consent at an earlier stage in the wider study (Appendix 8). The verbal consent was therefore reinforcing this earlier agreement and was audio-recorded for governance. Participants also provided informed verbal consent for their interview to be recorded. The process for obtaining participant informed consent was in accordance with Good Clinical Practice (GCP) guidelines.

Right to withdraw

Service users and service providers were informed that their participation was voluntary, and they were reminded of their right to withdraw before, during and after their participation. They were also made aware that a reason for their withdrawal from the research was not required.

Confidentiality and anonymity

Participants were all given assurance of confidentiality and anonymity. To safeguard participants' rights, minimum personally identifiable information was used. Participants were advised of their right to confidentiality and informed that legal and ethical practice would be adhered to, and that all information provided would be treated with confidence. Participants provided informed consent for anonymous direct quotes from the interview to be used for study reports. Furthermore, quotes from interview transcripts were assigned participant numbers to maintain anonymity. The audio recordings were stored on an electronic password protected file and deleted following transcription. Following transcription of interviews, all identifiable data (names/addresses) were removed from the transcripts, with the transcripts stored securely. Any identifiers, such as name, registered GP surgery, names of service providers and study therapists, names of participants and their family members were replaced with pseudonyms or omitted. All participants were made aware that safeguarding procedures were adhered to throughout the research, and that their participation in the doctoral study would only be communicated to their GP if it was deemed necessary to protect their safety or the safety of others. This was not required for any of the interviews. Most of the interviews were conducted over the telephone or face-to-face in an empty room at a primary care or secondary care location provided to the researcher by health care staff. One interview was conducted over WebEx as the participant was living abroad at the time of the interview.

Minimising harm to participants

The interviews were considered a minimal risk of harm to the participants. I was aware that there may have been potentially sensitive topics discussed, due to the nature of symptoms related to health anxiety. This may have potentially evoked negative feelings in participants through the recall and discussion of unpleasant memories. Participants were advised prior to the interview commencing that they could stop the interview at any time. Participants were reminded of their right to withdraw at any point and advised that they could choose not to answer any questions they did not wish to. They were also offered the opportunity to request breaks at any point and

provide as much or as little information that they felt comfortable with. All participants were provided with both mine and my research supervisor's contact details should they have wished to make further contact.

The PIS stipulated that participants would be asked to share their experiences of participating in the Urgent Care trial and to make their decision about taking part with this in mind. A self-selection process should therefore already have taken place, with those who may have not felt comfortable sharing their experiences deciding not to participate. Whilst this does not guarantee that participants would not experience any distress, they were made aware of what may be discussed prior to them deciding to be interviewed.

Payment of research participants

Service user participants were provided with a £15 gift voucher to thank them for their participation in the interview. There are concerns that paying participants could coerce or unduly influence encourage people to participate (Largent et al. 2017). Conversely, it could be argued that payment provides meaningful recognition of their effort and time and is a token of appreciation (Largent and Lynch, 2017). Hence, I sought to determine a compensation level aligned with the NIHR INVOLVE guidelines—striking a balance that avoided undue inducement while adequately acknowledging and expressing gratitude for participants time and contributions.

Data analysis

Transcripts from interviews are the raw data which are the descriptive record of the research, but they cannot provide explanations without analysing the data (Pope et al., 2000). Therefore, I needed to make sense of the data by analysing and interpreting it. While an inductive approach to data analysis derives themes from the available data, a deductive approach analyses data through a theoretical, "top down" based on an existing theory (Braun and Clarke, 2006 page 83, Maykut and Morehouse, 2002). The data analysis utilised an inductive approach. The analysis was inductive as it was not

guided by any theoretical frameworks, additionally it went beyond the prompts contained within the interview topic guide to include new themes, thus remaining open to the diversity of participants' experiences.

Thematic analysis (TA) is widely used within the field of psychology and is considered the most flexible qualitative analytical process (Braun and Clarke, 2006). TA is a method for 'developing, analysing and interpreting patterns across a qualitative dataset which involves systematic processes of data coding to develop themes' (Braun and Clarke, 2021 page 4). TA approaches are thought to offer more than just 'give voice' (Braun and Clarke, 2006 page 7) as researchers are required to take an active role in analysis through selecting aspects of the participants' accounts, identifying themes and patterns across datasets and reporting these in a worthwhile and systematic way to develop the knowledge of others. Although a method in its own right, TA refers to a collection of approaches, each one determined by differing paradigmatic assumptions (Braun and Clarke, 2021). The different approaches are described as being on a continuum, from, at one end, coding reliability approaches (Terry and Hayfield, 2020) to, at the other end, Reflexive TA (Braun and Clarke, 2019). The analytical approach considered most appropriate for this study was Reflexive TA (Braun and Clarke, 2021). Reflexive TA has been reconceptualised by Braun and Clarke from the original six step process (Braun and Clarke, 2021). It is an approach to analysing data which is fully embedded within the values of a qualitative paradigm and enables the researcher to recognise their own position within the research and to consider their individual impact on interpreting data (Braun and Clarke, 2021).

Rationale for and critical evaluation of Reflexive Thematic Analysis

Reflexive TA allows for theoretical and research design flexibility and means that multiple theories can be applied across a variety of epistemologies. Reflexive TA states the importance of subjectivity as a resource to develop knowledge (Burr and Dick, 2017).(Braun and Clarke, 2021 page 294) define reflexivity as the 'process and practice of a researcher critically reflecting on how their disciplinary, theoretical and personal assumptions and their design choices shape and delimit the knowledge they produce'. A researcher must

therefore attempt to understand their own perspectives to have a good quality analysis. Willig (Willig, 2013), stated that there are two types of reflexivity: epistemological and personal. Epistemological reflexivity is described as a researcher reflecting on how knowledge is understood and how their own assumptions and beliefs about the world can influence the research process (Willig, 2013). Personal reflexivity relates to a researcher reflecting upon how an individual's 'values, experiences, interests, beliefs, political commitments, wider aims in life and social identities have shaped the research' (Willig, 2013). Reflexivity is also about how the researcher(s) considers the power dynamics between themselves and participants and how they can strive to neutralise this. The researcher must also reflect on how the research may create change for the participants and researcher (Willig, 2013). Reflexive TA, therefore, appeared to fit well with the interpretivist and subjectivist stance of this research as it can be used to explore the reality as constructed by the participant, but also considers the impact of the social context on these meanings (Braun and Clarke, 2006, Braun and Clarke, 2019). This approach also aligned with my values that knowledge is developed through immersion and continual thinking and reflection. Due to similarities between IPA and Reflexive TA I spent some time considering which would be the most appropriate approach. I selected Reflexive TA because the doctoral study was exploratory, and as such took a more inductive approach consistent with Reflexive TA which allows for 'theoretical freedom', unlike other qualitative data analysis methods such as IPA (Braun and Clarke, 2006). I also selected Reflexive TA because I was looking to explore the perspectives of service providers and service users across the dataset, whilst acknowledging the wider socio-cultural context experiences both groups were situated within (Braun and Clarke, 2021). IPA tends to focus more on individual narratives. In addition, as the research questions were not based around language a discourse analysis did not seem appropriate, Limitations of Reflexive TA are that the 'theoretical freedom' it enables can mean that it has limited interpretative power if it is not grounded in a theoretical base (Braun and Clarke, 2021). Good Reflexive TA needs explicitly locating in terms of theory to give analysis more power and validity. It is thought that there is a risk that Reflexive TA could miss nuanced

data if the researcher uses it in a theoretical vacuum (Guest et al., 2012). This was addressed in the current research by being transparent about the ontological and epistemological approach and by making links between analysis, theory and research literature in Chapter Eight (Discussion Chapter). To ensure quality in the Reflexive TA, the 15-Point Checklist of Criteria for Good Thematic Analysis provided by (Braun and Clarke, 2006) was also utilised (Appendix 9).

In analysis of the interview data the following steps were taken, thus incorporating the stages proposed by Reflexive TA. Reflexive TA is a recursive process, and it is rare that a researcher would follow a linear path through the six phases (Braun and Clarke, 2021). However, in practice they are not independent processes but cyclic in nature. Therefore, both data collection and analysis processes were an iterative process and not a linear process. The stages involved in data analysis are described below.

Phase 1: Familiarisation with the Data

This phase involved becoming familiar with the data set by becoming both immersed in the data whilst retaining critical engagement (Braun and Clarke, 2021). For each participant, interview recordings were listened to numerous times whilst reviewing the transcripts to allow for immersion in the data and to check for accuracy. I made sense of the data by critiquing the data and made notes of my initial feelings and thoughts about the meaning of the data, which contributed to reflexivity, a necessary aspect of the analysis process. A Microsoft Word version of the document of the transcript with wide margins enabled for a recording of initial comments of analytic interest. This ranged from a few words to parts of sentences or whole paragraphs (see Appendix 10 for an example).

Phase 2: Coding

The second phase involved taking an engaged and systematic approach to developing initial codes and patterns of meaning in the data. The entire data set was coded using open coding – i.e., codes were not predetermined but developed in response to familiarisation with the data (Robson et al., 2018). An inductive, data-driven approach to data coding was initially adopted

(Braun and Clarke, 2006). Given the exploratory nature of the doctoral study, this initial data-driven approach was utilised to reduce the likelihood of key ideas not already identified within a theory being overlooked. However, it is acknowledged that codes may have been influenced by my theoretical knowledge and involvement as a lead researcher on the Urgent Care trial. Codes at both the semantic and latent level were considered, semantic coding identified the overt meaning explicitly stated in the data by participants whereas, latent coding involved exploring the more implicit and underlying meaning expressed by participants (Braun and Clarke, 2021). Coding was refined through various rounds and involved going through the dataset in different orders to ensure the codes were consistent and thorough and they were accurate reflections of data (Braun and Clarke, 2021).

I recorded my own reflexive thoughts, including my emotional responses which arose during this process, and these were noted in my research diary. This formed part of the continuous process of questioning the data and assumptions made (Braun and Clarke, 2021). I chose not to use data-analysis software such as Nvivo because I had re-read all the transcriptions multiple times and had already begun coding and felt immersed in the data. I felt personally invested in the process which allowed for plenty of time for reflection and insight to develop. I therefore felt the claim Nvivo made for 'faster and easier data analysis' was at odds with the slow and complex process I was already engaged in.

Phase 3: Generating initial themes

After initial codes were generated, analysis shifted towards clustering codes together based on collective meaning at code level to create candidate themes. It is important to note the change within Stage 3 Reflexive TA approach (Braun and Clarke, 2021) compared to Braun & Clarke's original paper (Braun and Clarke, 2006). This stage was initially named 'searching for themes', however in Reflexive TA it is now 'generating initial themes' (Braun and Clarke, 2021). This places me the researcher in an active role in the construction and generation of themes (Braun and Clarke, 2021). I clustered codes into broader patterns that were meaningfully telling me something important and relevant to my research questions. Visual maps

were generated to help me figure out patterns of meaning and possible connections and potential themes and sub-themes were generated. Codes and initial themes were checked throughout the analytical process with the PhD supervisors and other researchers to ensure they reflected an effective interpretation of the participants' experiences.

Phase 4: Developing and reviewing themes

In this phase, I re-engaged with the codes and the data for the entire dataset and revised candidate themes. The coding groups and tentative themes were developed and reviewed through the following process: All codes within a theme were re-read as one to see if they fitted together and moved if they did not fit within the theme or seemed better suited within another theme. This process continued until the data fitted coherently with the themes. This also allowed for any data that had been missed in the early stages of coding to be re-coded. Themes could be changed if they did not adequately fit within the question which led to a refinement of themes. The themes were re-considered to ensure they had a centrally organising concept and clear boundaries so as not to merge into one another. A review was carried out of the contents of the themes to ensure that the data offered an adequate level of evidence to support each theme. The original transcripts were revisited to ensure the extracts selected aligned with the developing themes. Throughout this process I reflected on the data and my analysis of it as well discussing it with my supervisors to enhance the analysis.

Phase 5: Defining and naming themes

This phase involved refining and defining the themes. I defined each theme in a few sentences to capture what each theme was about, how each theme was unique and specific and how it contributed to the overall analysis and its relation to the research questions. Appendices 11 and 12 show the generation of initial codes and final theme development for the service user themes related to recruitment.

Phase 6: Producing the report

Findings were presented at two levels; themes, which represent multiple facets and patterned meaning of concepts within the data set, and sub-themes which represent themes within one overall theme (Braun and Clarke, 2006). The narrative of each theme and related sub-themes are presented alongside extracts of verbal data from participant interview transcripts to evidence how what participants expressed created each theme in chapters 6 and 7. The themes are drawn together with reflections and interpretations stemming from my prior knowledge and experiences of being the lead researcher on the Urgent Care trial. The findings of the Reflexive TA data analysis are presented in Chapters Six and Seven and the findings are discussed alongside relevant theoretical frameworks, literature, and research in Chapter Eight.

Reflection upon my background as a health services researcher

Reflexivity means sensitivity in the approaches utilised by the researcher and the research process in data collection and taking account of the researcher's own personal experiences, theoretical biases and recognising the role of the researcher's values and a priori assumptions (Murphy, 2017, Mays and Pope, 1995, Pope et al., 2000). Since our views of the world are influenced by paradigms, our subjective perspectives and experiences can shape date interpretations, analysis and reporting of findings. Qualitative research is therefore reflexive, in that the researcher is part of the research. Reflexivity is the self-aware analysis of the interconnectedness between the researcher and the object of the research. According to Hall (Hall and Callery, 2001), incorporating reflexivity can enhance the rigor of the research. Reflexivity is a fundamental to Reflexive TA, which analyses and interprets the experiences of others (Braun and Clarke, 2019). I maintained reflexivity in the current research through having an awareness of how my own experiences and perceptions potentially influenced decisions made at each stage of the research process. This included the potential impact on the data collection and analysis process and the interpretation of data (Willig, 2013).

Therefore, it is important to reflect upon my own role in this research to illuminate how my role has shaped this study, given that I was not only the doctoral researcher, but also the lead researcher and study co-ordinator for the Urgent Care trial within which the doctoral study is nested. This has been included early on in this thesis, as opposed to at the end, so that the reader is aware of my own role in relation to that of participants. I am a British South Indian female born in England with a MSc in Health Psychology. At the time of conducting the interviews I was in my mid-thirties. I was working as the lead researcher on the Urgent Care trial whilst also registered as a part-time PhD student. I had six years' experience of working as a Health Care Support Worker (HCSW) in psychiatric hospitals and six years' experience working as a researcher on a range of mental health research studies in primary and secondary care settings. I acknowledge that both my personal and professional experiences may have influenced data interpretation, analysis and reporting of findings (Sparkes and Smith, 2013). Throughout the course of data collection, it was important to reflect on how my own thoughts and actions shaped the study. I adopted an open stance which involved being attentive and sensitive to participant experiences (Dahlberg and Ekebergh, 2008). I also questioned my understanding of the data and was aware of how my pre-conceptions may have influenced the analysis.

Most of the interviews were conducted with service user participants whom I had previously interviewed as part of the wider Urgent Care trial and conducted follow-up assessments with (n=20). This may have both positively and negatively influenced participants' willingness to discuss their trial participation and treatment experiences with me; the broad array of views expressed go some way to negating this concern. Prior to conducting qualitative interviews, I emphasised to participants that the aim of the interviews was to hear about their experiences of participating in the trial be that positive or negative. They were also reminded about their right to withdraw from the study participation at any time. Throughout the research process, I reflected on my own views, assumptions, and the role of my academic background and experience in the interpretation of the data. Discussing these interpretations with my supervisors supported the practice

of multivocality. I kept a research diary which was used to reflect on factors which may have impacted upon the research process. Having recorded initial thoughts during the initial contact with participants and during data collection, as analytical themes emerged, these notes played a key role in progressive subjectivity (Lincoln and Guba, 1985) which involved monitoring my own developing interpretations. I returned to the data after a few months and read all the transcripts again and analysed the data again as a whole. This iterative process enabled me to link participant accounts and refine themes and the analytical framework. I also ensured I had frequent debriefing sessions with my supervisors in which interviews were discussed. Debriefing sessions enabled me to share developing ideas and interpretations and expand on these in subsequent interviews. It also helped me to recognise any biases and preferences. Study progress was discussed in supervision and peer research groups to ensure that the process of theme development was coherent, auditable, and accountable to the data.

The specific quality criteria adopted in this qualitative study and how they were applied in the present context are discussed later in this chapter.

The findings of the Reflexive TA data analysis are presented in Chapter Six and Seven and the findings are then discussed alongside relevant theoretical frameworks, literature, and research in Chapter Eight.

Research participants and interview setting

The research took place in Primary and Secondary care services in the East Midlands and West Yorkshire. Service provider and service user participants were recruited from GP surgeries, an Emergency Department, a walk-in centre and two outpatient Departments (i.e. Endocrinology Department, Neurology Department). A wide range of services were selected to reflect a range of differing registered patient list sizes, patients of differing social and ethnic diversity and affluence or deprivation.

Chapter One described how the doctoral study was nested within the Urgent Care trial for which I was the lead researcher and co-ordinator. Access to

participants was obtained through prior contact I had established with service user participants and service providers or by contacting service user participants who had provided consent to be contacted for a further interview by a member of the Urgent Care trial research team.

Within any type of research study who to include is highly important, if the participants selected are not appropriate then the relevance of the data, analysis and findings are debateable (Greatrex-White, 2008). In qualitative research, a sample is selected to gain a deep understanding of a phenomenon, it consists of several different sampling approaches dependant on the research aims and objective, access to participants, the phenomenon being explored and the chosen method of data analysis and interpretation (Marshall, 1996). While there can be some overlap between the different sampling approaches the following three broad categories can be distinguished in qualitative research: convenience sampling, purposive sampling, and theoretical sampling. In convenience sampling participants are selected based on ease of access and no particular sampling criteria are applied when selecting participants (Ritchie et al., 2003). In purposive sampling the researcher selects individuals for study participation based on their particular experience of a phenomenon for the purpose of sharing that knowledge (Speziale et al., 2011). Purposive sampling focuses on strategically selecting cases that will provide information-rich cases to illuminate the area being investigated. Information-rich cases provides the researcher with in-depth information, as opposed to generalised information about the research area being investigated. Theoretical sampling involves building a theoretical interpretation from the emerging data and selecting further participants with a view to extending the developing theory; this approach is primarily used in grounded theory method (Conlon et al., 2020). Participants' selection in this study utilised an adapted purposeful sampling strategy to inform an understanding of their experiences of participating in the Urgent Care trial.

Recruitment of service provider participants

I wished to interview service providers who were approached to be involved in the Urgent Care trial to hear their experiences of participating in the trial

and referring patients. All service provider participants interviewed were provided with the study information sheet and signed a consent form before interviews commenced.

Service provider participants were purposefully sampled and invited to participate in individual interviews. Service providers who had participated in or had been approached to be involved but did not refer patients or chose not to be involved in the Urgent Care trial were invited to participate in this linked doctoral study. It was considered important to include service providers who had achieved varying levels of recruitment of participants and from different settings, because the aim of the doctoral study was to understand the different perspectives of those who referred and recruited many participants compared to those who did not. This was to develop an understanding of what aspects facilitated and hindered service providers from approaching patients about participating in the wider trial. Service providers from different settings and job roles were selected so that the barriers and facilitators from a wide range of service providers could be explored. In addition to service providers who were responsible for referring patients to the trial, three staff members from the Clinical Research Network (CRN) were also recruited. The CRN staff were responsible for promoting the trial to service providers and supported the study team in recruitment of participants; their inclusion was to gain their views on liaising with service providers and recruiting participants, and to enable comparison of these experiences with those of service providers.

Consequently, interviews were carried out with:

1) GPs in primary care providing care to patients with health anxiety.
2) Practice managers responsible for the day-to-day management of GP surgeries.
3) Consultants and nurses in secondary care services providing care to patients with health anxiety.
4) Clinical Research Nurses (CRNs) who approached and recruited participants to the Urgent Care trial.

The sample consisted of service providers who recruited well (n>12 participants recruited), those who recruited a moderate number of participants (n = 6-10) and those who did not refer/recruit many participants (n=0-3). The table below (table 15) illustrates the demographic data of the service providers interviewed. Some service providers were recruited from the same site (Emergency Department, Walk-in Centre) and the recruitment number reflects the total number of participants recruited from that site.

Table 15 demographic data of service providers interviewed

Participant number	**Gender**	**Referral site**	**Job title**	**Level of engagement/recruitment**
1 (SP001)	Male	Hospital outpatient	Neurologist	Referred and recruited 13 participants
2 (SP002)	Female	GP	Practice Manager	Did not refer or recruit any participants
3 (SP003)	Male	GP	General Practitioner	Referred and recruited 2 participants
4 (SP004)	Male	Hospital outpatient	Endocrinologist	Referred and recruited 2 participants
5 (SP005)	Female	GP (paired interview)	General Practitioner	Referred patients but did not recruit any participants
6 (SP006)	Female	GP (paired interview)	Clinical Studies Officer	Responsible for recruiting and consenting participants – their site did not recruit any participants
7 (SP007)	Male	GP	General Practitioner	Referred and recruited 3 participants
8 (SP008)	Male	GP	General Practitioner	Referred and recruited 32 participants – top recruiting site
9 (SP009)	Female	Walk in Centre	Specialist Lead Research Nurse Facilitator	Responsible for recruiting and consenting participants – recruited 5 participants at site
10 (SP010)	Male	GP	General Practitioner	Referred and recruited 9 participants

11 (SP011)	Male	GP	General Practitioner	Referred and recruited 1 participant
12 (SP012)	Male	GP	General Practitioner	Referred and recruited 1 participant
13 (SP013)	Female	GP	General Practitioner	GP surgery decided not to take part in the trial
14 (SP014)	Female	Walk in Centre	CRN Research Nurse	Responsible for recruiting and consenting participants – recruited 5 participants at site
15 (SP015)	Female	Emergency Department	ED Consultant	Referred and recruited 10 participants
16 (SP016)	Male	Emergency Department (paired interview)	ED Research Nurse Manager	Referred and recruited 10 participants
17 (SP017)	Female	Emergency Department (paired interview)	ED Research Nurse	Referred and recruited 10 participants
18 (SP018)	Female	GP	CRN Research Nurse	Responsible for recruiting and consenting participants – recruited 14 participants from GP surgeries in her region

Fourteen individual interviews were conducted with service providers between March and November 2017. Due to time constraints two of the interviews were paired interviews, this consisted of two service providers being interviewed in one interview. Therefore, in total sixteen interviews were conducted with eighteen service providers. Service provider participant interviews were conducted face-to-face at their place of employment (n=5) or over the telephone (n=11).

The demographics of the service provider participants indicate that the sampling aims were fulfilled, except for a lack of interviews with service providers who recruited well. The table highlights that there was representation from all other potentially important factors.

Recruitment of service user participants

Service user participants were recruited from Primary and Secondary unscheduled/urgent care services across the East Midlands who had been invited to take part in the Urgent Care trial (the eligibility criteria are defined in Chapter One)

Following completion of the final follow-up assessment, two weeks after a follow-up assessment was sent or upon withdrawal from the Urgent Care trial, participants were contacted about taking part in an interview. If the participant agreed, a convenient date, time and method for interview was arranged. Service user participants were only contacted if they gave explicit written consent to participate in a further interview when they consented to participate in the Urgent Care trial. Sampling in this study was purposive as service user participants who had been invited to participate in the wider trial and had experience of participating in the trial and trial processes were deliberately chosen (Luborsky and Rubinstein, 1995). Service user participants were selected with the intention of collecting data from a diverse cohort to obtain varying views on the reasons for deciding to participating in the trial and experiences of participating. This included ensuring perspectives from a range of ages, gender, ethnicity, and level of engagement (completed and non-completed) with the intervention and the trial itself. The aim was to recruit participants with a wide variety of trial experience and diverse perspectives on aspects that are important to people when deciding whether to participate and remain in an RCT. This sampling strategy would result in sufficient heterogeneity to provide an identification of barriers and facilitators to recruitment and retention to and RCT consisting of a DHI.

Consequently, interviews were carried out with:

1) Service user participants who withdrew from the trial, to understand participants' reasons for trial withdrawal.
2) Service user participants who remained in the trial and completed all outcome data and treatment sessions, to explore the experiences of

being in the study from the perspective of participants in the RCBT arm and Treatment as Usual (TAU) arm.

3) Service user participants who completed none or some outcome measures or some or no treatment sessions, to understand reasons for non-completion of both the research and the treatment aspects of the wider trial.

I had wished to interview service users who declined to take part in the trial, to provide insight into the reasons for declining trial participation. However, none of those who declined to participate in the Urgent Care trial consented to being interviewed.

Between January 2016 and December 2017, 28 interviews with service user participants were conducted. Interviews were conducted between twelve and fourteen months after participants entered the trial, and after the final follow-up assessments had been completed. This minimised the risk of unblinding of the researcher and bias in outcomes. Service user participants were not blinded to treatment allocation at any point of their participation. To minimise recall bias as much as possible, interviews occurred within 2 weeks of completion of the final follow-up assessment. There was also the issue of hindsight bias because service user participants had time to reflect and "sense make" over the 12-14 months they had been involved in the trial. These limitations are discussion in Chapter Eight.

Interviews were conducted at a time and place convenient for participants. Interviews were offered face-to-face (n=2), via videoconferencing (n=1) or over the telephone (n=25).

Table 16 illustrates the demographic data of the service user participants in comparison to the demographics of the trial sample. The table illustrates that there are few differences between the interview and the trial samples. A slightly older age was observed in the RCBT interview sample and a higher rate of unemployment in both interview groups can be potentially explained by these participants having more availability to participate in the qualitative interviews. Rates of health anxiety, generalised anxiety and depression were marginally lower in those interviewed from the TAU group compared to the

wider trial sample, suggesting that those with poorer mental health may be less inclined to be interviewed.

Table 16 Demographic data of service user participants in comparison to trial sample

Characteristic	**Interview sample: RCBT (n=17)**	**Trial sample: RCBT (n=78)**	**Interview sample: TAU (n=11)**	**Trial sample: TAU (n=78)**
Gender (%) Female	11 (65)	56 (72)	7 (64)	52 (67)
Age median, (range)	46 (21-66)	31 (18-79)	26 (19-60)	33(18-82)
Ethnicity (%) White	15 (88)	87 (86)	11 (100)	68 (87)
Relationship status n (%) married/partner	10 (59)	32 (41)	4 (36)	39 (50)
Occupational status n (%) Unemployed	4 (23)	12 (15)	3 (28)	13 (17)
SHAI (mean, SD)	26.24 (5.93)	27.31 (5.38)	25.82 (4.64)	26.41 (5.13)
GAD7 (mean, SD)	10.18 (5.94)	12.94 (5.49)	11.27 (5.52)	12.68 (6.13)
PHQ9 (mean, SD)	11.64 (6.05)	13.35 (6.50)	12.27 (5.29)	13.12 (6.71)

Table 17 illustrates the demographics of the service user participants interviewed. The table highlights that there was representation from all potentially important factors except for participants who declined participation in the Urgent Care trial. Representation from TAU participants enabled an exploration of the factors that influenced retention despite not being in receipt of an intervention.

Table 17 Demographic data of service user participants

Participant No	Interview ID	Age (years)	Gender	Ethnicity	Recruitment site	Treatment Allocation	Level of engagement
1	01007	22	Female	White British	GP	RCBT	Completes treatment and questionnaires
2	01015	22	Female	White British	GP	RCBT	Completes treatment and questionnaires
3	01046	65	Female	White British	Outpatient Dept	RCBT	Completes treatment and questionnaires
4	01024	47	Female	White British	Outpatient Dept	RCBT	Completes treatment and questionnaires
5	01023	26	Female	White British	Outpatient Dept	RCBT	Completes treatment and questionnaires
6	01051	38	Female	White British	Outpatient Dept	RCBT	Completes treatment and questionnaires
7	02001	63	Male	African Mauritian	GP	RCBT	Completes treatment and questionnaires
8	03002	46	Female	White British	GP	RCBT	Completes treatment and questionnaires
9	01002	22	Female	White British	GP	RCBT	Completes treatment and some questionnaires
10	01055	48	Male	White British	Outpatient Dept	RCBT	Completes treatment and some questionnaires

11	01001	66	Female	White British	GP	RCBT	Does not start treatment but completes all questionnaires
12	01008	46	Male	White British	GP	RCBT	Does not complete treatment but completes all questionnaires
13	01066	28	Male	British Pakistani	GP	RCBT	Does not start treatment and completes some questionnaires
14	04001	62	Female	White British	GP	RCBT	Does not complete treatment and completes some questionnaires
15	01077	39	Female	White British	Outpatient Dept	RCBT	Does not complete treatment and completes some questionnaires
16	01004	20	Female	White British	GP	TAU	Completes all questionnaires
17	01014	60	Female	White British	ED	TAU	Completes all questionnaires
18	01016	26	Female	White British	GP	TAU	Completes all questionnaires
19	01019	23	Male	White British	GP	TAU	Completes all questionnaires
20	01018	21	Male	White British	GP	TAU	Completes all questionnaires
21	01043	34	Male	White British	ED	TAU	Completes all questionnaires
22	01045	59	Male	White British	Outpatient Dept	TAU	Completes all questionnaires

23	03005	44	Female	White British	GP	TAU	Completes all questionnaires
24	03004	47	Female	White British	GP	TAU	Completes all questionnaires
25	01040	22	Male	White British	GP	RCBT	Referred to another service but completes questionnaires
26	01082	20	Female	White British	GP	TAU	Completed all questionnaires
27	03012	24	Male	White British	GP	TAU	Completed some questionnaires then withdrew from study
28	01112	21	Non-binary	White British	GP	TAU	Completes some questionnaires

Data collection and data management

Interview data

All interviews were audio-recorded with participants' consent. Interviews were audio-recorded using a digital interview recorder. The length of interviews ranged from approximately 20-90 minutes. The shortest interview was with a service user participant and it lasted for 20 minutes, and the longest interview was conducted with a GP, and it lasted for 1 hour and 30 minutes. All recorded material was saved into a USB device as a windows media player or MP3 format which made the process of transcribing on the computer more convenient. All recorded material was transcribed verbatim by a University of Nottingham approved transcription service. All recordings were stored and archived on a secure, password protected computer at the University of Nottingham. All interviews were saved using the participants unique Trial Identity Code (TIC) number. To prevent over-burdening the respondents, interview transcripts were not returned to respondents.

Researcher diary

I kept a diary in which all observations and reflections about the data collection process were documented using a word processor. Notes were recorded promptly after each interview to ensure that my observations and notes were recorded while they were fresh in my mind. These notes aided in paraphrasing some of the interview questions or adding a new question to explore new ideas and themes in subsequent interviews. These notes were also useful during the data analysis phase as they helped me to retrieve some of my feelings and perceptions about the interview process, its dynamics, and why things were said and what provoked them. This included diagrams of possible relationships between emerging categories to guide or reflect the analysis. This was found to be a highly useful way of recording thoughts that could be referred to later when reflecting on new data or new ideas. A considerable amount of time was spent thinking about the relationships between concepts in the data, the properties of themes and variations in the data. This in turn prompted further scrutiny of the transcripts and then further examination of the themes to ensure that the analysis was thoroughly grounded in the data and preconceived ideas were not being forced upon the data. This process continued throughout the study up to and including, the stages of writing up, as further insights were gained (Charmaz, 2006). Having a diary enabled me to have a reflective account of aspects relevant to recruitment and retention. They also allowed me to explore potential themes that emerged from my documented notes when carrying out additional qualitative interviews and analyse the similarities and patterns in the data. Brief notes were also taken whilst conducting interviews and expanded on following the completion of each of the interviews (see Appendix 13 for extracts from the research diary).

Transcription

All participants provided consent for their interviews to be transcribed verbatim by a professional University of Nottingham approved transcription service. All interview recordings were emailed to the transcription service within 24 hours of being conducted and were returned within 5-10 days. Transcribing the interviews as soon as possible is important to note anything

of interest within each transcript and to integrate issues to be followed up with subsequent participants as part of the constant comparison approach. Following return from transcription, interviews were anonymised by me, and the recordings were listened to, and the transcripts read line by line simultaneously, to ensure accuracy of the transcription. All transcripts were re-read several times to rectify any transcription errors, and to become familiar with the interview data. It also enabled me to add comments that reflected my observations and perceptions during the actual interviews and compare the recoded material with my notes to remove ambiguity, especially when participants' words were not coherent or clear.

Quality in qualitative research

Evaluating the quality of qualitative research is integral if the findings are to be applied in practice and inform delivery for care (Dingwall et al., 1998). In the past qualitative research has been criticised for lacking scientific rigour and transparency (Noble and Smith, 2015). Qualitative methods differ from quantitative methods in terms of the philosophical underpinnings and aims, and therefore different criteria to measure quality are required.

It is difficult to identify one set of criteria to evaluate all qualitative research because different qualitative traditions have different standards of excellence. According to Lincoln and Guba (Lincoln and Guba, 1985), trustworthiness is important in evaluating the worth of the research. Trustworthiness in qualitative research is evaluated in four ways. Credibility, transferability, dependability, and confirmability.

Credibility relates to confidence in the "truth" of findings and relates to the question of "how congruent are the findings with reality" (Merriam, 1998, Shenton, 2004). Lincoln and Guba (Lincoln and Guba, 1985), state that ensuring credibility is one of the most important factors in establishing trustworthiness. Qualitative research acknowledges that multiple realities exist. In qualitative research it is important for the researcher to clearly describe their experiences and personal biases and how this may have

resulted in methodological bias: "A researcher's background and position will affect what they choose to investigate, the angle of investigation, the methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusions" (Malterud, 2001 pages 483-484). Credibility can be achieved through thick description, crystallisation, triangulation and multivocality. Thick description refers to reporting rich and concrete detail, to offer a comprehensive picture of the phenomenon under study (Bochner, 2000). Thick description provides the reader with sufficient detail about the context of the interviews and the participants to arrive at their own conclusions. Crystallisation is concerned with the use of different data sources, researchers or theoretical frameworks. However, unlike triangulation, it aims to arrive at “a more complex, in-depth, but still thoroughly partial, understanding of the issue” (Tracy, 2010 page 844), rather than a more valid and reliable single finding. One of the ways in which this was achieved was by keeping a reflective diary of initial thoughts and perspectives, and documenting decisions made about data analysis and the identification and merging of themes.

Transferability relates to showing the applicability of the research to other contexts. This allows individuals to be able to relate the findings to their own situation. Lincoln and Guba (Lincoln and Guba, 1985) suggest that it is the responsibility of the researcher to ensure sufficient information is provided to enable the reader to be able to relate to the findings.
Transferability/applicability is obtained by providing thick description of the data and its findings. This enables the readers to evaluate how the findings could be transferable to other situations and people. This was achieved by providing rich detail of the context, settings and participants who participated so that study conclusions can be applied to other settings. The methods Chapter also provides detailed information about the data collection methods.

Dependability shows that the findings can be consistent and repeated. Lincoln and Guba (Lincoln and Guba, 1985), stress the close ties between credibility and dependability. To address the dependability issue more directly, the processes within the study should be reported in detail so that a

future researcher could repeat the study. Provision of in-depth knowledge allows the reader to determine if research policies have been followed. Dependability can be ensured by having an external audit. This consists of an external researcher who is not involved in the research examining the processes and products of the research. External audits foster the accuracy of the findings and implications. Dependability was achieved by providing transparent and clear descriptions of the research process from inception to reporting of findings. In addition, data findings were discussed in supervision. This provided an opportunity to summarise preliminary findings and assess the adequacy of the data and initial findings. Feedback from supervisors resulted in the collection of additional data and facilitated data analysis and interpretation.

Confirmability relates to the degree of neutrality of the findings and to what extent the study findings are shaped by the respondents and not researcher bias, motivation, or interest. This is achieved when truth value, consistency and applicability have been addressed. Steps must be taken to ensure that the findings are the result of the experiences and ideas of the participants and not the researchers. Triangulation can help to reduce investigator bias. Researchers must be honest about their predispositions. Decisions made and methods adopted should be reported. The researcher should also acknowledge weaknesses of their approach and why it was selected. Having a data orientated and theoretical audit trail may also be useful. The recording and transcription of interviews enabled me to re-read accounts and check that they reflected themes. The use of thick description and verbatim quotes in the data findings chapters will allow the readers to decide whether the final themes reflect participant accounts. In addition, the data methods and findings have been subject to peer scrutiny through work presented at conferences and shared with service user representatives and colleagues for feedback. I have also linked my work to previous research findings to see how congruent the findings are. These aspects of trustworthiness are further achieved in qualitative research through triangulation and reflexivity. Triangulation refers to using one method of data collection to validate another method of data collection. It also increases the comprehensiveness

of analysis, and the variety of data stimulates open reflexive analysis. Triangulation was achieved by exploring the views of a range of participants (service users and service providers). A wide representation of findings was possible by conducting 46 interviews across the sample population. This included participants with positive and negative experiences of trial participation, to enable comparison of individual interviews to build a richer picture of peoples' experiences, thoughts and feelings. There was also cross-site triangulation, because participants were included from primary and secondary care organisations from across East Midlands sites, which increased the credibility if similar findings emerged. Multivocality is the practice of providing room for a multitude of viewpoints, at times contradicting those of the researcher. Differences in race, class, gender, age, or sexuality may shape participants' world view. Considering such differences, and openly welcoming different meanings to popular viewpoints or one's own, raises the credibility of qualitative research findings. Methodological strengths and limitations will be discussed in greater detail in Chapter Eight.

Chapter summary

The qualitative research contained within this thesis was conducted from an interpretive paradigm. The thesis adopts a qualitative methods approach to allow for an exploration of the experiences and decision-making processes of service users and service providers invited to participate in a trial for a DHI.

This chapter provides a justification of using a qualitative approach and provides a rationale of the qualitative methods used. The methodological approach allowed me to explore recruitment and retention into a DHI trial from multiple service user and service provider perspectives. Semi-structured interviews and Reflexive Thematic Analysis were deemed to be the most appropriate research method for this study. To maximise the utility of the research findings to service providers and service users, quality was ensured by following the trustworthiness criteria proposed by Lincoln and Guba (Lincoln and Guba, 1985). A reflexive approach enabled me to critically

reflect on my role as a researcher and how this may have influenced the analysis and interpretation of the data.

Results from data analysis are described in the following chapters.

Chapter Six: Findings from qualitative interviews with service providers

Introduction

The aim of this chapter is to present and discuss the findings from the interviews with service providers in relation to their perspectives on the barriers and facilitators to participating in the Urgent Care trial. It does this by exploring what commonalities and differences might exist between the interviews.

The chapter looks at what aspects influenced service provider decisions to take part in the Urgent Care trial and the reasons service providers gave for referring patients or deciding not to approach patients about the trial. This is with the intention of shedding light on the following research questions:

RQ2- What are the factors influencing service providers decision to participate in the Urgent Care trial?

RQ3- What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?

Overview of service provider interviews

As described in Chapter Four, data was collected via individual semi-structured interviews with 18 purposively sampled service providers and analysed using Reflexive Thematic Analysis. Eleven (61%) interviews were conducted over the phone, with the remaining interviews conducted face-to-face at the participant's place of work. Interviews were conducted after recruitment of service user participants to the Urgent Care trial had been completed, but before the results of the Urgent Care trial had been analysed. The interviews ranged in length, from 25 to 90 minutes. Service provider participant information can be viewed in Table 15 (Chapter Four). This chapter will discuss the themes from the interviews, presenting illustrative

quotations. These themes and illustrations are drawn together with reflections and interpretations stemming from my prior knowledge and experiences of being the lead researcher on the Urgent Care trial.

Interview Themes

Three main themes and seven sub-themes were identified (See Table 18). Three main themes from the interviews were:

1) Service provider understanding and perceived credibility of the trial over existing interventions
2) Perceived benefits and costs of trial participation
3) Risk of the trial to service provider-patient relationship

Each theme will be presented individually, broken down into sub-themes and supported by verbatim quotes from the interviews. The quotations have been selected for illustrative purposes.

Table 18 Main and sub-themes in relation to service provider reasons for study participation and referring service users to the Urgent Care trial

Theme/sub-themes	**Description**
1. Service provider understanding and perceived credibility of the trial over existing interventions. 1a) Communication and promotion of the trial information by the Urgent Care study team 1b) Service provider perceptions about the credibility of the intervention 1c) Perspectives of service providers regarding the use of Digital Health Interventions (DHIs) in addressing health anxiety	How information about the trial was communicated to service providers The impact of this on service provider understanding of the relevance and benefits of the trial and their perceived credibility of the trial intervention over existing interventions. Service provider views about Digital Health Interventions (DHI) for treating health anxiety
2. Perceived benefits and costs of trial participation. 2a) Staffing and logistical barriers to trial participation	Service providers thoughts about the benefits and costs of participating in the trial, including practical considerations such as their workload and resources.

2b) Service provider views about trial procedures and randomisation	Consideration of the trial processes, such as how to identify eligible patients and their views about randomisation.
3. Risk of the trial to service provider-patient relationship. 3a) Communicating trial information to patients with health anxiety 3b) Continuity and patient trust in service providers 3c) Service provider perceived patient readiness	How the service provider explained the trial to patients, to include discussion of health anxiety How service providers thought their patients may feel about participating in a psychological intervention. Service provider perceptions of how demographic factors and culture might influence their patients' acceptance to participate in the trial.

1) Service provider understanding and perceived credibility of the trial over existing interventions.

Service provider participants reported that the decision on whether to participate in the research, and subsequently approach and refer patients to the trial was in part influenced by the research team and how information about the trial was promoted. This included aspects such as how information about the trial was communicated to service providers by the research team, as well as service provider's perceptions of the relevance and credibility of the trial over existing interventions. This section will start by explaining the ways in which the trial was communicated to recruiting sites by the research team, followed by service provider perceptions of the effectiveness of these communication strategies. The section will conclude with service provider views on the credibility of the trial intervention over existing interventions.

1a) Communication and promotion of trial information by the Urgent Care study team

Prior to deciding if they wanted to take part in the trial, service providers needed to understand the relevance of the research and what their involvement would require. Therefore, the research team played a vital role in communicating trial information to recruiting sites, making them aware of

the trial and the trial processes. The way the Urgent Care study trial information was communicated and promoted by the research team was essential in not only facilitating service provider understanding of the trial, but also in terms of highlighting the relevance and potential benefits of the study which influenced service provider decisions to participate in the trial.

i) Getting in through the door

The research team were aware that to communicate information about the Urgent Care trial they needed to get their foot in the door and make sites aware of the Urgent Care trial. This was done in several ways.

Regular meetings between Patient and Public Involvement and Engagement (PPI/E) representatives, researchers, GPs, Practice Managers, Nurses, Consultants, Clinical Commissioning Groups (CCGs) representatives, knowledge brokers, CBT Practitioners and NHS managers and commissioners were established and called a “Network of Practice”. The meetings were held on a quarterly basis and were well attended; the first meeting was attended by 16 people and the final meeting held had 65 attendees. This enabled all stakeholders interested in the study to share ideas, consider early findings from the study, and help overcome recruitment barriers. A key example of this was a brainstorming session during a Network of Practice about improving recruitment when rates were low. This led to the introduction of SMS texts that significantly increased recruitment. In total nine Network of Practice meetings were held between January 2015 and September 2017. Service user participants were invited to the final meeting and the findings of the trial were disseminated.

As discussed in Chapter One, the Urgent Care trial study researchers usually heard about GP surgeries expressing an interest in taking part in the trial via the Clinical Research Network (CRN). The CRN would provide email addresses (usually of the Practice Manager) to the study team. The research team also initiated contact with sites they had established existing relationships. An introductory email was sent to all sites that expressed an interest in hearing more about the Urgent Care trial, consisting of a brief overview of the study. Attempts were then made to arrange a for a face-to-

face site initiation visit. At these visits the study team would provide a rationale for the trial and advise on the level of commitment required for trial participation from a service provider and service user perspective.

The study was also advertised on the CRN portfolio website. This facilitated sites outside of the East Midlands becoming aware of the trial and expressing an interest. The Walk-in Centre that took part in the trial became involved after learning about the study in this way.

> *"We found the study on the CRN portfolio. I was specifically searching for studies that involved anxiety and that's when I came across yours"* (SP009).

One of the research nurses who had seen the study advertised on the CRN portfolio website and had contacted the study team expressing their interest in their region being involved in the trial described her initial feelings about the trial.

> *"Really interested, really keen, I know it's important research because I'm a, my background is in primary care. I used to be a district nurse and a practice nurse and probably more relevant, being a practice nurse I came across a lot of people who had anxiety related issues that impacted, you know, on their physical health"* (SP014).

ii) Using a gatekeeper to get in

The previous section illustrates that where possible, the research team endeavoured to arrange face-to-face meetings with sites expressing an interest in the Urgent Care trial. This enabled service providers to raise queries and concerns at the initial meeting and clarify trial processes and level of commitment for service providers and their patients.

In health care research patient recruitment primarily relies on individuals being referred by their health care providers. Primary and secondary care services are approached by many research teams, therefore there is the need to stand out in a crowded field and persuade staff to firstly decide to take part in your research, and secondly, to approach their patients and inform them about your research.

Gatekeeping is a common phenomenon in health care and can influence recruitment rates to trials. Gatekeepers in research can influence the progress of a research study because researchers are reliant on gatekeepers granting access to potential participants and sites for research. Positive influences of the gatekeepers can be invaluable to the research process by facilitating the smooth running of research activity to completion. In the Urgent Care trial, we identified that the key gatekeepers at the sites varied. At some sites the initial gatekeeper was a GP or the Consultant, at other sites it was the nurses. In GP surgeries, the initial gatekeeper was often the Practice Manager or a Receptionist because they would be the first point of contact for the research team and would provide access to Clinicians.

The research team were often reliant on the Practice Managers relaying trial information to their team and arranging an initial face-to-face meeting. Essentially, Practice Managers were the gatekeepers to accessing GPs' and it was not always easy to liaise with them.

> *"Practice managers can be quite difficult to get through as well 'cause obviously they have barriers and if they're not . . . again, you've got to get through them to get to the GPs in the first place"* (SP018).

If a face-to-face meeting was not convenient, the site received information about the trial via email. This led to delayed participation from service providers because any uncertainties around the relevance of the trial and its processes could not easily be clarified.

> *"So initially I was like, I don't understand it and I don't see how you'd get -, I didn't understand how we would actually, take part in it. So when I heard about it and I heard [CRN research nurse] gave me the thing I was like, I didn't understand how or what it was trying to achieve or -, and then the other problem I had with it, I didn't understand how I would even find those patients to do with that. So that was my initial impression that, interesting, but how would you even do a search or find these people and so I was a bit perplexed, to be honest"* (SP003).

The research team found that once a relationship had been established with a member of the practice team at the recruiting site it was easier to liaise via

email. Emails could be personalised and was sent by a recognised contact; furthermore, a follow-up phone call could also be made to clarify any concerns. Where face-to-face initial meetings were not able to be arranged a telephone call may have worked better but the research team did not have access to direct dial phone numbers for service providers. Trying to make contact via the GP surgery's generic phone number was time consuming and ineffective because even when the research team finally got through to a member of staff in reception it was highly unlikely that they were able to easily speak to the staff member who was influential in determining access to other members of the team or pushing the study forward.

Clinicians highlighted that the way in which the research was initially promoted to them by the research team influenced their preliminary thoughts about the trial. Research was likened to a product that needed to be attractive to service providers so that they would buy into it. Service providers who recognised the clinical need for the Urgent Care trial – which could potentially offer a clinical solution to a current service gap – were keen to be involved, as this GP highlighted:

> *"I thought that there was a need there, and yeah, I was keen to, to be involved, to get my patients involved. The, the biggest – the biggest thing with any research is – you need to sell it to them, which is a very easy sell, a project like this"* (SP007).

Most service providers highlighted that they needed to see the relevance of the trial and how it could benefit their organisation and their patients.

> *"I thought it would be a great thing to try and do to help people with this problem if we could"* (SP001).

The initial contact with service providers was key. The way in which the trial was explained to potential referrers could both be a facilitator and – as the following discussion shows – a barrier to service provider participation.

A GP, whose practice initially did not refer any patients but subsequently became the top recruiting site, expressed that the way in which the study was presented to them at the initial practice meeting was weak. The pitch did not emphasise the potential benefits of the trial to service providers in terms

of reducing practice workload or economic benefits such as reducing urgent care attendance in the long term. As a result, he and his practice did not initially engage with the study or refer any patients.

> *"Real hook here could have been and should have been actually 'these people are taking up an awful lot of your urgent on the day appointments and we think that by us engaging with them we could reduce your demand'… Some of this sounds extremely cynical, but what didn't come across in the first presentation is what's in it for me. I know we don't think that all studies should ask the question of how it's going to help my patients, but I think what activates an interest to doctors in primary care work mostly is how this is going to help me, how it's going to either reduce my workload or potentially make me money"* (SP008).

The above quote highlights that for service providers to refer patients into a research study, they first need to understand the importance of the research by understanding its benefit both to themselves and their patients. If service providers do not see the value of the research, they are less likely to actively promote the research to their patients resulting in poor recruitment to trials.

Service providers explained that for them to be actively involved in a study and refer patients, in addition to understanding the relevance of the study, they also needed to understand how patients would be identified.

> *"I read the protocol and I read the referral process and it seemed to tick all the right boxes, so I didn't have any concerns"* (SP004).

However, some service providers highlighted that it was not always clear from the initial study documents how they would identify suitable participants, and this presented a challenge to both GPs and Emergency Department staff.

> *"When you understood it, the study actually served a good purpose and it might help with our workload not just patients' behaviour, but the challenging thing was how do you identify them and also how do you make contact with them. Now I don't think it was as obvious from the flier regarding which way we went with that"* (SP003).

The above quote highlights that in addition to service providers seeing the relevance of the research trial, they also needed to understand how they would select eligible patients. To be able do this, study information that was provided by the research team needed to clearly explain both the rationale of the research and how eligible patients could be identified.

The GP (SP008) below explained that it was only after attending a project meeting several months after the initial practice meeting that he could see the relevance of the study and understood the referral processes. Following this, he initiated further contact with the research team, and familiarised himself with the trial and engaged actively in the trial. This included referring patients to the study and suggesting innovative referral methods to the study researchers to boost recruitment. He describes that up to this point their practice hadn't referred any patients, but after this it was *"like a floodgate"* (SP008) resulting in their surgery becoming the top recruiting site overall and enabling the study team to meet their recruitment target within the two-month extension period that was granted.

> *"It wasn't until I came along, and listened to what some of the other research that was going on locally and similarly and from the same group, when I thought actually do you know what we really can - this is relevant to a lot of our patients, so I think, yeah, I felt that there was something we missed there, there was as a definite gap and I think that was borne out as well by the fact that we hadn't really referred any until that sort of first contact"* (SP008).

The above quote highlights the importance of communication in sharing trial information, and of highlighting its relevance by the study team. Getting these messages right can have a positive influence on service provider engagement with a trial and its processes. This is corroborated by the quote below from the GP at the top recruiting site. He acknowledged that once he was able to see the relevance and benefits of the trial and understood the trial processes, he was very keen to refer all potentially eligible patients to the trial.

> *"When I realised what the study was going to do and how it could work and I had fairly quick feedback from a patient about how good the actual treatment was, then I was very, very enthusiastic to think, to see every potential urgent*

physical care to actually an urgent mental health care. UNever too far but it was in my mind and it was very clear in my mind. And now I have an answer and now I have something that I can offer them" (SP008).

The way in which the trial was marketed also impacted upon service provider willingness to be involved in the trial. One GP described that the trial came at a time when another similar intervention providing medical and psychological services was being trialled by their Clinical Commissioning Group (CCG). The CCG led project had a lot more publicity and the lead Chief Investigator personally met with all the staff within the CCG. On the other hand, the Urgent Care trial was not well known amongst their CCG.

"That's with an awful, awful lot of publicity, and him going to see every single practice personally. So, with those two small bits of publicity, you wouldn't expect a big game change at that point. For your project. So, it's no disrespect to your project, but it, it wasn't well known about – that's just – there's so much going on, that you have to keep banging your drum for a little while, to get GPs to take note, in general" (SP007).

Consequently, this GP acknowledged that within Primary Care there were often several research projects being promoted, and projects that were publicised more effectively were more likely to receive greater attention and engagement. At his surgery he was the only GP referring patients to the Urgent Care trial; the other GPs were referring patients to the highly publicised trial.

Initial face-to-face set up meetings with service providers were deemed to be helpful in facilitating service providers understanding of the trial and trial processes and resolving any apprehensions. Contrastingly, emails were perceived to be an ineffective way to promote the trial because GPs expressed that they received numerous emails and did not have the time or capacity to read them.

"Email is a really bad way, really, really bad way, actually this is probably my final golden nugget actually, don't bother emailing people to tell them about stuff, if they didn't want your email if they didn't ask for your email, they're hardly ever going to be - the only people who have time to read that are the

managers in ivory towers, to be honest, they're not engaged enough physically to have the option to actually be involved" (SP008).

Activities identified by service providers as key to maintaining their engagement in the trial included keeping sites informed about the study progress, communicating recruitment figures to participating sites via newsletters and rewarding sites for recruiting well. For example, over the Christmas periods the research team would have a competition whereby the three top recruiting sites would receive a Christmas hamper.

"I would suggest intermittently sending out you know something that 'well done practice … so you know you like to see your numbers go up and that drives you to do more so some sort of dangling a carrot to say 'well done, um, well done practice, you are, you are number 3rd in the league of recruiters this week' " (SP013).

To summarise, this theme acknowledges the importance of the initial contact by the research team and the significance of appropriate and effective communication of trial information. Service providers acknowledged that clear information about the trial with regards to the relevance of the trial and the potential benefits of trial participation to the organisation and patients should be prominent in all initial communications with recruiting sites. The format for communicating with recruiting sites also needs consideration because certain communication methods were deemed to be more efficient than others as it facilitated understanding of trial processes which influenced how quickly sites were able to commence referral of their patients.

1b) Service provider perceptions about the credibility of intervention

This sub-theme relates to service provider perceptions about the credibility of the Urgent Care trial. In this section, service providers perceptions about the clinical management of health anxiety, the perceived credibility of the trial intervention over existing psychological interventions and their views on remotely delivered psychological therapy as a treatment option are all considered in relation to the research question.

Chapter Two highlighted that two main current care pathways for treating health anxiety are medication and psychological treatment. Despite

extensive evidence identifying that Cognitive Behavioural Therapy (CBT) for health anxiety can be effective, access to CBT treatment is poor. Furthermore, there is a low uptake of CBT for the treatment of health anxiety attributed to stigma associated with health anxiety and a lack of acceptance that health anxiety is present. There is limited evidence regarding the effectiveness of the use of medication for treating health anxiety, it is also not the preferred option for service users. The Urgent Care trial was conducted at a time when remote health care consultations in mental health services were uncommon, not routinely offered and there were few videoconferencing platforms available.

Service providers who perceived that the intervention offered an opportunity to be able to help patients manage their health anxiety reported that they decided to participate in the trial and refer patients because they were keen to address health anxiety and understood its impact on health care services and their patients.

> *"I've been involved in research on and off. I'm not – our practice is a research practice, so we have had that experience. In this field, I've had a keen interest in medically unexplained symptoms of frequent attenders in mental health. I mean for you know, many years, probably, probably a decade. Probably two decades"* (SP010).

The intervention was perceived to be beneficial as it provided an additional treatment option that service providers could offer to patients to help them with their health anxiety symptoms.

> *"It's about having for us it's about having another tool under our belt which would help them along their therapeutic journey by saying well actually we can get round that because there's this option"* (SP013).

The trial was therefore, seen as an opportunity to help patients with health anxiety and reduce the economic cost to the NHS.

> *"I'm aware really of I think a figure of like three billion pounds are spent on unnecessary investigation in medically unexplained symptoms and there must be better ways of managing this which is a real opportunity of a win for patients and a win for the health service"* (SP010).

Prior knowledge of the research intervention also influenced the decision to become engaged with the research trial. The following service provider had previously taken part in a similar study and was passionate about supporting research in health anxiety.

> *"I was on the CHAMP study which means I have an interest in medically unexplained symptoms and therefore the study was within my field of interest. It dealt with the same group of patients and any research in that group of patients is to be supported"* (SP004).

The recruitment patterns observed in the sample revealed the significant impact of clinician enthusiasm, experience, and engagement with the research area on participant enrolment in the Urgent Care trial. Clinicians who demonstrated a genuine interest in the research area and had previous experience in similar studies played a pivotal role in referring more patients to the trial. Their enthusiasm was reflected in their active participation during face-to-face meetings, where they not only asked more questions but also expressed confidence in their ability to recruit participants. One noteworthy finding is that these sites were more likely to have a delegated staff member who would contact the study researchers with referrals and queries throughout their participation. The presence of a delegated staff member in these high-recruiting sites indicated a structured approach to managing referrals and queries throughout the participants' involvement. They were also more likely to suggest innovative ideas to the Urgent Care trial team about increasing referrals. For example, the second top recruiting site which was a GP surgery that recruited 25 participants expressed that they had set up a pop-up box on patients' medical records which would come up for any potential eligible patients during GP consultations demonstrating a commitment to optimising recruitment strategies.

Conversely, sites that referred fewer patients exhibited signs of disinterest during site visits. The lack of engagement was evident in them asking few questions and appearing distracted with other tasks. The ED Consultant recognised this during a meeting that the research team had with ED

clinicians and expressed receiving negativity from her colleagues with regards to the research topic.

> *"There was a lot of – one of the reasons I wasn't involved with it a little bit further on is because of the negativity that I experienced from my consultant colleagues at the beginning of this trial which you probably didn't know about as such . . . And they're negative because, well one of them just said he didn't believe in it, said he didn't believe that people came with anxiety. How do you change a consultant's view? You know, how do you say to them actually no, I completely – 'No, no I'm not asking those sorts of things in ED' and that was it'"* (SP015).

Thus, there was a lack of willingness from ED staff in speaking to patients attending about anxiety. Anxiety was not perceived to be an issue that ED staff needed to manage, even if it was the potential cause of a physical manifestation of symptoms that they were subsequently asked to deal with.

> *"This health anxiety study was a typical example of 'Talking about anxiety is not my problem. That's for psychs and GPs'. In so many words. They almost said that, in fact I think they've said that – 'It's not my problem and it's not something I need to talk about'"* (SP015).

The Research Manager in the ED highlighted that clinician readiness to broach the subject of health anxiety could be linked to the stage the patient is at in terms of investigations. They felt that Neurologists seemed much more *"open to the idea"* that health anxiety may be contributing to their patient's symptoms, because by this point the patient had been referred for all investigations when neurological conditions had been ruled out and they were at the "*final step".* Conversely in the Cardiac Rehabilitation Department clinicians found it *"easier to concentrate on the heart as an organ rather than a brain".* He associated the ED's reluctance to approach patients about health anxiety with risk. He felt that there was *"a much higher tolerance of that kind of risk in general practice" (SP016)* because GPs were more likely to know their patients and could say with a higher degree of certainty that their patient's symptoms were attributed to health anxiety. Within ED it was perceived that it could be potentially more of a risk to suggest health anxiety as an underlying diagnosis when patients were undergoing physical

investigations to rule out other diagnoses. In addition, service users who present to the ED are discharged or are transferred elsewhere for extended care and are not managed by the ED team for an extended duration.

Conversely in the ED low rates of referrals was explained through the service being associated with a "*medically orientated"* culture. In the ED health anxiety was not perceived to be something that the Clinicians were trained to identify, treat, or address, as a Consultant in the ED illustrated.

> *"So even in our training we don't do any, cover any of health anxiety. We don't do anything about holistic medicine. It's all condition based. We tend to get very wound up with it being a medical thing, when in fact my juniors are not addressing why they've come to A and E"* (SP015).

To summarise, this section of the chapter has explored how service providers who had clinical experience of managing patients with health anxiety or had been involved in similar research previously were enthusiastic about the intervention. The lack of enthusiasm from the ED was attributed to the siloing of medical specialists and task-orientated medicine within their department as it was not considered to be within their remit to treat. Furthermore, they lacked knowledge about health anxiety as a concept.

1c) Perspectives of service providers regarding the use of Digital Health Interventions (DHIs) in addressing health anxiety

Clinician views about Digital Health Interventions (DHIs) over current existing interventions influenced their perception of the Urgent Care trial. Remotely delivered therapy was seen as beneficial as it improved accessibility for patients and reduced waiting times.

> *"I thought it would be a good idea to get involved in this study because people can access, you know, something like cognitive behavioural therapy on the phone. And that might be helpful for them to deal with their conditions"* (SP012).

Current psychological therapy services were perceived to be difficult to access because of the way in which their processes operated. The

Consultant below described that once patients were referred to psychological services there was a two-stage process for accessing services. This, coupled with long waiting times, was likely to deter patients from remaining interested in accessing psychological services.

> *"Because the service is so precious in terms of time, they have a system of opting in. So, if you refer to a psychologist or psychology services or counselling services currently, they first approach the patient and say, 'Do you want to come for this' and they've got to opt in once. Then I believe there is a second approach where they, where if you really, really want to come and it's only at that point that they offered an appointment. So when there is a waiting list of a year and a half sometimes and then you're asked to opt in, I suspect there's a significant number of vulnerable people who need the service, either have lost interest or they may not even have received the invitation and they're classified as not interested"* (SP004).

In addition, high demand for psychological therapies meant that existing psychological interventions were being offered as group therapy, which was not always acceptable to patients. The intervention offered by the trial was perceived to be a more suitable alternative than existing forms of therapy because it provided individual therapy to participants.

> *"A lot of my patients were turning down talking therapies and it was only when I said to them you know you said to me you wanted this well I went there and it was a group session, I don't want a group session, I don't want to talk to everybody about this"* (SP013).

Health care providers who felt positive about using technology to communicate with patients felt that the remotely delivered therapy could improve accessibility for patients who were on long waiting lists to access psychological treatment.

> *"It's very useful. It's one way of delivering it. It's one way of delivering the therapy. It certainly beats waiting eighteen months as the patient told me herself"* (SP004).

Remotely delivered therapy was also perceived to be more accessible for patients; it offered flexibility and could be tailored to meet patient need and preferences. The GP below explained that remotely delivered therapy could

fit more easily into patients' lifestyles, and consequently this may increase adherence rates for accessing treatment as patients it would not impede on other priorities such as needing to take time off work.

> *"So you know if this came along in practice and I was exploring somebody with health anxiety, 'would you like to have a chat with somebody on the phone about this and think about therapy you know over the phone', that would be perfect odds, because actually I can fit it into my work life and be at work and not take a day off and because a lot of people don't do their talking therapies they do the first one but then they say I can't follow the six week programme because I can't get that time off"* (SP013).

Due to the nature of health anxiety service users are more likely to experience debilitating physical symptoms. Service providers acknowledged that remotely delivered therapy could be more convenient for patients with physical co-morbidities, because they would not have to leave their home to access treatment which could otherwise be more burdensome.

> *"Certain physical illnesses or even the psychological illnesses make people very tired and not able to get out of the house"* (SP004).

Service providers were also complimentary that the trial offered both videoconferencing and telephone as a mode of therapy. The potential benefits associated with videoconferencing included patients being able to see the patient and not losing visual cues to assist with interaction and discussion.

> *"Like with the WebEx, you can see them and they're looking at ya, and it's that eye contact I think. I like, it's people's body language whereas on the phone you don't know what they're doing and I think, um, if you're really going to get a benefit out of it then you need to be able to see the person you're talking to"* (SP017).

To summarise, service providers who were optimistic about remotely delivered therapy for the treatment of health anxiety were keen to refer patients to the trial because it offered patients an accessible form of treatment to manage their symptoms. Service providers who held a favourable view of remotely delivered therapy believed that the intervention

was better suited to patient needs. They saw it as a more convenient option for individuals dealing with health anxiety, providing access to therapeutic interventions with significantly reduced waiting times for patients.

2) Perceived benefits and costs of trial participation

When deciding whether to participate in the research, service providers spoke about a consideration of the benefits and costs of participating in the trial. This included considering whether they thought the study was achievable in terms of being able to refer and recruit patients to the trial and if they had the funding and resources to conduct it. Service providers also explained that their decisions were also influenced by their perceptions about the trial processes and their views on randomisation. If the trial was perceived to be well organised, with clear guidelines about the referral process and provision of sufficient resources, clinicians were more likely to agree to participate in the trial and approach patients. If service providers perceived that they had inadequate resources or were unsure of the referral processes, this contributed to them declining to participate in the trial or led to delays in referring patients.

This section of the chapter will start by presenting service providers discussion of the perceived staffing and logistical barriers to participating in a trial and will conclude with service provider perceptions and understanding of the trial processes.

2a) Staffing and logistical barriers to trial participation

The decision to be involved in research (generally – not just the Urgent Care trial) and actively recruit participants was influenced by structural factors outside of the research process, such as practice staffing and logistical issues. Heavy workloads within GP practices from clinical demands resulted in delays in referring patients to the trial or sites refusing to participate in trials altogether, both of which negatively impacted on recruitment.

> *"As a GP, you look at it and think well what's the impact, we all want to take part in research but we have to be realistic what's the impact on the practice, is it achievable and how would we deliver it but then also you look at the*

funding mechanisms and think well funding wise or the admin wise, does it work out or doesn't work out" (SP003).

As expressed by this GP, GPs do want to participate in research, but they must consider whether they have the resources to be involved in terms of time and adequate funding.

"GPs I'm afraid are the same, primary care practitioners are the same, you know, it's all about time and commodity" (SP008).

Service providers did not always have the time or capacity to engage in research related activities and bureaucratic processes such as having long meetings with their Research and Development (R&D) departments and needing to complete numerous forms prior to commencing research discouraged service providers from taking part in the trial.

"We had an incredibly long meeting that went on and on and on and I thought 'well, if it's going to be like this then I ain't got time to do this' because I'm a GP and I do lots of other things" (SP005).

A GP from a surgery whose practice declined to participate in the research trial after having a face-to-face site initiation meeting indicated that this may have been due to staffing issues.

"I suspect when you went to see them my guess is they were in a state of flux, … I suspect with the fact that the Practice growth was so big, they were probably firefighting rather than saying, 'ok we've got time to take on something else' because in all fairness from what I have seen we tend to be yes people to anybody and everybody so I suspect it was a sign of the times rather than not wanting to take part" (SP013).

Therefore, for this surgery non-participation in the trial was influenced by their staffing situation and at the time *"a no was better than a we'll do this half-heartedly"* (SP013).

Sites that had decided to participate in the trial but subsequently struggled to refer patients also highlighted that staff continuity and changes in staff impacted on referral of participants.

"Being a training practice as well, one more thing for your registrars to remember and I don't think we really got them on board as well as we might have done. They change every four months . . . they've got so much to think about when they're busy training that, and they're early on in their careers that probably we don't make enough of – it's probably our fault really that we don't push the research quite as much" (SP002).

For this practice, asking their temporary junior staff to approach patients about research whilst they were in training to be a GP would be challenging. The implications of this for the Urgent Care trial was that at this practice there was less focus on encouraging their staff to think about recruiting patients to research studies resulting in no participants being referred to the Urgent Care trial.

Recruitment in a secondary care service was also hindered by staffing capacity. In the following example, the lead nurse championing the trial at the walk-in centre left shortly after the site had decided to participate in the trial.

"What was challenging was that, because what I suggested they do was to arrange for one of the staff that's interested in doing research in the walk-in centre, you know, we could have a link nurse to us, so that worked very well but then she left, she moved. And I think, yeah, so it was difficult after that, and the manager works part time there so we weren't getting the referrals that we were in the beginning" (SP009).

At this site, the nurse championing the study leaving coupled with the Manager working part-time impacted on fewer referrals being made which subsequently affected recruitment rates. This highlights the significance of capacity within staffing to engage with and champion research studies. Research involvement cannot be left 'unattended' and requires active participation.

Service providers noted that engaging in conversations with patients about the trial was time-consuming, particularly given the complexities associated with the patient group. In the context of the time constraints within general practice, approaching patients about the research was not always feasible. This process necessitated "*changing doctor behaviour*" as GPs were required to initiate discussions about the study with their patients—

something that diverged from their usual practices. This posed a challenge, especially when time pressures were a factor, as illustrated by the explanation provided by a GP below.

> *"I mean it was difficult because a lot of these consultations are complex with this group of people, so sometimes it was a bit of an additional pressure and therefore sometimes you didn't do it. The more you didn't do it and unfortunately that then became 'we don't have time to do this'. So that was, trying to do it within the consultation I think was hard. I don't think we did try any other, I think we thought of writing to people, and I wrote and said 'were they interested' but we felt it was best and sensitive to do it within the consultation"* (SP010).

As a result, he and his team would not always approach patients about the trial; the more he refrained from discussing the trial with patients, the less likely he became in approaching his patients about the trial which further reiterated to him that he did not have the time to refer patients. His GP surgery did consider whether postal invitations may alleviate time pressures on GPs but due to the nature of health anxiety he felt it was more appropriate to approach patients during consultations.

Unsurprisingly, the research team found that sites that were on the Research Sites Initiative (RSI) scheme had the resources, systems, and funding to support research related activities compared to non-RSI practices. In addition, RSI sites had committed to participating in research and recruiting participants within set timelines. Therefore, GP surgeries that were registered on the RSI were more likely to approach patients about the trial and refer potential participants. It was more challenging to promote the research to GP surgeries that were not research active; they were less likely to be incentivised to participate in research as they had not committed to being involved in research and did not receive additional funding for their participation as highlighted by a CRN nurse.

> *"GPs that were on their RSI scheme, research site initiative scheme; so those are GPs who have made a commitment to being involved in research. So, we have a little bit of leverage with them because they actually had to deliver because they were getting a payment for being involved in research. The*

others, it was a little bit more difficult in that we were just trying to promote the study, get them involved and to see the benefit of it" (SP018).

This theme highlights that participation in research by service providers was influenced by lack of time, resources, and funding. These were often factors outside of the control of the research team. Research sites that were on the RSI were more likely to be actively involved and refer patients to the trial because they had resources allocated to enable them to spend time on research related activities and had committed to recruiting participants to research.

2b) Service provider views about trial procedures and randomisation

Clinicians stipulated a preference for participating in trials that were clear and simple to do. This related to aspects such as the level of commitment required from service providers, and what was required from them in terms of identifying and referring patients to the trial. Trial processes that were clear and comprising simple rather than complex procedures facilitated clinician understanding of the study processes and the commitment required. Service providers talked about the methods utilised to engage in the research and a preference for these to be simple.

"I like doing research. I'll be honest I always picked the studies that were easier to do" (SP005).

This GP expressed that for him a simple method would be a system comprising of a few primary care staff involved in a given research trial. He highlighted that involving too many primary care staff in a research trial could lead to more errors being made.

"I think the key is as with all of these things, having done some research, you want people to be on board and it's got to be the simplest method which will get people to do it but also retain it . . . , I'm a big believer in the simpler the system the more effective it usually is, and so the less people involved in the cog. The less, likely, um it is to go wrong, so if it just involved a GP and somebody in Admin sending you the details, I think that is the perfect system" (SP013).

As described in Chapter One, the Urgent Care trial employed two referral approaches: opportunistic and postal invitations. Most of the GP surgeries opted to approach patients opportunistically because they felt that within a consultation the information given to patients could be tailored individually. An opportunistic approach was preferred by GPs because they felt that this enabled careful selection of potential participants, based on clinical information, and patient identification could be more focussed to ensure that eligible patients could be selected. It also meant that each approach could be adapted and made more sensitive to individual patient needs.

> *"So, it was, it was all purely verbal. I know my patients very, very well. So, all three I knew very well, and I wanted –it's not like I would do a search on the system and say OK, all these patients have had anxiety code added in the last 12 months, so they were all of a certain – I wanted it to be much more focused, that I knew there was a clear health anxiety issue here"* (SP007).

The secondary care services, the Outpatient Departments (Neurology and Endocrinology) also opted for this approach. In contrast, in settings where the patient was unlikely to have a reoccurring relationship with the service provider, such as the ED and Walk-in Centre, electronic searches were conducted to identify eligible patients and patients were then telephoned by the research nurses employed by the Trust or sent study information via postal invitation. A Consultant in the Endocrinology Department expressed that he felt that the referral approach was *"fairly straightforward"* and reflected standard clinical practice well.

> *"I think the study was a very good model for good practice. I suppose it's to say that the research is usually used to identify what should be done but we have now moved to a stage, certainly in this kind of problem whereby it becomes embedded as a service rather than having to do more research, so it is now a question of funding it from various aspects of the health service to provide a service"* (SP004).

GPs highlighted that although approaching patients in a consultation was difficult, it seemed to be the most appropriate approach for this group of patients.

> *"Trying to do it within the consultation I think was hard. I don't think we did try any other, I think we thought of writing to people, and I wrote and said 'were they interested?' but we felt it was best and sensitive to do it within the consultation"* (SP010).

Conversely some GPs expressed that they found the referral process to be *"woolly"* (SP008). This resulted in clinicians reporting reservations about being involved in the trial, because they were concerned that identifying patients would be time consuming.

> *"I did have reservations, I'll be quite honest, to start with, because it did seem a bit vague and woolly if I'm honest and I did think 'oh, this is going to be a bit difficult to do' "(SP005).*

GPs highlighted the need for referral processes that were simple and the least time consuming. This GP acknowledged a preference for referral processes that required minimal time from the clinicians. He suggested a referral process consisting of providing potentially eligible patients with contact details of the research team.

> *"Here's a card, it's completely self-contained, if you give this to the patients then your management of that patient is finished' because the perception is this shortcut to be to having completed and successfully completed my engagement and provision for the patient, so I've done a good job, but it's taken me less time. And so any systems which works like that I think has greater engagement because it is, yeah, it, it's easier and takes less time"* (SP008).

The difficulty of such an approach is that whilst it would be less time consuming for clinicians, it would place the onus on patients to contact the research team. The response rates from the Urgent Care trial, when comparing opportunistic and postal invited participation showed that opportunistic recruitment yielded a higher number of interested patients. Where patients received postal invitations, a much smaller proportion of patients expressed an interest in the research.

Another GP highlighted that for their practice, a hybrid approach consisting of opportunistic and postal invitation referral approaches was deemed to be most appropriate.

> *"I think the ones that we actually recruited which was probably the best one worked out better that rather than giving them the pack. I think the GP spoke to them and they said they sounded interested and then we mailed it out to them. So, it was probably a kind of hybrid of the two, you know, so the patient was primed ready to expect it"* (SP003).

Service providers understood that upon deciding to participate in the Urgent Care trial the next step entailed identifying which of their patients would be eligible. There were some concerns highlighted by service providers in terms of participant identification. There was a consensus that clear inclusion and exclusion criteria would facilitate service provider willingness to be involved in the trial, whereas challenges in identifying eligible patients could hinder recruitment.

> *"The challenging thing was how do you identify them and also how do you make contact with them. Now I don't think it was as obvious from the flyer regarding which way we went with that. It was very ambiguous - we didn't understand; are they talking about A and E attendances, are they talking about out of hours attendances, are they talking about Walk in? You see that kind of understanding the logic of where you guys were trying to go was a bit more tricky"* (SP003).

Some GPs highlighted that in other research, participant eligibility could be determined using an electronic search. This did not require GP input and could be completed by an administrator. However, due to the complexity surrounding diagnosing health anxiety it was not easy to identify patients in this way.

> *"I think the clinical report perhaps didn't capture all. I don't know why because some of the names when I was going through the reports, I was thinking I don't know why these people are on it and it perhaps needed refining a bit. I think the criteria was perhaps, it was a little bit vague and it was quite difficult to construct the clinical reports I felt"* (SP005).

Opportunistic recruitment required service providers to approach patients. However, a practical barrier to this was GPs not remembering to speak to patients about the trial.

> *"We thought it was a really good idea but we really struggled to actually recruit patients to it. I think the doctors, even though we had lots of posters and things and stuff in their rooms, they're just so busy that they don't always remember that it's a possibility to recruit people. And it's not really something the receptionists can recruit to. Whereas in the past most studies we've done have been a database that's followed by a mail out"* (SP002).

Service provider confidence in introducing the trial was related to their knowledge of the trial, remembering to introduce the trial, and becoming familiar with the referral process.

> *"I think actually some of the fears and I think ironically, again, that realisation that you can probably overcome some of those and so you get used to doing it obviously then the study becomes known to them. I think there is that time of getting used to a new way of consulting, a new way of doing things, and then when you've got that, that takes time – a surprising amount of time, you know, six months to kind of change a consultation behaviour"* (SP010).

One aspect of the research process that service providers liked was that unlike other research they were involved in, the trial did not require them to consent patients. Their involvement was minimal in that they only had to select patients which made it simpler (and quicker) for them.

> *"I mean I'm involved with lots of NIHR portfolio studies, and this was one of the NIHR portfolio studies. The difference of this study from others actually was to do with the way the study worked. Like, we only had to select patient and the patient contacted you. So all those things are taken away from us that's why it was easy for us to recruit a patient in this study"* (SP012).

Service providers perceptions and understanding of randomisation and treatment preference were also significant in influencing their decision to refer patients to the trial. Whilst service providers acknowledged that they could see the potential benefits of the trial for patients, the challenging part was explaining to patients that it was a Randomised Controlled Trial (RCT) and knowing that they had a 50% chance of receiving the intervention.

Service providers expressed a preference for their patients to receive the intervention over treatment as usual and were put off by the risk of offering their patients a treatment option but knowing that they may not receive it.

> *"The process is sort of – is a very easy sell to the patients, because they can see the benefit they get, the difficulty from a clinician's point of view, is saying well you might be randomised to the arm of group therapy, or you might be randomised to the arm without. And obviously as a clinician, I want all my patients to get the therapy. But that's, that's the only downside to it"* (SP007).

Service providers were concerned about disappointing patients. They feared that introducing the trial created a sense of hope for participants that they would receive treatment to help manage their symptoms, despite there being only a one in two chance that they would be allocated to the treatment arm.

> *"Where it is a randomised trial and particularly where one arm of the randomisation might be 'and no extra care'. Because the difficulty with that is if we wait to apply randomised principles to people who are, or in crisis, then 50% of those people are going to be disappointed and when you invest in something we've got their hopes up and then we tell 50% of them 'there's nothing extra for you'"* (SP008).

A Consultant in the ED echoed these concerns about raising patient hopes for treatment.

> *"Then you were like oh, maybe I've told them too much. What if it's no good? What if they get randomised to the wrong part of the trial and it's like, yeah, 'cause they're always really keen. Actually, those who accept it are usually really keen to get a – yeah? To see if it improves"* (SP015)

There was a concern from a GP that RCTs may potentially cause more damage to patients who are allocated to the treatment as usual (TAU) group particularly if there is an immediate need for support. For this GP, a RCT could potentially increase the risk of harm to their patient.

> *"So I do think that is a risk. Where we have randomised therapeutic interventions and one of those therapeutic interventions might be perceived by the patient to be less than they need, we should be cautious about offering*

that choice to people who present with a clear, heightened need. Because our actual potential offering to then be whipped away actually is worse" (SP008).

To summarise, this theme highlights that due to the clinical demands and pressures placed on service providers when deciding to participate in research they preferred to be involved in trials that were least cumbersome. Service providers expressed a preference for trials that were simply to carry out, required minimal input from clinicians and had clear guidelines on how eligibility of patients could be determined. In terms of referral approaches, this differed depending on where patients were recruited from. Service providers who had established relationships with their patients preferred an opportunistic approach because they knew their patients well and were able to determine if they felt that health anxiety may be attributing to their patients' symptoms. Whereas service providers who did not have established relationships with their patients, such as those from ED and Walk-in centres, preferred to carry out electronic searches to identify patients to contact through postal invitation.

3) Risk of the trial to service provider-patient relationship

This theme addresses the perceived risk of the trial to service provider-patient relationships. As previously discussed, in most research conducted in primary and secondary care, service providers are the gatekeepers to patients accessing information about research trials. Researchers do not typically have consent to directly contact patients about research trials and are reliant on clinicians (or other health care staff) making patients aware about trials either through a verbal conversations or the provision of written information. Without service providers promoting a research trial to patients, they would not become aware a trial is being conducted. This section of the chapter will present data from service providers about approaching service users about a trial addressing health anxiety. This section will start with a description of how service providers presented the trial to their patients, the barriers to introducing a trial about health anxiety and its perceived impact on the service provider-patient relationship. It will conclude with service provider

perceptions on aspects they felt may have influenced patient readiness to accept a psychological intervention for the treatment of their symptoms.

3a) Communicating the trial to patients

As described in Chapter Two, health anxiety can have negative connotations and there can be a misconception about health anxiety that it is a factitious illness. Service providers were concerned that the diagnostic label of health anxiety could be perceived as a stigmatised condition and a term that patients may find offensive because of an assumption that it was all in their mind and there was nothing wrong.

> *"You know that's always a slightly sensitive issue with people, you know, about that perception it's in their head. You know, the direct aspect that people are very sensitive about, 'well you're saying there's nothing wrong with me. Am I imagining it'"* (SP010).

GPs expressed concerns that broaching the notion that a patient may have health anxiety was challenging and could make patients feel like they were not being taken seriously. This was particularly an issue where patients had not yet started to consider that there may be a psychological element to their physical symptoms. This conversation was made more difficult for GPs because consultations were routinely only ten minutes long.

> *"One or two of the patients I know that the doctors approached weren't very happy about the idea that we felt that they may, that anxiety might be the underlying problem. It's not the easiest conversation to have, and if you've got ten minutes it can be difficult, if they don't have the insight to realise that anxiety is playing a part. And they feel they're being fobbed off. I'm not saying they are being fobbed off I'm saying that's their perception"* (SP002).

GPs explained the different ways they used to explain the trial to patients and highlighted that the phraseology used was essential because it determined how accepting patients were.

> *"I suppose it's like any patient you know, you've got to say 'I can't find anything wrong with you. I think this is it'. If you communicate that properly I think people do accept it but there are those who will be hostile to it and it*

again depends on training, clinical staff on how to break the news that you are referring to psychology or psychiatry staff" (SP004).

The GP highlighted that the level of training clinicians had received in terms of talking about psychological interventions in primary care also influenced how receptive patients were in accepting that their symptoms may be related to anxiety and not a physical illness.

The Practice Manager at the GP surgery that did not recruit any patients explained that despite GPs at her site approaching patients, none of the patients expressed an interest in the trial. She acknowledged that a lack of patient receptiveness could be attributed to GPs not using the right terminology when explaining the study.

"They did approach some patients yeah. There weren't many that were receptive shall we say. Maybe they didn't use the right words, maybe, I don't know, it's hard to say. You can't be a fly on the wall all the time" (SP002).

Service providers were cautious of offending patients and the negative impact this could have on the service provider-patient relationship. This GP highlighted the importance of effective communication of trial information and the potential implications that miscommunication could have on patients, resulting in increased anxieties and attendances.

"You have to be very careful in how you explain things, because if you, as a doctor, if you are slightly vague or say something that can be misconstrued, patients usually pick up on it, I find. That you know and, and twist it is slightly the wrong word, but they can get the wrong end of the stick. And that can create unnecessary worry, further attendances, further appointments … So you have to put it across in a positive and affirming way, otherwise you can very easily build health anxiety. Absolutely. Communication, communication, communication, yeah. It matters" (SP007).

This GP recognised that despite the sensitive nature of health anxiety, the participant information sheets provided to participants were helpful.

"Engaging people and explaining what it's about. You know that's always a slightly sensitive issue with people, you know, about that perception it's in their head. You know, the direct aspect that people are very sensitive about, 'well

you're saying there's nothing wrong with me. Am I imagining it?' And I think some of that. I think the information sheets are good. They're helpful and helps people in the study" (SP010).

The phraseology used to introduce the study to patients was identified as imperative. Clinicians from both primary and secondary care requested guidance/training on how to introduce the study to potential participants without causing offence. In response to this a script of possible ways to introduce the study was produced by the study team in collaboration with PPI/E representatives. Prior to the script being circulated to all service providers, feedback was sought from the first two sites contacted. Both GPs and staff in the ED acknowledged that the scripts provided by the research team were helpful. The script provided service providers with suggestions on how to introduce the Urgent Care trial and explain the study processes to potential participants. The suggestions enabled service providers to explain the study using terms that were more appropriate to patients.

When thinking about the study name, the research team recognised that the language used for the study name would be of particular importance due to the potential for stigma amongst those suffering from health anxiety. As discussed in Chapter Two, health anxiety can be perceived to be stigmatised condition. Therefore, the study team consulted with the PPI/E representatives involved in the Urgent Care trial in selecting a study name. After much deliberation it was decided that including health anxiety in the study name could put off potential participants. The study name agreed was Helping Urgent Care Users Cope with Distress about Physical Complaints. This was seen to be study name that did not alienate patients and the study title highlighted that the intervention was focussing on helping individuals to cope with their physical symptoms. The GP below highlighted that when approaching patients about the study he found it helpful to use the wording in the study name. He felt that informing potential participants that the study was about coping with physical symptoms rather than health anxiety might have been more acceptable to patients because it reduced the implication that there was nothing wrong with patients.

"You could actually go through the sheet with people, just to look at how to support them, how they need to cope. I think that was a good construct. We all want to cope with life. We all want to cope with suffering and distress. That I think is a common human feeling. So, you know, we're not trying to say to people erm 'there's nothing wrong" (SP010).

This GP corroborated the significance of the phraseology used when discussing the trial with patients. Consistent with the above quote he recognises that it was important to focus on the presence of symptoms and acknowledging that this trial aimed to identify what might be causing these symptoms.

The hook was the correct phraseology in the end was, you know, do you have anxieties about your health that people aren't -, are you anxious about your health that people aren't getting to the bottom of problems. And lots of people say yes to that (SP008).

Furthermore, they divulged that it was only after talking to a study researcher that he reflected on the significance of the terminology used when introducing the study to potential participants.

"I started ringing people. And we, you know, started to get lots of no's and [study researcher] said 'well I think it's because you're asking like this'. And what that probably did was help inform me how I should recruit and steer patients towards this potential benefit, indeed in face-to-face consultations as well. I think it tells you an awful lot about health anxiety and about how you have to approach that with the patient. If you tell people 'you're health anxious' they do just hear 'you're a hypochondriac' . . . as soon as we mention the word 'anxious' in there, that says to them 'you think it's all in my head . . . I think that there is a really important outcome there for GPs to learn how to approach these folk" (SP008).

To summarise, this theme illustrates the apprehension service providers experienced when approaching patients about the trial. Due to the perceived negative connotations surrounding health anxiety service providers were cautious in how they introduced the study to their patients. Service providers emphasised the importance of the terminology used when communicating

with patients and found the constructs and suggestions offered by the research team to be helpful.

3b) Continuity and patient trust in service provider

The section above highlights that stigma around health anxiety persists and service providers were cautious of using the label of health anxiety when introducing the Urgent Care trial as it could have an influence on service provider-patient interactions. However, despite finding it valuable, service providers acknowledged that a script alone was not helpful in communicating trial information; rather, and it relied to a greater degree on the patient-clinician relationship.

> *"It's a variable, we can't control, 'cause different doctors have different relationships with different patients. So even if they had a script, it's still a massive variable"* (SP002).

Clinicians expressed the importance of making patients feel "valued" and for their symptoms to feel validated.

> *"That was helpful to a degree but also, you didn't want to sound like you were just reading from a script because this is people's feelings and if you want them to be part of a trial, um, you need them to make them feel like they've been taken seriously, um, and not just some, you've just rang because they meet the inclusion criteria. Do you know what I mean? They need to feel valued, don't they"* (SP017).

The relationship between service providers and patients was perceived to influence patient views about participating in the trial. Service providers highlighted that if there was continuity and the service provider knew their patient well, they were more easily able to approach the patient about the trial.

> *"I think the relationship with the GP is essential, yeah, in an ideal world if everybody had their own doctor and they only ever saw that one doctor and you built up that relationship with them over the years it would probably be easier to say to them "well we think anxiety's playing a part here"* (SP002).

In addition to continuity, the high levels of trust in service providers impacted on participant willingness to take part in the trial. GPs highlighted that they

needed to build trust with patients in consultations and discuss their presenting symptoms in detail before they could raise the possibility of health anxiety as a contributing factor. This required time and continuity to establish a therapeutic alliance. Having high levels of trust was seen by practitioners as very important in influencing patients' decision as to whether to refer patients to the trial.

> *"I think the problem with health anxiety first of all you've got to ideally, you've got to explore why they've come and address why it's not that condition, and to do that and then you've built up some trust hopefully, which then means they trust you to take your advice further and the problem is if you don't have that continuity there's a little bit of a break in that which then, that just leaves them anxious"* (SP013).

Service providers based in the ED highlighted that GPs were better placed to raise anxiety with patients during consultations because they had established relationships with their patients and were well informed of their patient's clinical history. In the ED there was less continuity, as staff were unlikely to see a patient again, even if they regularly attended. The lack of continuity and not knowing the patient's clinical history made it more difficult for ED staff to ascertain whether a patient's symptoms were anxiety related.

> *"I think for a lot of ED staff, they still feel that it would be about a relationship with a patient as such that you would need to know that they were probably anxious and they would see that as being something that general practice, that's what they're for, and we don't, because it is true. I mean if a patient comes in, even if they come in three or four times a week, the chances of seeing the same clinician are actually quite small so you wouldn't even, a regular attender"* (SP016).

ED staff highlighted the risk of suggesting a patient had health anxiety within the ED and its potential implications.

> *"It would have to be a really big leap of faith to be able to say actually you don't need any medical stuff, actually it's all health anxiety" (SP015).*

The above quote from the Consultant is supported by the research nurses.

"But that requires A&E to say this is what we think is wrong with you, you know, and that's the thing we're not wanting to do so it isn't yet an established diagnosis, which it might become, but it isn't at the moment and we are reluctant to make it so yeah that's the issue isn't it fundamentally we haven't got to that point of the conversation because yeah that would be the ideal thing to do" (SP016).

The challenge for ED staff in approaching patients about the trial was further exacerbated by the fact that within Emergency Departments there were no private spaces for discussions between staff and patients.

"It's often the environment as well. Can you imagine having a conversation about anxiety in a cubicle in blue when there's 15 people in the middle and it's noisy" (SP017).

To summarise, this theme highlights two things, firstly the nature of the relationship with the service provider and secondly continuity. There was a consensus that primary care practitioners may be better placed to approach patients about the trial because they were more likely to have established relationships with their patients and prior clinical knowledge of their presenting symptoms. Within the ED service, ED staff did not usually see a patient again and therefore it was more challenging for them to raise the issue of health anxiety during and an emergency attendance, when their responsibility is to quickly assess and treat the patient for their immediate presenting condition, and then move them onto more appropriate services.

3c) Service provider perceived patient readiness

Individual patient readiness to acknowledge or accept the possibility that an intervention focused on emotional, behavioural, and psychological wellbeing might be helpful was cited by service providers to play an important part in whether or not they broached the subject with those who otherwise fit the referral criteria.

Two reasons emerged to account for a service providers decision to refer a patient with the intervention in relation to their (patient) perceived readiness for it. This included stigma associated with health anxiety and accessing

psychological therapy and patient acceptance of psychological treatment for the management of their symptoms.

Service providers judged certain patients would not be receptive to the referral because of the perceived shame and humiliation attached to being recognised as mentally, behaviourally, or emotionally vulnerable. Health anxiety could be viewed as a stigmatised condition, as it implies that an individual required psychological rather than medical treatment. Medicalising symptoms still appeared to be more acceptable than psychological therapies and service providers expressed that certain patients would be resistant because of the perceived stigma associated with accessing psychological treatment.

> *"There is still some stigma associated with mental or emotional health and there is some respectability in medicalising it and saying that they going to see a specialist in a hospital. That's a personal opinion. I'm not certain that the patients believe that, but I think that's my take on why they would prefer to come to hospital rather than be referred, so that's the patient preference"* (SP004).

Service providers identified that certain demographic factors were barriers to engaging patients into a trial consisting of a mental health intervention, for example, male patients.

The ED Consultant explained that *"it's the boys that are hardest to engage in psychological treatment"* (SP015). She felt that this was associated with *a "social"* and *"cultural"* aspect to conceptions of mental health in relation to gender. For her, men were harder to engage in psychological therapy because of male perceptions about what is considered appropriate for men and women, and this influenced male acceptance of psychological treatment. She expressed that trying to broach the idea that there might be a psychological element associated with their symptoms to men was *"always harder, cause they're not going to accept it, just don't want to accept it"* (SP015).

She felt that emotional expressiveness and asking for help were constructed as forms of idealised femininity and men were expected to be in emotional

control and suppress their own health needs by not seeking help. Because of this, men may be reluctant to seek support for their mental health and may fear greater stigma if they do seek help.

> *"I don't know whether people are much more aware, certainly around guys, then they struggle with managing mental health. So it's going to be a big cultural thing if you like, a cultural regional thing or I don't know"* (SP015).

She expressed that there was often an interplay of demographic factors such as social class and age which impacted on these conceptions.

> *"Then you've got the builders. They're a lot harder you know, labourers. They're not part of that open society"* (SP015).

She felt that for the younger generation it was more acceptable for men to seek support for their mental health and there was more of a norm for men and women to express their emotional feelings.

> *"There's a social, cultural, all of this aspect. So there are lots of males who quite, you know, the young, young guys you know, actually talking about mental health according to school now, everyone's got, something wrong with their mental health, seems very popular at my daughter's age which is nineteen, to have something wrong with your mental health. Everyone's got to have something wrong with it. So they're all, they're much more open"* (SP015).

A GP, whose practice was in an area of high deprivation in Yorkshire, felt similarly about her patient list. She found it harder to persuade a male patient and an older patient to consider taking part than a younger female patient.

> *"The young girl I referred was very keen and she was 'oh yes, yes, I'm going to do this, it sounds great'. The older lady took a bit of persuading but, as I say, for reasons, older, anxious, deaf and all that sort of thing. And the bloke was never very enthusiastic in all this"* (SP005).

The above quote highlights that in addition to demographics such as male gender, and older age which could be boundaries to accepting psychological treatment, there were factors specifically related to the DHI that hindered participation such as hearing difficulties.

Service providers acknowledged that digital aspects of the therapy needed to be tailored to individual preferences as one type of format would not be suitable for everyone. For example, a GP identified that whereas WebEx was perceived to be *"very positive"* by a *"younger gent"* who was often traveling for work and appreciated the flexibility of the DHI, an older patient of his was *"reluctant"* to access therapy remotely because they did not feel comfortable using technology (SP007). Hence, for older patients offering telephone therapy may be more appropriate because they may not be comfortable using videoconferencing platforms.

Despite such apprehensions a GP serving in an ethnically diverse population conveyed that there was now more acceptability of psychological therapy within his practice population.

> *"I don't think there's as much stigma around it now because of course everybody knows where the therapy centres are . . . and there's virtually no stigma attached to going, by either local community and it's now very common for people to be usually accessing them through GPs, but of course people can self-refer but I think there's very even greater acceptability of the idea that talking to people can be helpful"* (SP011).

However, for this GP, limited language proficiency was identified as a barrier to referring patients to the trial. The outcome measures and the intervention were not translated in any other languages, therefore there was a requirement for participants to be able to speak and understand English. GPs from practices with ethnically diverse populations highlighted that limited language proficiency was a barrier to referring patients to the trial.

> *"The accessibility and the feasibility of this intervention as you know self-evidently for quite a lot of our patients there was an issue around language and unfortunately this study which is only obviously one study, it wasn't possible to offer the intervention in other languages"* (SP011).

Participation in the trial relied significantly on communicating trial information to service users, in the form of both verbal and written communication. A Practice Manager, whose surgery was unable to recruit any participants, expressed that communicating information about the trial to patients whose

first language was not English was challenging. This, coupled with low levels of literacy in the population they served, was an additional barrier.

> *"Because it's very difficult to explain, if English isn't your first language. And giving out posters and flyers and things in English because they don't read English, we do have also a high level as well of illiteracy in this area"* (SP002).

This GP acknowledged that in addition to language barriers, an individual's cultural background also played a part in perceived reluctance to participate in a mental health intervention.

> *"I think there's far more to it than just a language issue. I think going forward should this intervention show promise or show some effectiveness for those people who've participated any next step in addition to language is developing I think a greater understanding of some of the deeper cross cultural issues around what anxiety reflects, what people understand it to be in different cultures, and that how one might best seek to help people in the ways that we would normally talk about in terms of helping people understand what you know, you know what somatic anxiety is or you know what the physiological responses to anxiety and so on and so forth"* (SP011).

The GP expressed that if the intervention was found to be effective, that in addition to providing the intervention in other languages, there was a need to develop a greater understanding of cross-cultural issues around anxiety. To understand this, it was important to speak to people from different cultures to explore their perceptions and understanding of health anxiety.

The second readiness-related reason service providers gave for not engaging patients with the intervention was that they assessed some individuals as unable to see yet that their health issue/s may be related to health anxiety.

> *"Sort of always a little bit tentative when you mention health anxiety I think, er, especially if it hasn't come up directly in conversation so far. But a few people were a bit unconvinced perhaps that it referred to them but I think they were still agreeable to try"* (SP001).

Conversely, other GPs highlighted that patients were interested and accepting of the idea that their symptoms could be treated with a

psychological intervention. However, this may have been because they were more likely to approach patients who they perceived to be more receptive.

> *"I think actually people were quite interested. I think the idea of having psychological interventions was relatively acceptable, the other question might be am I biased to people who I thought might say yes. I guess I kind of discount that"* (SP010).

Service providers highlighted the challenges in approaching patients about the trial who had "*complex needs both social and physical"* (SP002) that were long standing and not simple to treat.

> *"So, I suppose, hopefully you've demonstrated great change, but they are – all I'm saying is they're not an easy group of patients to affect massive change in. I suppose if there isn't a huge amount of change, that, that wouldn't, wouldn't massively surprise me, because they are a very difficult group of patients and for many of them, it's already entrenched in them"* (SP007).

Service providers also expressed that patients' previous negative experiences of psychological treatment could be a barrier to patient acceptance of psychological interventions.

> *"Sometimes they had bad experience, sometimes they don't want to go through everything with somebody they don't know on the phone. There, there is a bit of resistance. It's particularly relevant for people who had issues like sexual abuse when they were a child or they are going to some sort of domestic abuse and stuff like that. They don't want to talk to anybody about their personal life"* (SP012).

In summary, this theme illustrates that service providers perceptions of patient readiness to acknowledge or accept that their symptoms may require a psychological intervention played an important role in whether they talked to patients about the trial. Service providers recognised that their own perceptions and experiences about patients influenced whether they approached patients about to participating in a trial consisting of a psychological intervention.

Chapter summary

To summarise, the findings from interviews with service providers highlight that the decision to participate and refer patients to the Urgent Care study could be explained by three themes.

The first theme highlighted the importance of the research team's role in communicating the research rationale and trial processes effectively and service provider perceptions about the relevance and benefits of the trial over existing interventions. The second theme highlighted that service providers consider the costs and benefits of participating in a trial. Service providers expressed a preference for clear simple trial processes requiring minimal input and placing little demand on their existing workload and acknowledged the importance of effective communication of trial information as this facilitated study understanding and relevance. The final theme related to service providers fears on undermining their relationship with patients. Service providers perceived that patient readiness and the risk to service-provider patient relationships were both barriers and facilitators to their willingness to approach patients about the trial.

Several factors were found to influence the action of service providers. This related to level of understanding and perceived relevance about the research, how the study information was communicated to them issues and concerns about perceived patient readiness. One recurring issue seemed to relate to the sensitive nature of the study and the deeply held attitudes and values of service providers. The findings highlight the importance of researchers needing to engage and involve service providers early in the research process to identify potential barriers to recruitment so that they can be addressed prior to a trial commencing.

The next chapter will report the findings from interviews with service users regarding their decision to participate in the Urgent Care trial (recruitment) and their reasons for completing all remotely delivered Cognitive Behavioural Therapy (RCBT) sessions and/or completing follow-up assessments (retention).

Chapter Seven: Findings from qualitative interviews with service users

Introduction

This chapter presents the findings from the interviews with service users regarding their decision to participate in the Urgent Care trial (recruitment) and their reasons for completing remotely delivered Cognitive Behavioural Therapy (RCBT) sessions and/or completing follow-up assessments (retention).

Chapter Three highlighted that two of the most important challenges in health care trials are those of recruitment and retention. This data chapter will look at the views of service user participants to explore the factors that influenced their decision to participate in the Urgent Care trial and consider what commonalities and differences might exist amongst participants views. The chapter will then look at what aspects influenced service user decisions to continue with RCBT and complete follow-up assessments and compare these with the explanations service user participants gave for discontinuing therapy or not completing follow-up assessments. In doing so, this chapter will address the following research questions:

RQ4- What are the factors influencing service user participants decisions to participate in the Urgent Care trial (recruitment)?

RQ5- What are the factors influencing service user participants decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial (retention)?

The chapter begins by examining service user decisions to participate in the Urgent Care trial (recruitment) to illustrate the factors that may have influenced participation in the trial. The chapter will then address aspects that impacted on service user decisions to remain in the trial and/or complete all RCBT sessions (retention). Unlike the previous chapter where recruitment and retention were discussed together, in this chapter, they are analysed

separately. In Chapter Six, the separation of trial participation and patient referral was not deemed necessary, as the analysis of transcripts revealed that these two aspects were frequently interconnected. However, distinct themes influenced the recruitment and retention of service user participants. Therefore, I deemed it important to address recruitment and retention separately in this chapter. The chapter will discuss the themes from the interviews, presenting illustrative quotations. I will present a description of the data along with its analysis and relate it to existing literature in Chapter Eight (Discussion Chapter).

Overview of interviews

This chapter discusses data which was collected via individual semi-structured interviews with twenty-eight purposively sampled service users and analysed using Reflexive Thematic Analysis. Twenty-five (89%) interviews were conducted over the phone, two interviews were conducted face-to-face at the participants GP surgery and one interview was conducted via videoconferencing.

Interviews were conducted between twelve and fourteen months after participants entered the trial. This enabled the interviews to be conducted following completion of the final follow-up assessment for the wider trial which this PhD was nested in, to minimise the risk of unblinding of the researcher and any bias in outcome assessments. The Urgent Care trial was a single blinded trial; therefore, service user participants knew which group they had been allocated to immediately after being randomised. The interviews ranged in length between 20 to 65 minutes.

Recruitment themes

The interviews aimed to understand the service user participants' reasons for deciding to take part in the Urgent Care trial, exploring how they came to take part in the trial and understanding how they felt about being referred to

the study. Figure 5 presents the coding tree of codes and main themes identified from a service user interview related to recruitment.

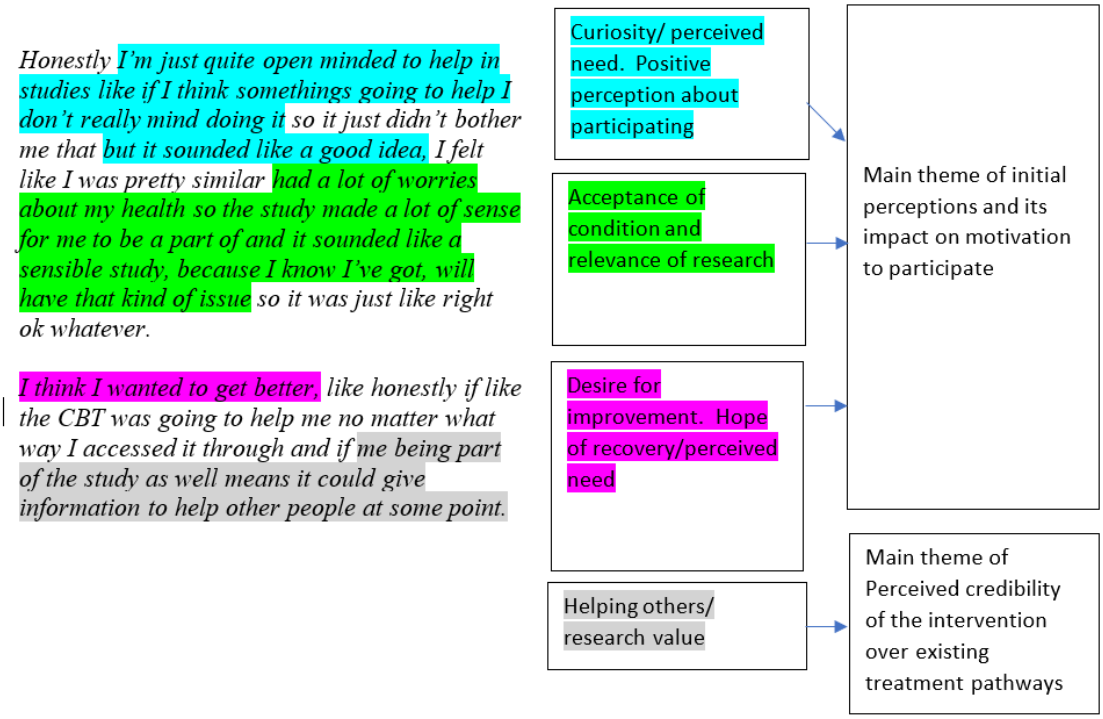

Figure 5 An extract of an anonymised transcript presenting codes with corresponding main themes

Two main themes and five sub-themes were identified (See Table 19). The two main themes from the interviews were:

1) Initial perceptions and its impact on motivation to participate

2) Perceived credibility of the intervention over existing treatment pathways

Each theme will be presented individually, broken down into sub-themes and supported by verbatim quotes from the interviews. The quotations were selected for illustrative purposes. These themes and illustrations are drawn together with reflections and interpretations stemming from my prior knowledge and experiences of being the lead researcher on the Urgent Care trial.

To maintain anonymity, participants are referred to by a code, consisting of the participant trial number participant gender (M/F), and their treatment

group allocation (RCBT/TAU). Service user participant information can be viewed in Table 17.

Table 19 Main and sub-themes in relation to recruitment of service user participants

Theme/sub-themes	Description
1. Initial perceptions and its impact on motivation to participate 1a) Communication of trial information 1b) Perceived relevance of the Urgent Care trial 1c) Hope for recovery and improvement of symptoms	How information about the trial was communicated by service providers and study researchers and the impact of this on service user understanding and perceptions about the relevance of the trial. The stage service users were at in terms of acknowledging that health anxiety may be causing their symptoms and the hope that trial participation may help them to improve their symptoms also influenced decision to participate.
2. Perceived credibility of the intervention over existing treatment pathways 2a) Improved access to treatment and services 2b) Value of research and its potential benefit to other people	Service users' thoughts about the credibility of the trial over current treatment pathways for treating health anxiety. Service users also considered the value of research and the benefit their participation could have on others.

1) Initial perceptions and its impact on motivation to participate

Participants' initial perceptions about the effectiveness of the trial were influenced by how information about the trial was communicated to them by service providers and the study researchers. This influenced participant's motivations to participate in the intervention and how they felt about taking part in the Urgent Care trial. Furthermore, decisions to join the trial were influenced by aspects such as the perceived usefulness of the intervention and participants hope for recovery and improvement.

1a) Communication of trial information by service providers and the research team

Chapter Six highlighted how patients became aware of the Urgent Care trial through their service providers. Clinicians referred participants to the study verbally during consultations or by postal invitations. Therefore, the way in which trial information was communicated to potential participants was essential in facilitating their understanding of the trial and its relevance. Service providers explanation of the trial influenced service user's initial perceptions about the trial.

Participant views about being referred by service providers varied, irrespective of treatment allocation. The participant below described that their clinician raised the possibility that health anxiety may be contributing to their symptoms because medical investigations had not found anything wrong. This patient recognised that they had health anxiety and accepted their clinician's referral to the study research team.

> *"I can't remember what I had at the time, I think it was a brain tumour I thought I had, and he said that basically I'd got nothing neurologically wrong with me, but he thought I'd got severe health anxiety, which I knew I'd got anyway, and he suggested I went on this study and wrote to yourselves"* (01046/F/RCBT).

Similarly, the participant below acknowledged that upon hearing about the trial from her GP when, she felt that participating int the Urgent Care trial would be appropriate because she was aware of her health worries and participating in the trial offered her an avenue to receive therapy aimed at improving her well-being.

> *"It sounded like a good idea, I felt like I was pretty similar had a lot of worries about my health so the study made a lot of sense for me to be a part of and it sounded like a sensible study … I wanted to get better, like honestly if like the CBT was going to help me no matter what way I accessed it . . . So getting CBT and learning how to deal with my worries and what worries to deal with and what worries that I just had to live with, was just what I needed to do to keep going in life"* (01082/F/TAU).

The participant mentioned below received information from their consultant, who highlighted the potential benefits of participating in the Urgent Care trial. Firstly, it could be advantageous by providing her with the opportunity to access therapy more promptly, considering her prolonged time on the waiting list. Secondly, the remote delivery of therapy was seen as beneficial, eliminating the need for her to depend on family members for transportation to therapy services.

> *"One of his main reasons for doing it, is I've been on the waiting list for quite a long time to CBT and he said would you be interested in doing one via Skype he said because I think it would actually help you as well, because part of the problem was when I first started with this condition I couldn't get out. So, the fact that I could do it from home and I wasn't relying on people to take me was brilliant"* (01051/F/RCBT).

The participant below expressed that he was pleased to be referred and it was an effortless process, in the past he had been asked to self-refer to services which he found challenging to do because of his symptoms.

> *"It was a bit more like he was kind of concerned that there's this different avenue that he's going to recommend instead of just putting me on medication or telling me to call different services basically"* (01040/M/RCBT).

However, sometimes the way in which study information was conveyed by clinicians caused some misunderstanding about the study purpose, trial processes and study expectations. The participant below had not realised that the intervention would be delivered remotely and expressed that had they known the intervention would not offered be face-to-face he would have declined participation.

> *"To be honest with you, like, when I took part, I thought it would be some kind of a therapy I have to go in you know a walk-in session with you basically I was thinking more into a counselling kind of a stuff. So basically, face-to-face, someone that I'll talk to, I'll tell them my problems and they give me some advice on how to overcome the pain. So, I had that kind of idea"* (01066/M/RCBT).

Consequently, the participant only had one RCBT session before deciding to discontinue.

Another participant described how he was not entirely sure why he was being referred by the GP but decided to take part in the trial partly out of curiosity, and to investigate further whether his pain was attributed to a physical diagnoses or whether it was in his mind.

> *"I was suffering from quite bad fatigue and to some extent unexplained pain, so there was no real diagnosis for it, so it was kind of passed onto you guys. I don't really truly understand what he was trying to get at and I just kind of allured out of curiosity . . . see if there was any form of help for what I'm going through or that the, you know, some counselling or, or genuine investigations to confirm they're legitimately symptoms or is it all perhaps in my head"* (03012/M/TAU).

Another participant shared their experience of being misinformed by their General Practitioner when given details about the trial. Relying on the information conveyed by the GP, this participant presumed that participating in the trial would guarantee them access to RCBT. Their decision to participate was driven by the desire for access to treatment, as they were unaware that the trial operated as a Randomised Controlled Trial (RCT) with a 50% chance of receiving therapy (I denotes interviewee and R refers to the doctoral researcher).

> *"I: Basically, they turned round to me (laughs) and told me I was going to get cognitive behavioural therapy out of it but I didn't.*
>
> *R: OK, thank you. So in terms of your reason for taking part in the study, what was your sort of reasons for taking part?*
>
> *I: The fact that they told me I was going to get CBT from it.*
>
> *R: Right, OK. So when they told you it was more of a "you would get it, not that you had a 50% chance"?*
>
> *I: No, they didn't tell me I'd have a 50% chance, they said that I'd definitely get it, from the way she sort of worded it was sort of, like, oh she doesn't need to send me to like the mental – like refer me to the mental health department or anything because this should like help me and, if it doesn't, like, then come*

back kind of thing. That was the kind of way that she explained it all to me" (01012/F/TAU).

The participant revealed that it wasn't until the researcher contacted her midway through the study for the second follow-up questionnaire that she realised she wouldn't be receiving any treatment as part of the intervention. This late realisation occurred despite the participant receiving an initial telephone call from the study researcher, where the rationale of the trial, its Randomised Controlled Trial (RCT) nature, and the content of the participant information sheet were explained. The excerpt emphasises the potential lack of understanding among participants regarding trial requirements and procedures. This situation raises ethical concerns regarding the consent process and underscores the importance of ensuring that participants fully comprehend the trial, its requisites, and its processes before providing informed consent. While participants were given the chance to pose questions, there's a possibility that the study researchers didn't explicitly prompt participants to confirm their understanding of the trial processes.

The quotes below delineate the study team's role in explaining the study rationale and communicating the level of commitment expected from participants. Neither of the quotes are from individuals I interviewed; they pertain to other researchers involved in the study.

"It was good, it was very clear, very precise as to what was going to be happening um so that was kind of good" (01051/F/CBT)

"She explained it really well and she gave me options of you know, I could do it on my own or she could do it over the phone or she could even come to the house and do it, you know, she made it very, sound very supportive and the fact that she'd come to my house was really helpful at the time" (03005/F/TAU).

Participants in both groups (RCBT and TAU) expressed concern that their clinicians had not explained the study well. The participant below describes that it was only after they had spoken to the study researcher that they understood the significance and purpose of the trial. This encouraged them

to change their mind about participating in the trial despite her earlier reservations.

> *"I: Saying you know 'you'd be good at this study' erm, but then once, you know, we met for quite a long time and talked through the reasons why you were doing the study and about the control groups and you actually wanted to find something out and I found that interesting, so it changed my mind.*
>
> *R: And do you think it would have helped if the GP gave you more information? Would you have liked more information at that point when they spoke to you?*
>
> *I: It probably would have helped yeah if I'd have sort of known exactly what I was going to, as it stands it would – experience it was fine. But I think having done research myself that it's not got a very good uptake. People don't follow things through very well. So, they might perhaps be more participants if they'd known more initially"* (01016/F/TAU).

One participant expressed that they had seen a flyer advertising the trial in their GP surgery and they had chosen to self-refer to the study because they had misinterpreted the study purpose. They had decided to contact the researchers because they assumed that the study was about patient views of the NHS services. She wanted to participate to express the dissatisfaction about the NHS care she had been receiving.

> *"When I initially read the flier, I thought I was just going to be able to have a bit of a rant at how useless the NHS were at diagnosing things, like I said, that was what I thought the study was because it seemed to indicate that people who had long term issues that require them to have to keep going back to seek emergency are, so I thought because it was to do with that it was to do with people not being supported properly from a medical point of view. I didn't realise it was to do with psychological aspects of having a longer-term chronic issue"* (03002/F/CBT).

She disclosed in the interview that had she initially understood the actual purpose of the study she would not have referred herself to the trial. However, after discussing the trial with a study researcher she understood the purpose of the trial and its relevance and decided to participate. Prior to speaking to the study researcher, she had not contemplated that CBT may

be useful for her symptoms. After talking to a study researcher, she was able to reflect and acknowledge that CBT may be helpful, and she really hoped to be allocated to receive RCBT.

> *"I didn't fully understand (laughs)! And had I have known what the study actually was, I wouldn't have signed up for it . . . I had a bit of a laugh about (laughs) what my initial thought was! But then it just sounded so interesting and actually it was relevant and then I was fortunate enough to get actually randomised into the therapy side of things . . . Well I didn't actually realise that I had issues that might mean that being randomised into the CBT would have been useful for me. It was through speaking to [study researcher] that I actually analysed myself and realised I could probably do with some CBT. So then at that point once I'd spoken to [study researcher], I actually hoped that I would get randomised into the trial"* (03002/F/RCBT).

To summarise, this theme highlighted the role of service providers and study researchers in communicating trial information to participants. The initial information provided to service users was imperative in influencing service user initial perceptions about participating in the trial because it provided participants with knowledge about the trial and commitment required.

1b) Perceived relevance of the Urgent Care trial

This theme relates to service user perceptions about the relevance of the Urgent Care trial and the point service users were at in accepting that health anxiety may be causing their symptoms. This theme was pertinent to both RCBT and TAU groups. Participants who recognised that their symptoms may be related to health anxiety chose to participate in the intervention because they felt that the therapy was relevant to their health needs and may help them to cope better with their symptoms.

A participant allocated to TAU was pleased to be referred to the trial because from her experience, discussions around mental illness was not always raised by GPs and needed to be talked about more.

> *"I was quite pleased really because anxiety and depression and stuff, mental illnesses aren't talked about as much as I think they should be so for my GP to bring it up at all, I was quite grateful really, because I don't think you can ever have too much information"* (03005/F/TAU).

Some participants were pleased to hear about a trial delivering an intervention for health anxiety. It provided a sense of shared experience and connectedness because the presence of a trial indicated that participants were not alone in their health worries. It legitimised and normalised their anxieties about health.

> *"It's nice to know that there are other people out there who are doing it as well who are a little bit crazy because we've got such bad anxiety and our mental health is a mess but at least we're worrying about it together"* (01082/F/TAU).

For participants who were coming to terms with accepting that health anxiety may be causing their symptoms, there were some initial apprehension about whether a psychological intervention would be the most appropriate form of treatment for them. For these patients, despite the uncertainties as to whether an intervention focussed on health anxiety would be suitable, they decided to participate in the trial to see what might happen, as expressed by the participant below.

> *"I think in the back of my head I realised it was health anxiety all along but obviously when you're in that situation there's half of you telling you that and then the other half thinking the worst. So, when he did say 'look, you probably need this sort of thing', obviously I took it and waited to see what was going to happen"* (01018/M/TAU).

Where participants had only recently started to acknowledge that they had health anxiety despite feeling anxious that participating in the trial may exacerbate their anxiety symptoms, the desire to access some form of help to manage their symptoms encouraged them to take part in the trial.

> *"I think I was nervous at first. It was still my first sort of foray into acknowledging what I had, that I had like anxiety and I was still nervous about the whole process so I was scared of I guess what it would entail and if I would, you know – I think partly it was maybe that it would cause some extra anxiety but I knew that I needed to get involved in something and I knew that needed to get a handle on what I had because it was causing me problems so I knew it was important for me to seek these sort of things out"* (01019/M/TAU).

However, not all participants were welcoming of a trial focusing on a psychological intervention to help them manage their symptoms. Some participants, regardless of their group allocation, felt offended that their health worries were being dismissed as being psychological by their Clinician. These individuals opted not to join the trial due to recognising its relevance to their symptoms. Instead, they felt compelled to participate, driven by a desire to prove their clinician wrong.

> *"I: Nobody believed me . . . they thought that I was just wasting their time.*
>
> *R: and in terms of when you said yes you would be happy to be contacted can you tell me why you sort of agreed to be contacted? What was your reason for that?*
>
> *I: Erm initially to shut them up . . . I felt pressured into it, and I did it to sort of shut them up telling me that it was all in my head"* (01077/F/RCBT)

These feelings are echoed by the participant below who expressed that a GP whom he had not met before came in with a pre-existing idea that he needed to be referred for the trial for his symptoms. He felt that the GP was pressing for him to participate in the trial without listening to him, which made him feel sceptical about the study.

> *"Yes, it was the first time I'd, I'd met him, there's a nurse there that I would regularly speak to and she thought, she needed a second opinion as she had an idea as to what it could be. But he came in almost with a pre, yeah, he had an idea basically of what it was beforehand and irrespective of what I said that was it. So yeah, I, I don't know his affiliation with the study, but it just came across he was pushing too much so that made me dubious as well"* (03012/M/TAU).

There were a few participants who felt doubtful about the suitability of the study from the outset. They did not believe that their symptoms were related to a psychological issue, but decided to participate anyway, to explore what may be causing their symptoms. Participating in the trial was a way of exploring whether their symptoms were related to a medical or psychological illness. This participant expressed that whilst they acknowledged that their

symptoms could be related to a psychological health condition, they were unconvinced.

> *"I thought it was more of a medical, underlying medical problem rather than a psychological, it very could be down to stress, you know, it's at the root of a lot of things that we don't quite understand but I didn't, you know, I wasn't totally convinced"* (04001/F/RCBT).

To summarise, the decision to participate in the trial was influenced by service user perceptions about the relevance of the trial and the stage they were at in accepting that they may have health anxiety. Participants who were more open to the suggestion that health anxiety may be causing their symptoms decided to take part in the trial because they hoped to receive treatment to help them manage their symptoms. Participants who had not yet accepted or were unsure if health anxiety was causing their symptoms were not convinced that the intervention would be appropriate for their symptoms and took part out of curiosity and to legitimise their symptoms.

1c) Hope for recovery and improvement of symptoms

This theme highlights participants hope for receiving an intervention as part of the Urgent care trial that could help improve their symptoms. All participants interviewed expressed that one of the main reasons they decided to participate in the trial was because they hoped to receive treatment to help them to manage their symptoms. Participants in both groups expressed being open to anything that would help them to feel better, develop a greater self-awareness of their health anxieties and learn strategies to self-manage their anxieties.

> *"I hoped that it would help and that it would you know help me come to terms and help me understand more and you know provide me techniques with which I could handle my anxiety because you know previously I didn't really know what to do when I had it, I was panicking, so I was hoping it would provide me with ways of controlling it and ways of learning about it"* (01019/M/TAU).

The participant below expressed that they had a long-term health condition, and they were keen to take part in the trial because it offered them an

opportunity to receive therapy that could provide them with coping mechanisms to manage their pain.

> *"To help work through, coping mechanisms and when you're having to deal with the longer-term health condition. In particular, things like pain and that kind of thing, learning how to self-manage better during the process"* (03002/F/RCBT).

As described in Chapter Two, the trajectory for health anxiety is often lifelong. Interviews with service user participants echoed these findings. Participants who acknowledged that they had health anxiety described that they had been experiencing it for several years. The interviews highlighted that most of the participants had been seeking help for many years and were desperate to receive treatment to improve their symptoms. They recalled being referred to numerous services to help them with their symptoms, such as pain clinics, but being turned for being inappropriate referrals.

> *"Anything to try and help coz I've just gone from one person to another to another and it's, you know, no help or offer of help so when he said about this, it was just, you know, nice to, you know, go somewhere where I could be helped a bit really, rather than the door always being shut"* (01024/F/RCBT).

The Urgent Care trial offered patients with longstanding health anxiety the hope of receiving treatment that could help improve their symptoms.

> *"When you've been like this for so long you look for anything, just hope there's some hope in it"* (01008/M/RCBT).

This hope for receiving some form of therapy to help participants to manage their anxieties and reduce distressing symptoms was not specifically related to it being delivered remotely. It was about receiving any form of treatment that might help, rather than it being innovative or a different mode of delivery.

> *"I think he mentioned health anxiety, I think he mentioned symptoms with no medical explanation and said you know would I be interested and explained that you know, it would be a form of therapy. And frankly at that time my view was that any help offered was a good thing to do really, was a good thing to accept"* (01055/M/CBT).

"I think I wanted to get better, like honestly if like the CBT was going to help me no matter what way I accessed it through" (01082/F/TAU).

To summarise, the Urgent Care trial provided participants with hope and an opportunity to access a form of therapy when they had been seeking support to manage their symptoms for a long time. Participants were keen to be enrolled to the Urgent Care trial because they hoped to improve their symptoms and develop self-management strategies to cope with their symptoms. This hope for receiving treatment was related to any form of therapy and not specifically related to receiving an innovative intervention that was to be delivered remotely.

2) Perceived credibility of the intervention over existing treatment pathways

Participants' perceptions about the accessibility of the Urgent Care trial in comparison to existing treatment pathways influenced their decisions to participate in the trial. The Urgent Care trial enabled participants to potentially access therapy more quickly and overcome lengthy waiting times. Furthermore, the remotely delivered aspect of the intervention appealed to those who were restricted from accessing face-to-face services due to physical limitations or transport issues. The decision to participate in the Urgent Care trial was also influenced by the value participants placed on research and their desire to contribute to improving health care services for people with anxiety. Furthermore, participants expressed that they wished to participate in the trial to benefit themselves but also to help others.

2a) Improved access to treatment and services

Participants' initial perceptions about the accessibility of the intervention over existing treatment pathways influenced their decision to participate in the trial. This was highlighted by both groups. Those who perceived that the intervention would increase accessibility were more positive about participating in the Urgent Care trial.

Participants acknowledged that psychological treatments offered by the NHS were subject to long waiting times, leading service users to access treatment privately. Thus, the trial offered participants the opportunity to receive therapy more promptly and at no personal cost at a time when there was a high demand of NHS resources.

> *"See with the NHS I don't think they've got resources to actually do it for you, so that was a big, you know, bonus as well… Well I felt quite glad because obviously it's not just to do with money but to go privately CBT I was paying £80 an hour"* (01046/F/RCBT).

One participant was due to go abroad as part of their university placement and was pleased to be able to access therapy before they travelled. For her, the timing of the trial felt like fate, and she felt lucky to be offered this opportunity.

> *"I was open to anything and everything to get me better. I didn't have a lot of time to get better you see um because I was going abroad, so anything that might speed up the process yeah, I was all for it … It seemed to me a bit like chance and fate really and so I'd been given this opportunity to take part and I suppose not everyone who has anxiety could get that" (*01015/F/RCBT).

Participants expressed that accessing psychological treatment was difficult, and that this created a barrier to seeking help.

> *"To be honest with you, it's so hard to get even an appointment or to get a foot in the door, yeah, I did do but just, sort of, it sort of put me off and stuff like that and it's just I don't know, never really got round it"* (01043/M/TAU).

Furthermore, the remotely delivered aspect of the therapy appealed to those whose were restricted in terms of transport due to physical health limitations. The participant below described that the ability to be able to access therapy remotely was conducive to her needs because she experienced physical symptoms that limited her mobility. It was a challenge to leave the house to access treatment and she needed to rely on others to transport her. Being offered treatment remotely was ideal for her because it overcame these barriers.

"I've been on the waiting list for quite a long time to CBT and he said would you be interested in doing one via Skype he said because I think it would actually help you as well, um because part of the problem was when I first started with this condition I couldn't get out. So, the fact that I could do it from home and I wasn't relying on people to take me was brilliant" (1051/F/RCBT).

In summary, this theme highlights that some participants felt that the current treatment options for accessing psychological treatment were not adequate. Long waiting times coupled with logistical barriers made it difficult to access existing psychological services. The Urgent Care trial offered participants the opportunity to access a psychological intervention more quickly and had the potential to be more convenient for those who were unable to leave their home to access treatment.

2b) Value of research and its potential benefit to other people

This theme illustrates that in addition to personal benefits of taking part in the trial some participants from both groups were motivated to participate in the intervention because they valued research and hoped that their participation could create new knowledge and develop services which could help others. Some of the participants interviewed expressed that they hoped that their participation could benefit themselves but also lead to the provision of resources to help others with similar symptoms.

"Well I hoped that it would help people be able to like me manage long term conditions, particularly pain, to be able to find some sort of resource that can help people because at the moment in health you sort of have diagnostics, you then find out what's wrong and then there's just a long period of you live with something and there's a bit of a gap so I wanted to know if there would be a way to help people" (01016/F/TAU).

Participants also recognised the value of research in developing health care services. Participants acknowledge that research has the potential to add to existing evidence thereby creating meaningful research. Therefore, the decision to participate was because of the potential benefit of the research in general as it could lead to an improvement of health services and resources for people with anxiety.

"I went to the GP, I was going on a regular basis to my GP, so he recommended to me that would you like to take part in a study, I say that's fine, sure, no problem, so that time I had some free time so I thought why not, just give some time to someone, it might, that study, help someone else, that would be great. That's why I took part" (01066/M/RCBT).

Participants acknowledged that it was important to be involved in research to advance knowledge and address gaps in the treatment of anxiety.

"My hopes were that the generalised, you know, treatment for anxiety and you know, the awareness of everybody, everyday people were having mental illnesses, would improve, 'cause I do find it's not brill and you know but I'm not the only one that suffers with it so therefore I wasn't just thinking of it from my point of view, I was just thinking of it from a whole that it needs to improve generally and if this can help then I'm happy to partake" (03005/F/TAU).

Participants also highlighted that they decided to participate in the Urgent Care trial because they recognised the need for more research to be conducted to reduce stigma surrounding mental health and improve understanding of mental health.

"I'm in support of anything that tries to improve you know, help for depression and mental health issues" (03005/F/TAU).

Service users recalled that they had been offered gift vouchers for their research participation. Whilst this was appreciated, the financial incentive was not identified as a motivating factor for involvement.

"I think just to help other people really and personally no gain at all. Marks and Spencers vouchers were just a bonus" (01043/M/TAU).

To summarise, service user participants' reasons for participating in the Urgent Care trial included personal satisfaction derived from contributing to research that held potential benefits for both them and others. Trial participation was also associated with a desire for increased knowledge and a commitment to contributing to the enhancement of health care services.

Overall summary

To summarise, the themes related to service user recruitment highlight the factors influencing participants decisions to participate in the trial. Reasons for deciding to participate in the trial included quicker access to therapy and improved accessibility and convenience. The remote nature of the trial appealed to those were restricted in accessing traditional face-to-face psychological therapy due to logistical barriers. Participants' perceptions of the trial in terms of the effectiveness of relevance of the trial and their hope for recovery and desire to develop coping mechanisms to self-manage their anxieties encouraged them to take part in the trial. Participant decisions to participate in the trial were also influenced by altruism, and their views about the value of research and the wish to be able to contribute to improving mental health services and benefitting others. The relationship with the research team was identified as a key factor in determining whether a participant decided to become involved in the trial because it helped to clarify the study rationale and overcome any misconceptions.

Retention themes

Having explored why people chose to participate in the trial, attention now turns to what they explained kept them engaged with the trial. As discussed in Chapter Three, in addition to challenges in recruitment of participants to health care trials another common problem is that of retention.

As described in Chapter One as part of the Urgent Care Trial all participants were asked to complete follow-up assessments at 3,6,9 and 12 months post randomisation. Follow-completion rates for both groups at all time points were comparable. This highlights that despite the TAU group not receiving the intervention, there were reasons for why they remained in the trial and completed follow up assessments. Factors influencing decisions to continue with the trial for both groups are illustrated in the themes below.

Three main themes and six sub-themes were identified (see Table 20). The three main themes from the interviews were:

1) Research related aspects and its impact on therapy and questionnaire completion

2) Perceived change in circumstances because of study participation

3) Digital Health Intervention (DHI) factors influencing retention to RCBT treatment sessions

Data on retention was analysed using the same approach as previously described in Chapter 5, Reflexive Thematic Analysis. Each theme will be presented individually, broken down into sub-themes and supported by verbatim quotes from the interviews. The quotations were selected for illustrative purposes.

Table 20 Main themes and sub-themes related to retention of service user participants

Theme/sub-themes	**Description**
1. Research related aspects and its impact on therapy and questionnaire completion 1a) Building a rapport with the Urgent Care trial research team 1b) Study commitment and understanding the importance of data in research	The relationship service user participants built with the study team including the researchers encouraged therapy and questionnaire completion. The therapeutic relationship was essential in establishing and maintaining this rapport. Therapy and questionnaire completion was also influenced by service user understanding about the importance of data in research and study commitment.
2. Perceived change in circumstances because of study participation 2a) Perceived change in symptoms through study participation 2b) Referral and access to other services	Service user participants expressed change in symptoms following therapy and/or questionnaire completion. For some participants these changes were positive whist for others they were negative, and this influenced decisions on continuing with therapy/questionnaire completion. For some service users, trial participation facilitated referral and

	support from other psychological services. The referrals were made by study therapist and study researchers.
3. Digital Health Intervention (DHI) factors influencing retention to RCBT treatment sessions 3a) The accessibility and convenience of RCBT 3b) Stigma and privacy of DHIs	There were specific aspects related to the DHI that influenced whether service users completed RCBT sessions. These themes were only relevant to the RCBT group. Aspects such has being able to access therapy from their home was perceived to be an advantage. However, for some participants accessing treatment from home felt less private.

1) Research related aspects and its impact on therapy and questionnaire completion

Service user participants' decision to continue with RCBT sessions and complete questionnaires was influenced by the rapport built with the study researchers and study therapists. Participants in both groups highlighted that their relationships with the study team encouraged them to continue with therapy/questionnaires. Participant motivations to remain in the trial and complete RCBT sessions and follow-up assessments was also influenced by participants views on research in general and their understanding of the importance of research data. Service user participants also expressed that by deciding to take part in the study they had committed to carry out all trial requirements.

1a) Building a rapport with the Urgent Care trial research team

Chapter Six and the above section on recruitment highlights the significance of the role service providers and study team researchers played in communicating trial information to service users. It also acknowledges the importance of the initial recruitment consultation to include adequate discussions about nature of the study intervention and what is expected from participants.

The importance of the relationship between health care providers and their patients played a pivotal role in prompting service providers to approach

patients about the Urgent Care trial. The initial interaction with study researchers significantly shaped the understanding and perceptions of service users regarding their participation in the trial and the level of commitment it entailed. Throughout the trial's duration, the relationships participants established with the research team influenced their perception of therapy and the overall research process. This impact spanned from the initial contact with the researcher to the receipt of therapy and the completion of questionnaires. The initial interaction with the researcher proved crucial in alleviating any initial concerns about the trial and fostering a clearer comprehension of the study, the RCBT, and the therapists involved.

The quote below describes how the study researcher helped to alleviate a participant's initial reservations about receiving RCBT from a male therapist. This participant expressed a preference for a female therapist due to concerns about her having to interact with a male, this was due to the personality of her husband and his lack of patience towards her.

> *"It was funny because I'd said to [study researcher] when, if I got randomised in I didn't want to speak to a man! [Laughs] And that was kind of one of my like, you know, 'I'm not going to change my mind on this and then if I get randomised, you know, fine, but I'm only going to speak to a woman'. And she just said 'well, you know, we have got some really good therapists and, you know, if you got randomised and if you got [male study therapist] for example', so she -, and I just sort of remember thinking yeah well we'll cross that bridge. And then, yeah, then the rest is history I guess, I did get [male study therapist]"* (03002/F/RCBT)

The participant explained that when she was allocated to receive RCBT, and a male therapist contacted her, despite her initial apprehensions about having a male therapist her views about this changed because the therapist was very patient and helpful in getting her set up with videoconferencing. This altered her perceptions about receiving the intervention from a male therapist and she completed all RCBT sessions.

> *"I: So, when he initially rang you, as you say, you didn't want a man, so how was that when he sort of first called you and you thought well actually it is a man, how was that?*

R: I had some technical issues on the first call so we had, you know, sort of, my complete technical ineptitude to get around first. And he was just so patient with all of that that I started to just get over my initial concerns because he was just helpful on that point. And anybody who can talk me through technological stuff has to have the patience of a saint. Because not even my husband can do that, you know" (03002/F/RCBT).

Furthermore, she expresses that she was able to establish a therapeutic relationship with the therapist remotely and the therapist characteristics were crucial in this.

"[Male study therapist] was just so influential and inspirational and he just did it in such a good way, that so much of what he said just, it stuck, it was sticky CBT (laughing)! So even when I was at my worst, the things that he would have said just kept popping into my mind, like OK just change the story, change the script, go back and start again, just go back a step. You've got all these safety mechanisms beneath you" (03002/F/RCBT).

The above quote is supported by the quote below from a participant who compared a therapist she previously saw face-to-face. She described finding it easier to talk to the therapist from the Urgent Care trial and believed that building a rapport was essential in developing an effective therapeutic relationship.

"I found it easier talking on the phone to actually talking to somebody in a room, I think. I don't know why. I think the person I saw before, although I think she was good, I didn't have much of a rapport with her and I think whatever therapist you have, you've got to have a rapport or I don't think it works" (0145/F/RCBT).

Participants in the TAU arm of the trial described how they found the relationship they established with the study researchers to be helpful, and this impacted on their overall experience of study participation. As the participant below explains, she liked that the initial assessment was conducted in a relaxed manner which did not feel as though the research team was only interested in accessing data from the participants. She felt valued and listened to, and whilst completing follow-up questionnaires

independently she could imagine the researcher asking the questions based on her initial assessment experience.

> *"I found it was a very broad, really positive study and the questionnaires itself because I remember us meeting and I could almost hear you saying them when in conversation 'I can hear her!' Say it was a conversationalist type so it wasn't like, it didn't feel like scary quantitative research. It felt like nice, relaxed qualitative and everything's okay. I find that really, really beneficial and I just hoped that other people responded to make some sort of change"* (01016/F/TAU).

Another participant in the TAU arm who completed follow-up questionnaires with the study researcher over the phone expressed that participating in the trial was a positive experience, and it did not inconvenience her in any way. She liked that the researcher was flexible in arranging phone calls to complete the questionnaires to accommodate her needs and always ensured that she was okay.

> *"It was a good experience and I don't, like it was a really easy study to do, it really didn't affect my life, you were really great, like you always made sure we were ok, we weren't stressing out and like it was always worked around us like it, like it was literally the best, one of the best experiences, that I could have had, I have no negative responses to it*" (01082/F/TAU).

Another participant in the TAU arm expressed that it helped him to be able to talk about his feelings with somebody he did not know. He found that he was able to build a trusting relationship with the researcher and was complimentary of the researcher's approach in talking to him.

> *"It was a nice, it was a positive experience, in fact in the early part of the study, the first and second time you called, it was nice to be able just to tell somebody who, you know, I mean, I don't want to use the term 'stranger' because I think that's wrong but I will in lieu of the fact that I don't have a better term, but to tell a stranger how I am and how I feel because it's easier to do that in many, many cases and there's a certain amount of anonymity that comes without ever seeing it, you know, and that makes life easier to be honest and open about it. So in some ways like that early part of it while I was telling you about it, it acts as a form of catharsis anyway. I'm sure it had a*

positive experience, it must have done, a positive influence even, er, it must have done because stuff improved … you were lovely, you're really, really kind, lovely, nice to talk to, well your way of dealing with people talking about anxiety, it's very difficult to build up a level of trust and, yeah, I appreciate it, thank you" (01043/M/TAU).

There were some suggestions from some participants receiving RCBT that an initial face-to-face contact with the therapist may have enabled a rapport with the therapist to be established quicker.

"I wondered whether or not at the very beginning or the very end the sessions should have been face-to-face rather than over a link. I wondered whether doing that once at the beginning may have just fast tracked the rapport bit – do you know what I'm trying to say . . . But I absolutely accept that you know, that for cost reasons or location reasons, venue, that may, may not be possible at all, but I actually think, my heart tells me that the WebEx video conferencing would be more powerful with a client therapy sort of session, client therapy session, if you already have met each other in the real world" (01051/M/RCBT).

The participant further elaborated that remotely delivered therapy could impact on the therapeutic relationship due to factors such as *"the risk of talking over each other and you know the delay, the inevitable delay you get because of the technology".* He also highlighted that DHIs had "fewer nuances of eye contact and body language" which could make therapy "*slightly less powerful".*

To summarise, this theme highlights the significance of the relationships between service user participants and the study team. For the TAU group the relationships established with the study researchers was important in encouraging participants to complete follow-up assessments despite not receiving the RCBT intervention. For the RCBT group the online therapeutic relationship participants were able to build with study therapists encouraged completion of RCBT sessions.

1b) Study commitment and understanding the importance of data in research

Participants in both treatment groups described that one of the reasons for why they remained in the trial was because they felt a sense of commitment to complete the therapy and/or study questionnaires. The participant below continued to complete follow-up assessments despite withdrawing from the intervention after two sessions and explained that she did this because she had agreed to participate in the study.

> *"Well because I'd said I'd take part in the study so that's what I was doing"* (01001/F/RCBT).

Others in the RCBT group felt grateful to have received therapy and felt a moral obligation to participate in all aspects of the research study.

> *"Because I've committed to the study and it was, you know, part of my responsibility of being lucky enough to have the CBT, it wouldn't have been right if I hadn't filled them in. I'd signed up to be part of a study and took that responsibility seriously"* (03002/F/RCBT).

All participants in the TAU arm expressed their disappointment at not being allocated to receive RCBT. Their primary reasons for participating in the Urgent Care trial was because they hoped to receive treatment that could alleviate their symptoms.

> *"I was really disappointed to be honest. I understood that obviously it's part of the process of the study and that you need to have people that don't receive treatment to compare the results, so I understood it but I was very disappointed not to be in the side that received treatment. You know, when I first heard about it I felt OK, this could be a really good solution for me, so when I didn't have it I was disappointed"* (01019/M/TAU).

Despite not receiving the RCBT intervention, participants in the TAU group explained that they completed questionnaires because they recognised the significance of having data from both groups to improve research in health.

"Because you need people in the control group, I mean, it's really maths and stats, I'm well aware that the control group is the one that people pull out of the most, generally speaking" (01043/M/TAU).

Participants in both groups expressed that they completed follow-up assessments because they valued the importance of research.

"Oh I knew that if I completed them you'd have something to work with. If you don't have any data you can't make a change. No one's going to invest in a project if they don't have some sort of data for it and I just thought, you know, we don't get anywhere in health unless we do something" (01016/F/TAU).

Participants felt reassured to know that research was being conducted to help people with health worries. They explained that this focus legitimised how they were feeling and provided a sense of connectedness.

"I just think like it was a good experience for me just to be a part of the study like it was nice to know that if there was a study about it I wasn't go crazy like because if you're studying how people's mental health and physical health and worries about their physical health are connected then it means I'm not crazy for constantly worrying about things I'm not on my own if there's a study going on about it. So, I was actually quite nice to know that there were other people out there even just like finding that out about the study was nice" (01082/F/TAU).

One participant in the TAU arm who had withdrawn from the study experienced mixed emotions when making the decision to withdraw from trial participation. He understood the need for a control group and the importance of his data for research, but he did not find participation was beneficial to him, and this led to him deciding to withdraw from the trial.

"Well mixed emotions really because I understood that you need to have a control sample to understand that what you're doing is right, but I kind of felt like I'd been palmed off once again that . . . I couldn't go back to the doctors because they weren't helping me. They just referred to you guys to see if you could do anything by *participating in the study and then I, I was kind of stuck between a rock and a hard place, I, I didn't go back to where I was basically saying you know sort of the symptoms are persisting, they are persisting, and I think they're getting worse . . . So that kind of . . . I kind of felt a bit hmm*

about it, I thought I'll continue anyway to see, you know if I . . . if I can help in any way that I can . . . But it just grew on me, like that wasn't really the case, I couldn't really see what I was doing, I was just filling out these forms every now and then, getting the £5 gift cards like. I wasn't that interested in the gift card it's just, you know I feel like they were no updates or where we are with the study or anything. So it's kind of, yeah a kick in the teeth really" (03012/M/TAU).

Participants also acknowledged that their health anxiety had a significant impact on them and their loved ones. Their desire for improvement was both for their own benefit but also for their family; this sense of responsibility discouraged them from discontinuing therapy.

"Just wanted to try and improve in any which way really because, you know, not just for myself but my family as well, you know, I just wanted to, you know, any type of improvement, anything, you know, no, would never have dreamt of stopping and I never even thought about it, no" (01024/F/RCBT).

To summarise, this theme highlights that participants from both groups expressed that their decision to remain in the Urgent Care trial and adhere to study requirements was in part because they had committed to trial participation. Participants felt grateful to have received RCBT as part of the Urgent Care trial and wanted to show this gratitude by completing study questionnaires. Participants in the TAU group recognised the importance of data in research and were keen to complete questionnaires despite not receiving the intervention.

2) Perceived change in circumstances because of study participation

Service user participants in both groups acknowledged that trial participation provided them with the opportunity to reflect on their symptoms and learn self-management strategies to overcome their anxieties. For the RCBT group this was primarily through RCBT sessions with the study therapist, whereas for the TAU group this was via the completion of the questionnaires and the contact they received from the study researchers. Service user participants

also acknowledged that study participation had enabled them to access other services which they had not otherwise been referred to. They were grateful to have been referred to health care services and receive support for co-morbid mental health illnesses that they were experiencing in addition to health anxiety.

2a) Perceived change in symptoms through study participation

This theme was applicable to participants from both groups. For participants in the RCBT group the intervention provided participants with the opportunity to develop self-management strategies to overcome their anxieties. It enabled participants to accept their condition, have a greater understanding of the cause of their symptoms and develop coping strategies to manage them.

> *"CBT's helped me understand when my condition is starting to come on, because even though I was aware of it sort of physically, mentally it, I wasn't and I was shutting a lot of it out, and sort of thinking I'm ok, I'm ok I can carry on, and then I would become ill. So it was you know [study therapist] helped quite a lot to go you know you need to stick to your boundaries, you know your boundaries, and I was ignoring them to be honest, because I think a lot of, a lot of my struggle with my condition has been accepting I have it"* (01051/F/RCBT).

Participants who perceived the tasks and techniques of therapy to be useful in managing their anxieties were more likely to complete the therapy sessions. This participant compared the RCBT to another therapy she was having at the same time which was addressing Post Traumatic Stress Disorder (PTSD) that she was also experiencing. She felt that the RCBT intervention was more beneficial to her because it provided her with strategies to understand her anxieties and develop strategies to manage them.

> *"I found the therapy with [study therapist] were incredibly useful, it allowed me to acknowledge what parts of my lifestyle were off balance and what would make my anxiety worse, what would feed it and it also allowed me to recognise when I was relapsing and strategies to calm myself down and to try and you know get back onto the straight path, which the other therapy had*

none of that and so I didn't find the therapy outside of this study useful" (01015/F/RCBT).

Conversely, some participants felt that the therapy did not meet their initial hopes and expectations, resulting in the discontinuation of therapy. Participants who hoped that participating in the trial would cure their anxieties were disappointed when their anxieties persisted despite receiving therapy. For example, the following participant, although he was aware that the intervention may not work, said that he participated in the trial because he wanted to be cured. When he did not find an immediate cure, he decided to withdraw from the trial after three sessions.

"In some ways I was hoping it would be a cure but obviously it's not but I think that was just me just dwelling on that you know, 'cause that's what I was hoping, just to make you know, that I could wake up one day without having to worry, do you know what I mean? But I knew obviously it might not work, it might help, it might – I knew it wasn't a cure but stuck in my head somewhere along the line I was looking for that, do you know what I mean" (01008/M/RCBT)

As described previously, as part of the research trial process, participants in both treatment arms were required to complete questionnaires. Participants in the RCBT arm described that completion of the questionnaires allowed them to reflect on their anxieties and enabled a greater sense of awareness about their symptoms. For example, despite discontinuing therapy after two sessions this participant completed all follow-up assessments. She found it interesting to complete the questionnaires because she could reflect on her responses and overall, she felt that over time her responses improved.

"It was interesting actually to, although I couldn't remember exactly what I'd put on the previous one it was interesting to see the question again and see what my answer was. And I think, I think generally it improved. I don't know, I mean you may be able to tell me. I don't know. But you know it was interesting to think oh yeah, I did that last time" (01001/F/RCBT).

Participants in the TAU arm also expressed how through questionnaire completion they were able to reflect on their symptoms. Participants were able to monitor their use of health services and developed an awareness of

their health seeking behaviours and symptoms experienced. Completing the questionnaires was perceived to be therapeutic; it allowed participants in the TAU group to develop their own coping mechanisms to deal with their anxiety.

> *"You know, doing the things, it helped me think about them and it helped me you know put my issues down on paper, so it was therapeutic in a lot of ways just to do that and to realise OK, what stage am I at in myself and how have I come on and if I'm feeling this way, what can I do to solve it or whatever. So those were the two main reasons why I contributed"* (01018/M/TAU).

The data from the TAU group suggests that questionnaire completion was perceived to be beneficial and empowering. Participants felt encouraged when they saw an improvement in their health and a reduction in anxieties.

> *"When I found out I was in the non-therapy group, I was like 'oh no! don't get therapy' And then I was like actually I've improved without the therapy. So maybe it's I've, where I've had therapy previously, maybe it's shown that actually this is about something I can do"* (01016/F/TAU).

However, not all participants benefitted from completing questionnaires. A participant in the TAU group who decided to withdraw from the trial explained his reasons for discontinuing. He understood the importance of completing questionnaires but explained that he was not personally gaining anything positive from participating in the trial and found study completion to be an inconvenience and meaningless.

> *"I was quick to realise that actually no, it wasn't helping and I didn't really, didn't see the point in my participating. I understand that they need a control sample but at the same time it just wasn't really meaningful for me, well sort of eventually in the past six months I didn't find it meaningful . . . I was hoping for some answers in that way and it's kind of fill some forms every few months and then that was it, I don't really get any feedback about what's going on with the study, I don't . . . yeah so that's basically it . . . I kind of just had to withdraw because I just kind of felt like there wasn't really any point in my continuing because I don't know what I'm aiming for to be honest. So it is, I admit it's a nuisance but I don't know so I think it was a case of, I would say*

lots of hassle for 10 or so 15 minutes answering these tick box questions" (03012/M/TAU).

Moreover, for some participants in the RCBT group, the sessions exacerbated existing anxieties leading to a discontinuation of therapy. The participant below explained that although he had built a good rapport with the therapist, he struggled with the negative emotions evoked by the RCBT sessions resulting in him deciding to withdraw from therapy sessions.

"Once I got into it, you know I got to know [study therapist] and talking to him and then talking to him was fine. He's a nice chap, pleasant, wish him all the best. But after, eventually after I was left with like questions whizzing through my head, and sometimes I felt quite – not all the time but sometimes I felt worse than before, do you know what I mean? Not all the time that I'm, that's just sometimes, but I found it left me thinking. And when I start thinking my head goes doolally" (01008/M/RCBT).

The RCBT sessions involved addressing underlying issues which evoked negative emotions making it harder for participants to continue therapy. Although this led to some participants ending therapy early, others persevered with therapy sessions and could see the beneficial effects after a few sessions.

"I didn't realise how much better I'd feel. And after the first, like the first few were not, not great because I'm, I wasn't OK and then suddenly it was like, it was like, like a light switch, like I was just like oh OK, right, this is helping, I do feel better. It's really, it's really hard to put it into words, like it literally, one meeting I was crying and the next meeting I was absolutely fine again" (01007/F/RCBT).

Some participants explained that their reason for continuing with the therapy, despite the emotional distress it evoked, was because they felt grateful for being offered an opportunity and did not want to let the chance pass. They understood that to see an improvement you sometimes had to go through difficulties initially.

"R: Oh I never, ever thought about not carrying on. So I never even thought about that, no, didn't even think about not going, it never even came into my mind, no

I: OK. So even when sometimes you did become upset, sort of, you carried on

R: Yeah, never even come to my mind, that didn't, yeah, never even thought about -, and as I say, so grateful for some help that no, that didn't even cross my mind. And, you see, the thing is to get better you do have to go through things that aren't always nice, don't you, you know" (01024/F/RCBT).

Some participants in the TAU group also described how the questionnaire completion evoked distress and negative emotions.

"A few times I did come away from them, like, feeling actually quite triggered, just, and, like, it would sort of make me just a little bit over aware of my own emotions and the thoughts and what was going on and everything. But I found the last one alright to do, like, I think that was the only one I've done where I haven't cried afterwards" (01012/F/TAU).

To summarise, service user participants in both groups expressed that trial participation enabled them to develop coping strategies to manage their anxieties. However, some participants expressed that trial participation exacerbated anxieties, which for some, did lead to discontinuation of RCBT sessions.

2b) Referral and access to other services

For some participants, regardless of which arm they were in, involvement in the trial led to referrals to other appropriate services. The participants were grateful that they had finally received a diagnosis through participation in the trial and were receiving additional support to help them manage pre-existing co-morbidities.

A participant in the RCBT arm divulged that participating in the trial instigated a referral to the Early Intervention Psychosis (EIP) services. Prior to participating in the trial, he had not disclosed to his GP that he was hearing voices. It was only after he had his initial session with a therapist as part of the RCBT intervention that it was recognised that because he was hearing voices, RCBT for health anxiety would be unsuitable for him as it would increase his anxieties, and instead he would require a referral to EIP services. The study therapist referred him to his local EIP services, and he

began receiving support from the EIP team. The participant continued to complete follow-up-assessments for the Urgent Care trial, where he expressed that participating in the trial had improved his life and he was grateful because study participation enabled him to be referred to appropriate services that he may have never known about.

> *"If I remember rightly, we were just going through some basic questions and then I was asked if I hear voices, which then obviously I responded 'yes'. Which was a bit of a turning point good and bad cause, one side of me was saying, now you know going to have this problem, and that problem's going to happen but also it helped towards getting more recommendations towards EIP, which since then literally everything's turned around everything's got a lot better"* (01040/M/RCBT).

For a participant in the TAU group, when the study researcher was completing the penultimate follow-up assessment, she disclosed that she believed she may have bipolar disorder which had not been diagnosed. After the completion of the follow-up assessment and with the participant's consent, the study researcher contacted their GP and recommended a referral to a psychiatrist. As a result, they were referred by their GP and were under the care of a psychiatrist. The participant was very grateful for this referral because she had been trying to access support for her difficulties for long time and was relieved to finally receive a diagnosis and help in managing her difficulties.

> *"Well, I found you, like, really helpful, like, you helped me get my referral up, you sent that email to the doctors and it helped push forward for me to get my bipolar diagnosis and my OCD diagnosis so, like, super grateful for that… If it wasn't for you, I could have just continued getting looped round the system with the GP and everything so, like, yeah, thank you, like, I'd gone to the doctor so many times since I was, like, thirteen about my mental health and now you finally managed to get that pushed through to the doctor to get me that, like, help I needed, so that was helpful, thank you"* (01012/F/TAU).

The quotes above highlight that participation in the Urgent Care trial enabled participants to not only access treatment as part of the intervention, but it also facilitated access to other services which participants may not otherwise

have been referred to. As the participant below explains, participating in the trial was life changing.

> *"Yeah, it was kind of literally life changing from then because that's when more doors towards help opened up and yeah made a lot of things better. It sounds dramatic but it literally was life changing, and I think if I didn't take part in this then I wouldn't have learned about EIP and I wouldn't have received any help, I wouldn't have obviously I've been able to reflect on the problems that I do have and just how bad it can be at times, but yeah, very thankful for it"* (01040/M/RCBT).

In summary, trial participation for participants in both groups led to referral to health care services for co-morbid mental health symptoms identified by the study research team. Participants were grateful to receive support for symptoms that had been undiagnosed by other health care professionals.

3) Digital Health Intervention (DHI) factors influencing retention to RCBT treatment sessions

The themes discussed thus far in the chapter are not specific to the Digital Health Intervention (DHI) nature of the Urgent Care trial. Factors such as the rapport participants built with the research team, their understanding of the importance of research data and perceived change in circumstances or anxieties impacted on trial retention.

However, the interviews also highlighted that there were specific aspects related to the DHI that influenced whether service users completed RCBT sessions. These themes were only relevant to the RCBT group and are explained in more detail below with supporting quotes.

3a) The accessibility and convenience of the DHI

Participants who were allocated to receive the RCBT expressed that the intervention enabled more flexibility, choice, and improved accessibility. The participant below had been on a waiting list to access face-to-face CBT for quite a while, she was pleased to receive RCBT as part of the trial almost immediately.

"It was literally a couple of weeks, and I started it straight away so yeah, that was good" (01051/F/RCBT).

RCBT appealed to those with physical limitations and mental health difficulties such as anxiety. Participants felt more comfortable being able to access treatment from their own homes and not having to go out.

"I am not one for getting out of bed where I don't have to … it was nice to be able to do it from my own bed but I'm also not very good at getting up and getting dressed on my days off so I did it in pyjamas with no makeup on and greasy hair a lot of the time" (01007/F/RCBT).

The benefit of being able to access the intervention remotely was favoured by participants as they did not have to get dressed, or out of their bed which made it more practical.

"I could be in my pyjamas or whatever, so from my point of view at the time my mobility and stuff wasn't great, so the fact that I'd not had to like force myself to get up and go anywhere and sort of struggle meant that I wasn't completely exhausted by the time I'd got somewhere. So it meant that I didn't have to have a rest for a little bit first before having to do anything, like it was a lot easier sort of from that point of view" (01023/F/RCBT).

Being able to access therapy remotely improved accessibility and resulted in fewer cancelled sessions. This was because it removed logistical barriers for participants with physical limitations and they were easily able to rest immediately after their therapy session.

"It's like even now I'm doing CBT through [outpatient hospital department] and I'm struggling to get to the appointment sometimes because if I've had a bad day I can't drive, so you know I'm unable to get to the appointments whereas when I was doing it with [study therapist] even if I'd had a bad day I could get myself into, into a space where I was just on my own, to be able to just sit and talk to [study therapist] and then I didn't have to drive away from the appointments I could literally just get down on the settee and have a sleep afterwards…that really helped… so the fact that I could do the activity and then literally just put the, the computer down and go straight to sleep was, was brilliant" (01051/F/RCBT).

However, for some participants receiving therapy remotely was a barrier, such as for those with hearing difficulties. The participant below explains why they chose to discontinue treatment after two sessions.

> *"I just found it a little bit uncomfortable using the Skype. Probably I would have been better face-to-face, I don't know. I do have a hearing problem, so telephone conversations aren't always that good, which was why I opted to see you personally today because I thought if I'm trying to talk to you over the phone, I don't hear everything you say. I mean I wear a hearing aid but even so it's still sometimes, if the line's not very good, it's not easy"* (01001/F/RCBT).

To summarise, this theme highlights that participants who perceived the RCBT to be more accessible were more likely to complete treatment. They liked that RCBT enabled them to access therapy from their home, which was more comfortable and reduced practical barriers. However, RCBT was not viewed to be favourable such as for those with hearing difficulties and led to a discontinuation of therapy.

3b) Stigma and privacy of Digital Health Interventions

Stigma and privacy of RCBT was a double-edged sword. Some participants expressed that RCBT felt more comfortable and less stigmatising than face-to-face psychological treatment. However, others felt that the lack of a separate, personal space to engage with difficult issues felt less private.

> *"It was a little bit sort of surreal and I guess not actually seeing the person in the same room, like I know it was face-to-face in that you could see them but not sort of physically being in the same room as them, I think possibly made it a little bit easier sometimes and possibly made it a bit harder"* (01023/F/RCBT).

RCBT was perceived to be more private for some participants. Participants liked that they did not have to wait in a public room before being seen for a therapy session. Remotely delivered therapy enabled participants to feel more comfortable and open during therapy.

> *"The fact that I didn't have to go and sit in a waiting room and have other people sort of look at me and have to sit and look at other people wondering*

why you're here, what are you doing, like you do when you do stay for counselling, it's a very private experience having it online and I really liked that" (03002/F/RCBT).

However, for other participants, accessing therapy from home was less private because they were in shared accommodation and were wary of their conversation being heard by others. This impacted on the therapeutic relationship because participants could not be as honest during the session.

"Yes, and maybe there were things that I wanted to say to [study therapist] that I couldn't because my husband was in hearing distance. It was a nice idea but it's just I would have liked more of this (meeting face-to-face), sort of, scenario" (04001/F/RCBT).

Consequently, the participant above discontinued with RCBT sessions.

To summarise, in terms of DHI specific factors, those who perceived the RCBT to be more accessible were more likely to complete treatment. They liked that RCBT enabled them to access therapy from their home, this was more comfortable and reduced practical barriers. However, RCBT was not perceived to be beneficial by all. For some participants accessing treatment from home felt less private especially for those who were not living alone. Practical aspects such as hearing difficulties were also likely to lead to discontinuance with RCBT.

Overall summary

To summarise, the findings from interviews with service users highlight that recruitment to the Urgent Care study could be explained by three themes. The first theme highlighted that the decision to participate in the trial comprised of several components. Firstly, the way in which information about the trial was communicated to service users influenced their perceptions of the trial in terms of study understanding and relevance. Service providers and research team explanation of the trial influenced participant expectations and views and their decision to participate in the trial. Those who felt hopeful that that trial participation may help them cope with their symptoms were

positive about taking part and keen to see how it might help. Conversely participants who were not convinced about the relevance of the trial for their symptoms approached the trial with a sense of scepticism about the perceived effectiveness of the intervention. Participant decisions to participate in the trial were also influenced by perceived value of research and the desire to help not only themselves but others too.

In terms of retention there were some common themes pertinent to both groups and one theme which was applicable only to the RCBT group. For the TAU group despite not receiving the intervention remaining in the trial was associated with a sense of commitment to the research and the research team. They valued the importance of research data in advancing health care and therefore were keen to contribute. They also highlighted the benefits of completing outcome measures because it enabled them to monitor and reflect on their symptoms which improved their overall health. The therapeutic nature of the relationship with the research team was highlighted in both groups. For those allocated to receive RCBT the relationship with the therapist was highlighted to be key, whilst those in the TAU group identified the relationship with the researchers collecting outcome assessments. There was one theme that was only relevant to the RCBT group: DHI factors that influenced retention to RCBT treatment sessions. Service users who perceived the DHI to meet their needs in terms of accessibility were more likely to express positive views about the treatment and complete therapy. However, there were participants who did not like the DHI because it was not conducive to their personal circumstances. Participants who found RCBT to be useful were likely to complete all treatment and reported the benefits of therapy sessions.

The final chapter of the thesis will offer a comprehensive discussion. It will succinctly summarise key findings from each part of the study and establish connections with pertinent literature and theoretical frameworks in relation to the research questions. The broader implications stemming from the findings, along with the strengths and limitations of the research and methodological approaches, will be presented. Additionally, the chapter will put forth implications and recommendations for researchers and clinicians.

Chapter Eight: Discussion

Introduction

This final chapter brings together the thesis, pulling together the data and literature presented to respond to the research questions posed and illustrate how this doctoral study has contributed new knowledge to the field.

The overall aim of the doctoral thesis was to contribute towards a wider understanding of the recruitment and retention issues to a Digital Health Intervention (DHI) trial, using participants invited to participate in a DHI for health anxiety as a case study, and the potential strategies that could be implemented by researchers in the future to address recruitment and retention challenges. The research questions (RQs) framing this thesis were:

RQ1- What are the factors reported in previous research affecting the recruitment of participants into depression, anxiety and somatoform DHI trials?

RQ2- What are the factors influencing service providers decision to participate in the Urgent Care trial?

RQ3- What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?

RQ4- What are the factors influencing service user participants decisions to participate in the Urgent Care trial?

RQ5- What are the factors influencing service user participants the decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial (retention)?

To address these research questions three work packages were conducted. Chapter Four, a qualitative systematic review, reviewed the published evidence relating to the factors that facilitated and hindered service user recruitment and retention to DHI trials for depressive, anxiety and somatoform disorders. Chapter Six explored original, empirical qualitative

data that addressed the factors influencing recruitment and retention into a DHI trial from the perspective of service providers. This was complemented by Chapter Seven, in which the factors influencing recruitment and retention into a DHI trial were again explored, but this time from the perspective of service users.

This final chapter commences with a summary of the main findings from each of these chapters. Key findings from each will be combined and summarised to present a synthesised description of the potential barriers and facilitators to recruitment and retention to a DHI trial. The chapter will then interpret the findings in the context of the wider literature before examining the methodological strengths and limitations. Finally, the chapter will reflect on the overall implications arising from the doctoral study and make recommendations for researchers recruiting to trials and suggest further research, before closing with a short conclusion.

Main findings

The relationship between the research questions, the work packages, the methods used and their location within the thesis is summarised in Table 21.

Table 21 Research summary and thesis structure

Research questions	**Work package**	**Key methods**	**Thesis Chapter**
RQ1 What are the factors reported in previous research affecting the recruitment of participants into depression, anxiety and somatoform DHI trials?	One	Systematic review	Four
RQ2 What are the factors influencing service providers	Two	Qualitative interviews	Six

decision to participate in the Urgent Care trial?			
RQ3 What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?	Two	Qualitative interviews	Six
RQ4 What are the factors influencing service user participants decisions to participate in the Urgent Care trial?	Three	Qualitative interviews	Seven
RQ5 What are the factors influencing service user participants the decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial (retention)?	Three	Qualitative interviews	Seven

Work package one – Qualitative systematic review and meta-synthesis exploring factors affecting recruitment and retention of service users to Digital Health Interventions (DHIs) for depressive, anxiety and somatoform disorders.

Work package one found that DHIs could be perceived both positively and negatively, which was unsurprisingly influenced by participants' expectations and preferences. The findings highlighted that engagement in DHI trials is a dynamic process; individual expectations and pre-existing beliefs about a

DHI and its perceived effectiveness can impact on participant willingness to participate in a DHI trial, and this in turn, could influence overall experience and treatment completion. Therefore, addressing expectations prior to, as well as during, participation in a trial is important in addressing misconceptions and early barriers to recruitment which would subsequently improve retention.

Furthermore, the review highlighted the value of personalised support and the personalisation of DHIs in increasing reasons to continue with treatment. The key means of personalising treatment identified as helpful by participants was the addition of rapid and responsive personal/human support. The recommendations proposed in this review underscore the importance of investigating the factors influencing the recruitment and retention of individuals with health anxiety in DHIs.

Work package two – Qualitative study exploring service provider barriers and facilitators to participating in the Urgent Care trial and referring patients

Work package two found that service provider decisions to participate and refer patients to the Urgent Care trial was connected to research, service provider and service user related factors.

Research related factors highlighted the significance of study promotion and communication of the trial information by the research team in aiding service provider understanding of the Urgent Care trial and study processes. Service provider related factors deemed to be important included aspects such as the perceived credibility of the intervention over existing treatment pathways and the perceived costs and benefits of study participation.

Service providers who viewed the Urgent Care trial as an opportunity to help their patients manage health anxiety and could see the value of the intervention in terms of improving accessibility were more likely to refer patients. Service user related factors identified by service providers that influenced service provider willingness to approach patients including

perceived patient readiness and the risk to the service-provider patient relationship.

Service providers also acknowledged that certain demographics of patients such as gender, age and culture could impact on patient acceptance of a psychological intervention, and this influenced whom they approached about the trial.

Work package three – Qualitative study exploring service user barriers and facilitators to participating and remaining in the Urgent Care trial

Work package three found that the decision-making processes of service users when considering participation in the Urgent Care trial, were intricate and involved a dynamic interplay between factors related to the research and those specifically related to the service user.

The decision to participate in the Urgent Care trial was comprised of multiple components. Firstly, the way information about the trial was conveyed to service users influenced their perceptions of the research, encompassing their understanding of the study and its relevance. The explanations provided by service providers and the research team regarding the trial significantly impacted participant expectations, perspectives, and their ultimate decision to participate in the trial. Additionally, participants' decisions to engage in the trial were influenced by the perceived value of research and the altruistic desire to contribute not only to their own well-being but also to the well-being of others.

Regarding retention, common themes were identified that were relevant to both participant groups, and one theme applied exclusively to the group that received remotely delivered Cognitive Behaviour Therapy (RCBT). Once again, an intricate interplay between research-related aspects and service user-specific factors influenced decisions to either continue or discontinue trial requirements. The therapeutic nature of the relationship with the research team was emphasised in both participant groups. Furthermore, there was a theme specific to the RCBT group: Digital Health Intervention (DHI) factors that influenced retention in RCBT treatment sessions. Participants who perceived the therapy as beneficial were more likely to

complete the entire treatment and reported positive outcomes from the therapy sessions. Those who chose to discontinue treatment did so after carefully weighing the burden versus the benefits of trial participation.

Contribution of findings to overall aims and research questions

Data collected reinforces the literature reviewed and suggests that recruitment and retention to DHI trials is a complex social process and involves an interplay of the factors that contribute to service user and service provider decisions to participate. This thesis sheds further light on what the factors are and how they might be managed. It recognises the need to identify potential barriers to recruitment or retention from the outset so that these can be addressed prior to a trial commencing, as well as the need to continue to actively address them during the trial. I will now discuss each research question in relation to the themes and how they mapped onto recruitment and retention models described in Chapter Three.

RQ1- What are the factors reported in previous research affecting the recruitment of participants into depression, anxiety and somatoform DHI trials?

The first research question was addressed by conducting a systematic review and meta-synthesis. The review found that enhancing the alignment of digital health interventions (DHIs) with service users' initial expectations could enhance recruitment to DHIs trials. Additionally, incorporating prompt and supportive personal or human assistance, even when provided remotely, may contribute to increased participant recruitment and retention in DHIs. Thus, DHIs need to be responsive to individual preferences and circumstances to optimise therapy uptake and completion. Work package one emphasised the importance of receiving individualised support in DHIs, consistent with the conclusions drawn by O'Connor et al (2016) and Knowles et al (2014). Both reviews highlighted the crucial role of personalisation and the availability of support in DHIs. The meta-synthesis also informed some of the research priorities identified by Hollis et al (Hollis et al., 2018).

The limitations of the review were that there were no studies focussing on somatoform disorders. In addition, there was little data specifically focussing on recruitment and retention to DHI trials and the data focused on service user experience of using or choosing to stop using a DHI. Therefore, the findings highlighted the need for further qualitative work to understand the experiences of individuals with health anxiety who participated in a DHI trial with a specific focus on recruitment and retention as this was not systematically addressed in previous literature.

RQ2- What are the factors influencing service providers decision to participate in the Urgent Care trial?

Work package two found that the service providers' decisions to participate with the Urgent Care trial was primarily based on the initial information they were provided with from the research team. Prior to deciding to participate in the Urgent Care trial service providers determined whether they thought the intervention would be of relevance or value. To do this, they needed to place a judgement based on the information provided by the research team. Service providers needed to understand the rationale of the trial to determine its significance and they also needed to understand the level of commitment required from them as an individual, their organisation, and their patients.

Service providers were more likely to participate in the Urgent Care trial if they could see the perceived credibility of the intervention over existing treatment pathways, and if they saw the trial as a valuable opportunity to help manage patients with health anxiety and reduce waiting times. Previous research experience and an interest in health anxiety were facilitators to participation in the Urgent Care trial, whilst working in an organisation that did not place an emphasis on research was a barrier to trial participation. Work package two highlighted that there were variations in how the Urgent Care trial was perceived by service providers, which impacted on trial participation and referral rates. This is consistent with a previous review that found that a key facilitating factor for clinicians approaching patients about depression trials was if they themselves perceived the trial interventions to be a potential resource for meeting patient needs (Hughes-Morley et al.,

2015). Within the Emergency Department (ED) there was a culture (perhaps not unexpected given the nature of the work at the ‘front-door’ of the hospital) in which certain areas of research were given a low priority, and as such the Urgent Care trial was not perceived to be relevant within their clinical setting. For some clinicians within the ED, research was not even perceived to be part of their role or practice culture, and they did not feel a particular responsibility for participating in a trial about health anxiety.

Service providers also expressed that they considered the impact of the Urgent Care trial on their capacity to deliver healthcare, and how involvement would affect their organisation and their patients. They considered the costs of being involved in terms of staff resources and whether they had the capacity to carry out additional research related activities. As such, the decision to engage was a balanced consideration of the potential advantages over the challenges that might result. According to Rogers (Rogers, 2003), an innovation is an idea, process, or a technology that is perceived as new or unfamiliar to individuals within a particular context. As such, his Diffusion of Innovations (DIO) theory can be applied to the Urgent Care trial, where a relatively novel and innovative DHI (at the time of data collection) was being offered for the treatment of health anxiety.

Rogers (Rogers, 2003), referred to the decision-making process to participate in an innovative action (trial participation in this instance) in relation to relative advantage, complexity, compatibility, trialability and observability. As the data presented and discussed in Chapter Six illustrated, when deciding to participate in a trial, service providers considered the perceived credibility of the innovation (RCBT intervention) over existing treatment pathways, and its benefits (relative advantage), their understanding of the trial processes (complexity), the degree to which the intervention was perceived to be acceptable for the treatment of health anxiety (compatibility), the level of commitment and work load required (trialability) and perceived benefits and change in symptoms (observability).

The findings from work package two also resonate with the wider implementation science approach described as Normalisation Process

Theory (NPT) (May et al., 2011). NPT is a theoretical framework designed to understand how new practices are implemented, embedded and integrated into existing systems. The findings from work package two echo what the NPT model refers to as coherence ‘sense making’. Service providers considered their participation in the trial based on how well they were able to understand the relevance and aims of the Urgent Care trial (coherence or sense making) and if they believed it would be a valuable study (cognitive participation or engaging). This sense making impacted on their participation engagement as it influenced whether service providers decided to participate in the Urgent Care trial. While one might argue that trial participation doesn't equate to directly to implementation, the choice to engage in the trial essentially implied that service providers were recognising the necessity to incorporate a change in their current practices and implement this action to enable the activity to happen. For instance, this would involve proactively discussing the Urgent Care trial with patients during consultations or retrospectively identifying potentially eligible participants through the screening of medical records. The findings also mapped onto several of the constructs in the Theoretical Framework of Acceptability (TFA) model (Sekhon et al., 2017). This influenced the decision of service providers to participate in the Urgent Care trial but impacted to a greater extent on their likelihood to refer patients. Service providers who recognised the relevance of the Urgent Care trial (affective attitude), understood the study processes and how to identify patients (intervention coherence), and saw the benefits of the Urgent Care trial (perceived effectiveness) for both their organisation and their patients were more inclined to participate in the Urgent Care trial and refer patients. The distinction between anticipated and experienced acceptability is a key feature of the TFA model, which explores the notion of acceptability at three different time points in relation to the intervention delivery period: (1) pre-intervention delivery, (2) during intervention delivery and (3) post-intervention delivery. The TFA model argues that prior to experiencing an intervention, both patients and health care professionals can form judgements about whether they perceive the intervention to be acceptable or unacceptable. Within the Urgent Care trial context, it became apparent that in some cases, service providers' initial affective attitude and

perceived effectiveness shifted as they gained a better understanding of the trial processes and its significance.

RQ3- What aspects are important in determining whether service providers did or did not refer their patients to the Urgent Care trial?

Work package two explored factors influencing service providers' decisions to refer patients to the Urgent Care trial. Service providers expressed that clarity on how eligible participants could be identified, and receiving clear instructions on the referral processes, was more likely to lead to patients being referred to the research team. If service providers did not fully understand how to identify eligible patients, they were less likely to refer patients. This aligns with the NPT model's concept of coherence, often described as "sense-making". These findings also map on to several of the TFA constructs. When making decisions, service providers evaluated the effort needed to refer patients to the Urgent Care trial (burden) and the potential benefits they might forego by participating (opportunity costs). They also gauged their confidence in explaining the trial to their patients (self-efficacy). This requirement to handle the complexity of information about the innovation resonates with the points raised by Rogers (Rogers, 2003), service providers were less likely to refer patients if they struggled to understand how eligible patients could be approached and directed to the Urgent Care trial.

In addition, staffing and logistical barriers led to fewer/no referrals because service providers lacked the resources or dedicated research staff to approach patients about the trial. As discussed in Chapter One in the Urgent Care trial, two referral approaches were utilised. The Urgent Care trial findings showed that opportunistic referrals resulted in higher recruitment rates in comparison to postal invitations. This could be because within consultations service providers were able to tailor the communication of the trial information to individual patients. It also allowed patients to ask questions or address any uncertainties within the consultation. It is also worth considering that maybe patients were less easily able to decline consent to being contacted within a consultation and may have agreed to it.

However, it is important to note that staffing and logistical barriers led to fewer/no referrals in some instances because service providers lacked the resources or dedicated research staff to approach patients about the trial. This is supported by a recent meta-synthesis which found that additional time required for participating in clinical trials and recruitment was identified as a barrier to participation due to busy workloads (Farrar et al., 2022). Healthcare organisations often face constraints in dedicating time to refer patients to research trials because of competing demands and limited resources. Consequently, the likelihood of referring participants to a trial increases when the perceived effort, time, and resource requirements are minimal. Therefore, researchers need to ensure that trial processes require minimal input from service providers because, as work package two demonstrated, clinical workload was highlighted as a barrier to trial participation. Utilising a combination of referral approaches may maximise referral rates enabling a study to more easily meets its recruitment target. This observation can be illuminated through various aspects of the Theoretical Domains Framework (TDF) model (Atkins et al., 2017), referral of patients was influenced by how confident service providers felt about approaching patients about the Urgent Care trial (beliefs about capabilities). An essential insight gleaned from the TDF relates to construct of environmental context and resources which highlights that the decision to recruit and refer patients wasn't solely cognitive; it also involved environmental considerations such as feeling overburdened or understaffed. Therefore, the choice to refer was influenced not just by the research's credibility or practicality, but also by external factors beyond the study itself.

Work package two highlighted that a key factor influencing referral of patients was the perceived impact this could have on the service provider-service user relationship. Barriers to referring patients included the fear of offending the patient by raising the possibility that there may be a psychological element to their physical symptoms. As discussed in Chapters Two, Six and Seven, a diagnosis of health anxiety can hold negative connotations and may offend service users. Service providers recognised that suggesting to a patient that they may have health anxiety had negative implications and were

wary about causing offence and distress. This is consistent with a previous meta-synthesis (Hughes-Morley et al., 2015) which found that decisions by clinicians on inviting patients to participate in trials about depression were influenced by aspects such the impact of the trial on their patients' health and whether participation would overburden and distress the individual. This also echoes the findings of Mason et al (Mason et al., 2007) who acknowledged that clinician concerns about the impact of trial inclusion on the doctor/patient relationship can influence whether patients are approached about study participation. Service providers in the present study also acknowledged that certain patient demographics, such as gender, age and ethnicity could impact on their beliefs about a patient's acceptance of a psychological intervention, and this in turn influenced whom they approached about the Urgent Care trial. This is consistent with the findings of Pywell et al who found that trust plays a crucial role in influencing the participation of older individuals with mental health conditions in a Digital Health Intervention (DHI) trial (Pywell et al., 2020). This connection to trust operated on both an individual level, involving trust in the DHI itself, and a broader level, encompassing trust in those endorsing the DHI, including the pivotal role of the GP. The provision of a script by the research team was perceived to be helpful in facilitating discussions between the service provider and service user. Work package two showed that service provider decisions to approach patients about the Urgent Care trial was also dependant on their own perceptions about the burden of study participation on service users. These paternalistic attitudes suggest that service users may not be given a choice about taking part in a trial due to the gatekeeper role of service providers, even though this paternalism was usually unintentional and rationalised as a concern for their patient. The self-biasing of service providers when recruiting patients for the Urgent Care trial raises concerns about the representativeness of participants and the transferability of the study findings.

The findings from work package two link in with several of the domains of the Non-adoption or Abandonment of technology by individuals and difficulties achieving Scale-up, *S*pread and *S*ustainability (NASSS) (Greenhalgh et al.,

2017) framework. NASSS aims to analyse and understand the complexity of health care technology implementation. Unlike the other theoretical models summarised in Chapter Three, NASSS considers the condition or illness and how the complexity of a condition can impact on why a health care technology may not be implemented. As elucidated in chapters Two and Six, health anxiety is a complex condition and can be linked to physical morbidities, adding to the difficulty for patients in accepting the potential psychological aspects of their symptoms. Work package two highlighted the challenge of introducing psychological interventions to patients, as clinicians had concerns about upsetting them. Notably, this apprehension was not specific to the intervention being a Digital Health Intervention (DHI) but rather stemmed from the psychological nature of the intervention itself. According to the NASSS framework, an intervention is less likely to be adopted if the adopter system and organisation is complex and requires staff to undertake new roles and puts additional pressures on them. In terms of referring patients, service providers who did not have sufficient resources or struggled to understand how eligible patients could be identified or approached were less likely to refer patients to the Urgent Care trial. Through its focus on social interactions, NASSS also acknowledges the role of organisations and individuals, including staff and patients, and the social interactions between them all influencing the implementation of technologies. Within this doctoral study, the relationships, and social interactions between staff within the NHS care providing organisations and the study research team, and between service providers and services users, all contributed to whether service users were approached about the Urgent Care study.

RQ4- What are the factors influencing service user participants decisions to participate in the Urgent Care trial?

Work package three, consistent with the results of work package two, highlighted that the communication of trial information was integral in shaping initial perceptions about the trial, which ultimately influenced service user decisions to participate in the Urgent Care trial. Given that service users only came to know of the trial through service providers, the information provided by service providers was central in determining service user trial

participation. However, service user participants were not always fully informed about the study and what it would involve. Work package three showed that the initial contact with the study researchers facilitated study understanding and, in some situations, helped in overcoming initial apprehensions about participating in the Urgent Care trial. Consistent with previous literature, the decision to take part in the trial was influenced by how information about the trial was communicated to service user participants by service providers and the research team and the relationship between service users and service providers (Hughes-Morley et al., 2015, Houghton et al., 2020, Borghouts et al., 2021). Work package two highlighted the pivotal role of service providers as gatekeepers in patient recruitment. Their decisions to refer patient to the Urgent Care trial were influenced by their perceptions of the trial itself and its impact on their patients. This has important implications for research participation because in most health care trials service user participants only come to know of the research through their health care providers.

Service users highlighted that if the rationale for the Urgent Care trial and the level of commitment required was explained, they were able to make an informed decision on whether to participate, highlighting that they needed to be fully informed about the trial purpose and processes. Work package three acknowledged that service users were sometimes ambivalent about participating in the Urgent Care trial if they did not consider the trial to be relevant or deem themselves to be ineligible. This was often influenced by whether they considered their symptoms to be attributed to health anxiety and whether they felt a psychological intervention was appropriate for the management of their symptoms. In mental health research in particular, aspects such as stigma could discourage patients from participating (Hughes-Morley et al., 2015, Borghouts et al., 2021). This highlights important issues with the informed consent process, and the importance of the research team spending additional time with study participants to clarify the purpose of a trial and trial processes and explaining the implication of taking part and addressing any initial concerns. This links to the complex inter-relationship between service users, service providers and the research

team echoing Roger's (Rogers, 2003) DOI theory. According to Rogers, when considering adopting an innovation, information exchange is crucial, facilitated through various communication channels, including interpersonal interactions. This highlights the importance of the relationship between researchers and service users in shaping trial participation.

The decision of service user participants to take part in the Urgent Care trial was also shaped by their hope for recovery and the desire to receive a treatment that could effectively manage their symptoms. Participants demonstrated a more positive inclination towards trial participation when they believed that the intervention could be beneficial. Conversely, those who were sceptical about the psychological aspect of their symptoms were less enthusiastic about participating. Some felt obligated to participate due to being referred by their clinician. Alternatively, service users who had begun to acknowledge the potential psychological origins of their symptoms showed a greater inclination to participate in the Urgent Care trial.

Service user participant decisions to participate in the trial was also influenced by perceived value of research and the desire to help not only themselves but others too. This is consistent with existing literature that has identified altruism to be an important consideration for patients deciding to part in depression trials (Hughes-Morley et al., 2015, Sheridan et al., 2020, Houghton et al., 2020).

Service user decisions to participate in the Urgent Care trial can be understood by considering several of the TFA constructs. Constructs such as affective attitude and perceived effectiveness significantly influenced how service users viewed the Urgent Care trial and its value. Additionally, the extent to which the intervention aligned with their ethical values (ethicality) and their understanding of the trial, and its requirements (intervention coherence) also influenced their decision to participate in the Urgent Care trial.

The findings can also be elucidated through Rogers' Diffusion of Innovations (DOI) theory, which suggests that innovations perceived by individuals to offer greater relative advantage while being less complex, are more likely to

be adopted more rapidly. Service user participants were more likely to participate in the Urgent Care trial if they understood the relevance of the trial and the processes and believed that their participation would provide treatment to help them manage their symptoms.

The findings from work package three also aligns with certain constructs of the TDF; Service user decisions to consent to trial participation were influenced by the information they received information about the trial and its procedures (knowledge), and the belief that trial participation would aid in managing their symptoms (optimism). These decisions were mediated by their interactions with service providers and the research team (social influences), which acted as facilitators for recruitment.

The findings from work package three do not seem to align with both the NPT model and the NASSS framework. This disparity may arise because these models mainly address the implementation of new practices or healthcare technology, placing greater emphasis on service providers, health care practice organisation and intervention characteristics.

RQ5- What are the factors influencing service user participants the decisions to continue or discontinue therapy and/or questionnaire completion in the Urgent Care trial (retention)?

Work package three highlighted that the rapport built with the study team, including the study researchers and therapists, impacted upon participant retention. Contact with the researchers and therapists enabled trial participants to build trust and a rapport with the research team, and this increased uptake and retention. An interesting and novel finding emerging from the retention findings was that the therapeutic nature of the relationship with the research team was highlighted in both groups. For those allocated to receive RCBT the relationship with the therapist was highlighted to be key, whilst for the TAU group, completion of questionnaires and regular contact with a researcher appeared to be a therapeutic intervention, albeit an unanticipated one.

The Urgent Care trial findings and the interviews highlighted that despite fears, a therapeutic relationship can be formed virtually, and the inter-personal qualities of the research team were essential in facilitating this. For the TAU group, despite not receiving the intervention, remaining in the trial was associated with a sense of commitment to the research and the research team. They valued the importance of research data in advancing health care and therefore were keen to contribute. They also highlighted the benefits of completing outcome measures because it enabled them to monitor and reflect on their symptoms which improved their overall health. The existing literature on recruitment/retention in health care trials does not focus on TAU groups, yet this is an important gap in the knowledge base to consider when looking at Randomised Controlled Trials (RCTs) because participants will have a 50% of receiving an intervention, thus meaning half of study recipients will not receive the intervention – but their data is still important to collect as a comparator.

Work package three builds on the literature on research participation as altruism (Houghton et al., 2020, Hughes-Morley et al., 2015) and showed that one of the reasons participants in the TAU group provided for remaining in the Urgent Care trial was because they had committed to taking part and understood the importance of research participation in advancing health care. However, where it differs – and as such offers a novel contribution to the knowledge base, is that in addition to notions of altruism, those participants in the TAU arm of the study talked about the positive impact of study participation on their self-reported symptoms, despite initially being disappointed of their treatment allocation. Trial participation offered them hope and the opportunity to self-reflect on their illness experience, which appeared to be a therapeutic intervention. This is consistent with the findings of Haas (Haas et al., 2022) who highlighted “the power of placebo effects” and its contribution to symptom improvement, suggesting that additional attention and care received from trial participation alone and hope that an intervention may be beneficial can have positive effects for both groups. It could be argued that the additional attention and care provided such as through the collection of follow-up assessments in trial participation alone are

all non-specific effects that apply to both treatment groups rather than a placebo effect affecting only the control arm and could account for symptom improvement in both groups.

Factors related to the Digital Health Intervention (DHI) that impacted the retention in the RCBT treatment sessions were identified. Service users who believed that the DHI catered to their accessibility needs were more inclined to express favourable opinions about the treatment and were more likely to complete the therapy sessions. Conversely, some participants disliked the DHI because it did not align with their personal circumstances. Those who perceived the therapy as beneficial were more likely to complete the entire treatment, highlighting the positive outcomes of the therapy sessions. On the other hand, participants who opted to discontinue treatment did so after carefully weighing the burdens against the benefits of trial participation. These findings resonate with work package one and earlier reviews (Knowles et al., 2014, O'Connor et al., 2016)

Service user decisions to remain in the Urgent Care trial and complete outcome assessments or RCBT treatment sessions can also be explained through the lens of several of the TFA constructs. How service users initially felt about the trial and intervention not only influenced recruitment to the Urgent Care trial but was also likely to influence retention. Participants who had participated in the trial because they felt compelled by their service providers (affective attitude) and were unsure of the relevance of the trial for their symptoms (perceived effectiveness) were more prone to discontinuing RCBT sessions and failing to complete follow up assessments.

Retention could also be explained through Roger's DOI theory (Rogers, 2003). The perceived characteristics of the intervention played a role in both the decision to be involved in the Urgent Care trial (recruitment) and to continue to adhere to trial requirements or remain in the trial (retention). For example, the participant who did not perceive their participation was creating any benefit (relative advantage) and found it burdensome to complete questionnaires (complexity) decided to withdraw from the Urgent Care trial.

None of the models explain why a participant may remain in an RCT despite not receiving an intervention which is a significant omission in the existing theoretical models of innovation behaviour, and which this thesis has identified. Work package three sheds some light on this, the findings suggest that trial participation offered service user participants hope and legitimatised their symptoms. It offered an explanation which came across as non-judgmental, and the provision of support and structure. The implications of this are significant because often in RCTs decisions to participate are influenced by treatment preferences which can be a barrier to recruitment (Hughes-Morley et al., 2015). The findings from work package three and the main Urgent Care trial findings suggest that participants randomised to a control group may still benefit from trial participation and show an improvement in their symptoms.

Wider study implications

The findings arising from this thesis have wider implications for future research exploring recruitment and retention issues in DHI trials, and more so, for research trials in general. These are discussed below. Comparing work packages two and three highlighted that trial participation involves weighing up decisions by the service users and service providers, rather than either the service user or service provider alone. What was apparent for both was the weighing up of the perceived credibility and benefits of trial participation was largely mediated by the role of the study research team. This personal effect was important in determining both participation and engagement in the trial.

The findings from work packages two and three recognise the role of initial perceptions about a trial in terms of acceptability and its influence on the decision to participate, but also in terms of remaining in the trial. The TFA framework (Sekhon et al., 2017) argues that acceptability is an important aspect to consider when designing, evaluating and implementing a complex health care trial, because it can impact on whether a patient or health care provider decides to take part in an intervention (recruitment), and will also

influence whether or not they continue to utilise the intervention (retention). One significant aspect of the TFA framework is its acknowledgment that acceptability encompasses various facets, reflecting how individuals delivering or receiving a healthcare intervention perceive its appropriateness based on their cognitive and emotional responses. From a service user's perspective if the content, context and quality of care received is perceived to be acceptable, they are more likely to adhere to intervention and benefit from it (Hommel et al., 2013). For health care providers, if an intervention is perceived to be acceptable by themselves and their patients, they are more likely to approach patients about the intervention and be involved in the trial which has an overall impact on the effectiveness of the trial (Proctor et al., 2009). The findings from the thesis reinforce the TFA framework conclusions, because aspects such as affective attitude, intervention coherence and perceived effectiveness were commonalities found in work packages two and three and influenced service provider and service user decisions to take part in the Urgent Care trial. Furthermore, these aspects also influenced retention to the trial. For service providers this resulted in a higher number of referrals being made, whereas for service users, it increased the likelihood of completing RCBT sessions or follow-up assessments.

In relation to this study, low expectations about the relevance of the Urgent Care trial were likely to lead to service providers not approaching patients about the trial. Service users who were less optimistic about trial expectations were more likely to discontinue RCBT sessions or withdraw completely from the trial. The data from the interviews also acknowledges that initial expectations about the trial (anticipated acceptability) was not fixed and could change based on experiences gained (experienced acceptability). For some service providers and service users, initial apprehensions about acceptability were overturned after discussions with the study researchers. This highlights the key role the trial research team plays in actively and continually negotiating the ongoing activity of recruitment and retention, and the mediating role researchers can have in influencing expectations about a trial.

However, despite service provider fears and perceptions about patient readiness to consider a study about health anxiety, work package three found that service users attitudes towards the research and the trial were more positive than service providers. This has implications for future research studies, because as described in Chapter Six, service providers are often the gatekeepers to service providers becoming aware of research and trial participation.

The TFA provides a theoretical lens through which to understand and assess the factors that influence the acceptance or perceived acceptability of a trial from a service provider and service user perspective. In the context of recruitment and retention in health care trials, the acceptability of a trial has implications for service providers and service users. The constructs proposed by the TFA framework offers an understanding of identifying the facilitators and barriers to recruitment and retention in the following ways. Considering the affective attitude of service providers and service users enables an understanding to be gained of how their initial emotional responses and feelings about a trial may influence the decision to participate. The analytical construct of intervention coherence is applicable here to focus on the clarity of the trial, and in turn has implications for recruitment because to decide whether to participate in a trial both service providers and service users need to understand the rationale of the trial and what the intervention consists of. The TFA burden lens is applied to this dataset to understand aspects of workload and inconvenience associated with trial participation, both of which have been seen to impact recruitment and retention narratives. Perceived Effectiveness assesses service provider and service user perceptions regarding the potential impact of the trial, this also has implications for recruitment and retention.

The barriers and facilitators to recruitment and retention can also be understood through the lens of the DOI theory. In deciding whether to take part in a trial, service providers and service users need to understand the rationale of the study to determine its relevance to them. From there, they need to comprehend the trial processes, and the commitment required before agreeing to participate in the trial. The decision to remain in the trial

and actively engage with trial requirements is determined by service provider and service user perceptions about the trial. Each of these key processes are influenced by several factors that affects how service providers and service users progress through the trial participation journey As suggested by Rogers (Rogers, 2003), the communication channels, the perceived relevance of the intervention, the characteristics of the service providers and service users who could both be regarded as consumers of the intervention, and the social system, all contributed towards recruitment and retention for the Urgent Care trial.

Whilst the NPT framework provides and understanding of why service providers decided to participate in the Urgent Care trial and refer patients and some elements of the NPT theory can inform recruitment and retention, it is insufficient for a full understanding of the recruitment and retention issues from a service user perspective. The NASSS primarily framework focuses on why technologies may not be adopted. The findings from this doctoral thesis emphasise that recruitment and retention to the trial was not influenced much by the DHI aspect and was related more to other aspects such as communication of trial information and perceived costs associated with trial participation.

In bringing together the novel knowledge contribution of this doctoral study, Figure 6 illustrates how incorporating elements from various theoretical models allows for the comprehensive consideration of recruitment and retention from a service user and service provider perspective. Figure 7 offers a new conceptual framework through which to understand recruitment and retention to an RCT in primary and secondary care. Figure 7 combines the elements from the theoretical models and integrates additional aspects uncovered by the thesis which are the novel theoretical contributions of my thesis. These frameworks serve as useful heuristics to help researchers think through key recruitment and retention aspects that merit attention. The frameworks also highlight the next steps that could contribute towards the further development of a conceptual model of factors influencing recruitment and retention to DHI trials. Further exploration of these aspects will be

necessary to determine the relative importance of the different elements of the conceptual framework.

The key findings from this doctoral thesis also address the research priorities identified by the Prioritising Recruitment in Randomised Trials study (PrioRiTy) (Healy et al., 2018) in relation to recruitment and retention. The thesis has demonstrated the value of qualitative research in helping to provide the necessary evidence to guide researchers on how to improve the process of recruitment and retention in randomised trials which persists as a challenge to trialists.

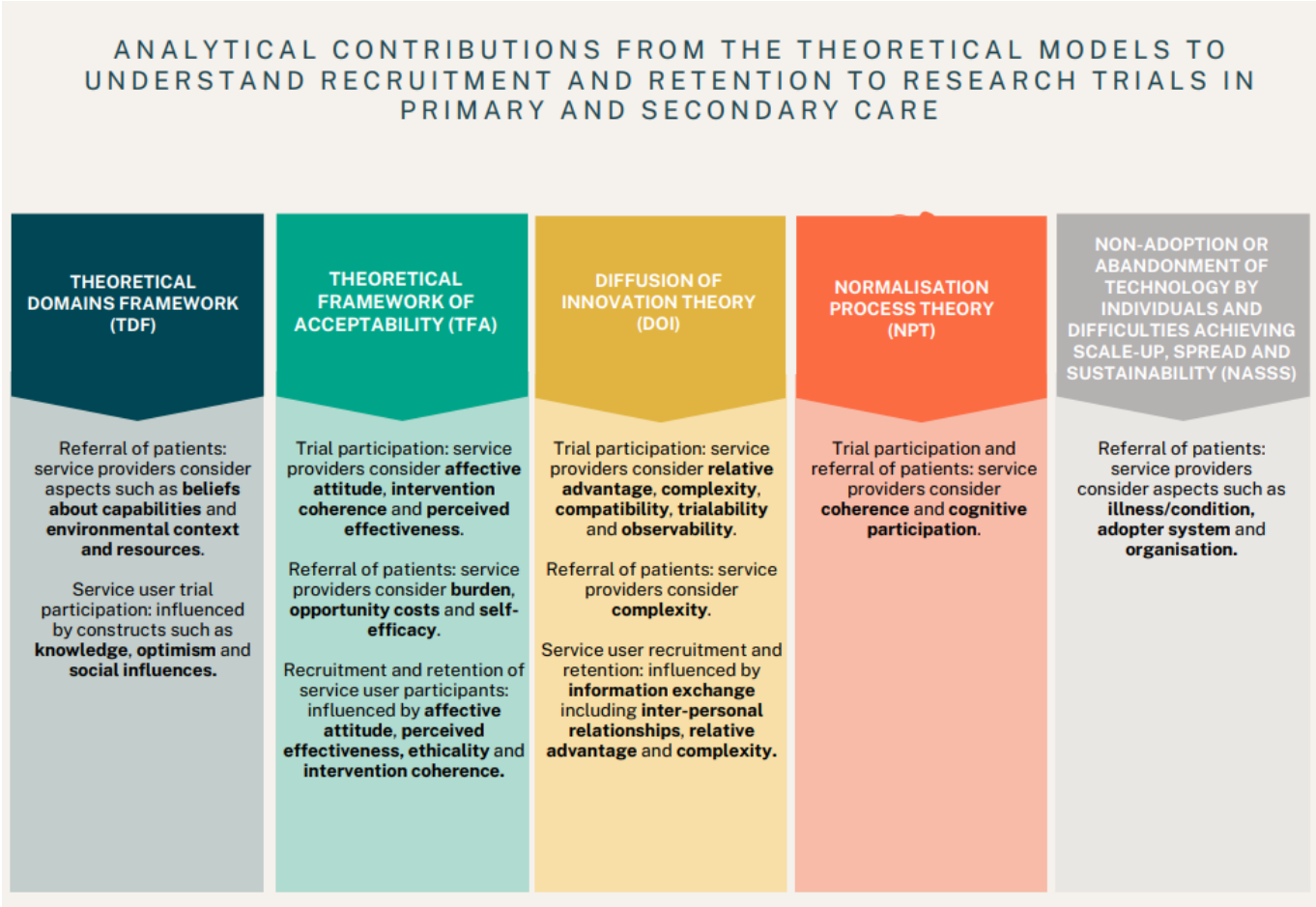

Figure 6 Analytical contributions from theoretical models

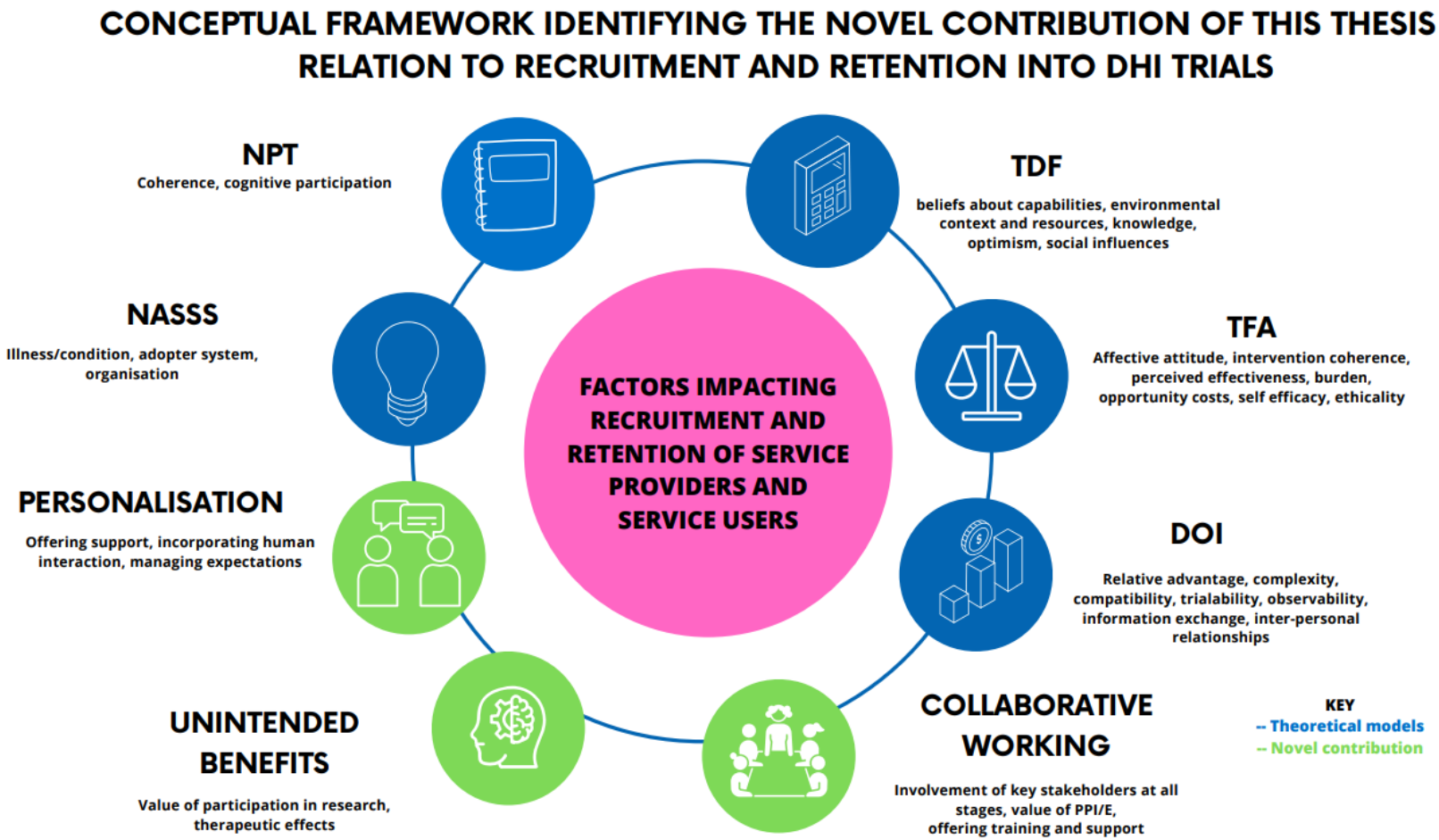

Figure 7 Conceptual framework identifying the novel contribution from this thesis

The themes identified within the doctoral thesis maps onto the following 10 questions related to recruitment in trials.

Table 22 Mapping of themes onto PrioRiTy questions in relation to recruitment to trials

Questions identified by PrioRiTy	**How it mapped onto doctoral study themes**	**Recommendations**
What information should trialists communicate to members of the public who are being invited to take part in a randomised trial in order to improve recruitment to the trial?	**Service provider understanding and perceived credibility of the trial over existing interventions.** **Initial perceptions and its impact on motivation to participate.**	Trial information should be communicated clearly and concisely to service providers and service users outlining the trial's purpose, emphasising trial rationale, participation benefits, and study processes. Regularly share study updates with service providers and service users through newsletters, infographics, study meetings.
What are the best approaches for designing and delivering information to members of the public who are invited to take part in a randomised trial?	**Service provider understanding and perceived credibility of the trial over existing interventions.** **Perceived benefits and costs of trial participation.** **Risk of the trial to service provider-patient relationship.** **Initial perceptions and its impact on motivation to participate.** **Perceived credibility of the intervention over existing treatment pathways.**	Incorporate early and meaningful PPI/E involvement to ensure trial information such as advertisement documents and participant information sheets and trial processes are acceptable to service providers and service users prior to submission of study documents for ethical approvals.

What are the barriers and enablers for clinicians/health care professionals in helping conduct randomised trials?	**Service provider understanding and perceived credibility of the trial over existing interventions.** **Perceived benefits and costs of trial participation** **Risk of the trial to service provider-patient relationship.**	Involve service providers in designing the trial to ensure simplicity of trial procedures and protocols. Discuss study processes with service providers to ensure that workload is kept to a minimum. Ask service providers about their concerns in approaching participants or delivering the study at an early stage. Provide training to service providers so that they have knowledge and confidence to approach patients and consent them.
What are the key motivators influencing members of the public's decision to take part in a randomised trial?	**Service provider understanding and perceived credibility of the trial over existing interventions.** **Initial perceptions and its impact on motivation to participate** **Perceived credibility of the intervention over existing treatment pathways**	Provide clear detail on the nature of trial, the interventions and what is expected from service providers and service users. Discussions between study researchers and study participants are important in clarifying trial information as this could help manage expectations. Involving some form of human communication even if the trial is a DHI can help build rapport and

		clarify trial protocols and processes.
What are the best approaches to ensure inclusion and participation of under-represented or vulnerable groups in randomised trials?	**Risk of the trial to service provider-patient relationship.** **Initial perceptions and its impact on motivation to participate** **Perceived credibility of the intervention over existing treatment pathways**	Ask service providers to highlight any challenges to including these groups and how they might be overcome. Offer researcher support in explaining study processes and setting up DHIs. Consider how initial trial information is conveyed to service users, including the choice of wording and whether verbal or written communication is more appropriate. Co-develop recruitment documents with PPI/E representatives and adapt them to different groups. Consider compatibility aspects such as language barriers and whether translation of documents or an interpreter may be required.

The themes uncovered in the doctoral thesis align with the following 10 questions pertaining to retention.

Table 23 Mapping of themes onto PrioRiTy questions in relation to retention to trials

Questions identified by PrioRiTy	**How it mapped onto doctoral study themes**	**Recommendations**
What motivates a participant 's decision to complete a clinical trial.	**Research related aspects and its impact on therapy and questionnaire completion**	Ask service users about their initial expectations about the trial and their understanding of study rationale and processes. Highlight therapeutic benefits of trial participation for both groups such as gaining knowledge and skills. Emphasise why trial completion is important when the study is first explained.
How can trials be designed to minimise burden on staff and participants and how does this affect retention	**Perceived benefits and costs of trial participation.** **Risk of the trial to service provider-patient relationship.** **Research related aspects and its impact on therapy and questionnaire completion**	Explain from the outset what is expected from service providers and service users discuss if this fits with their other demands. Simplify trial and data collection processes so that they are least burdensome. Offer flexibility and choice in terms of referral approaches for staff and how data is collected from participants.
What are the best ways to encourage trial participants to complete	**Research related aspects and its impact on therapy**	Enhance data completion options such as recording preferences for how

the tasks (e.g. attend follow-up visits, complete questionnaires) required by the trial.	**and questionnaire completion**	participants wish to complete outcome measures at the initial contact. Contact with a researcher albeit remotely can facilitate data collection. Where possible, ensure researcher continuity and flexibility.
What are the most effective ways of collecting information from participants during a trial to improve retention.	**Research related aspects and its impact on therapy and questionnaire completion**	Highlight the importance of data in research. If resources allow, consider researcher led data collection. Reminder texts from researchers may facilitate data completion. Simplify data collection processes and provide choice. Monitor data collection regularly and seek feedback from service providers and service users on challenges experienced in data collection and modify strategies.
How does a participant 's ongoing experience of the trial affect retention.	**Research related aspects and its impact on therapy and questionnaire completion**	Initial expectations and experiences of trial participation needs monitoring throughout the trial participation to overcome any challenges. Recognise the importance of the role of study researchers.

What information should trial teams communicate to potential trial participants to improve trial retention.	**Perceived benefits and costs of trial participation.** **Research related aspects and its impact on therapy and questionnaire completion**	Provide clarity of trial processes from the outset and seek participant views on any concerns they may have when deciding to participate. Highlight the importance of the research and data.

Implications of thesis and recommendations

Each key finding and the consequences for implementation will be discussed, and recommendations made for further research.

1. Effective communication of trial processes

As this thesis has shown, the communication of information was integral in shaping initial perceptions about the trial, which then ultimately influenced not only service provider and service user decisions to participate in the trial (recruitment) but also how much they engaged with the trial (retention). The initial approach by the research team was key in influencing whether service providers decided to participate in the trial and if they approached service users. It is therefore recommended that service providers and service users are provided with clear and concise information about the rationale of the trial and study processes. This will facilitate study understanding and emphasise the benefits of trial participation.

In terms of communication of information, this thesis showed that service providers and service users expressed a preference for regular study updates, which was important in terms of continuing and consolidating their engagement. Therefore, it is recommended that research teams provide study updates to recruiting sites and study participants throughout the study, not just when data analysis has been completed and the study is in a reporting phase. This could be in the form of newsletters or written or audio infographics. The costs of this dissemination activity should be in funding applications and not overlooked.

2. Managing expectations

This thesis reiterated findings from prior literature regarding how understanding the significance of a trial and existing beliefs about the effectiveness of an intervention can impact recruitment and retention. Therefore, addressing these expectations when introducing a trial, or building this into the initial conversations would help manage any misconceptions and address early recruitment barriers. Responding to recruitment barriers could aid engagement and, in turn, based on the experience of this study, lead to improved retention rates.

Researchers should consider how the design of their trial may contribute to non-recruitment and non-retention through initial and ongoing discussions (coproduction) with service providers and service users and where possible, modify the trial design or processes to improve recruitment and retention experiences. Researchers should dedicate additional time to speak to the participants and listen to their experiences (thus designing in-engagement, and by virtue retention, from the start of the research study). Underlying beliefs, preferences and expectations from service providers and service users about trial participation should be explored and unpacked fully during initial discussions. Providing more detail on the nature of the trial interventions and what can be expected by 'participation' (for example, when and how data will be collected) at the consenting stage may prove helpful to manage expectations.

It is also important to note that a remotely delivered intervention was not deemed to be suitable for all. The Covid-19 pandemic has led to an increase in the provision and acceptance of DHIs. However, this more routine use of DHIs may have also led to a greater digital divide due to aspects such as access to and confidence in using DHIs (Clayton et al., 2023). Therefore, it is especially important to understand the barriers for underserved populations such as older people, ethnic minority groups and those with hearing difficulties and address how they may be overcome, so that health care

research interventions are trialled on the diverse population that our health service serves.

3. The importance of incorporating human support in research trials

This thesis highlighted the significance of building human support into research trials, even if it included a DHI. Service user participants in both the RCBT and TAU arm acknowledged the importance of building a rapport with the study researchers and therapists. This can be advantageous in terms of improving recruitment and retention to DHI trials. Human support facilitates understanding generally, but particularly in underserved populations such as individuals with mental health conditions where misconceptions about the trial purpose can discourage participation and those from ethnic minority groups or older people or who may require additional support in understanding and using DHIs.

The thesis findings reinforce the existing literature base, and shows that a blended research delivery strategy, combining both human and digital approaches is advantageous and can offer the optimal model for DHI delivery (Clayton et al., 2023, Riadi et al., 2022, Iflaifel et al., 2023). The data also supports the notion that a strong therapeutic alliance can be formed online, despite fears that DHIs remove the human element of the care interaction. The data highlights the need for a blended human/online approach particularly in overstretched, underfunded services and for research focusing on underserved populations.

Based on the findings from this doctoral study it is recommended that to improve recruitment and retention rates, DHIs should incorporate some form of human support in their trials. This can be remotely provided and should consider aspects such as offering continuity and flexibility. Taken together, this doctoral study recommends that human connection is a vital and valued ingredient for research engagement, and that all DHI trials should include some form of human contact to improve recruitment and retention rates. It also highlights the importance of building rapport and the key role the research staff can play in improving recruitment and retention in DHI research.

4. The unintended benefits of trial participation

A novel finding of this doctoral thesis is the apparent therapeutic effect of participation from service users who were allocated to the TAU group. This research suggests something happening beyond a placebo effect – which might be particularly pertinent for patients with health anxiety who can feel like their symptoms are being dismissed by health care professionals. Participation in the Urgent Care trial legitimatised their symptoms and provided a sense of hope and being listened to. It gave a label to symptoms and behaviour, and enabled sense-making. This may have led to the improved outcomes on the assessments for both groups. In this respect the trial being a DHI was not significant, and the study findings are applicable to trials in general and not DHIs alone.

Key strengths and limitations

There are several strengths with the design of this nested doctoral qualitative study. This is the first piece of work to have qualitatively explored factors influencing recruitment and retention to a trial consisting of videoconferencing as a format of a DHI for patients with health anxiety. As such, it has provided a much-needed opportunity for transferring knowledge to research groups in an area that lacks prior exploration. Qualitative studies enable a more in-depth understanding of human experience, yet in the existing literature base, there is a clear absence of studies qualitatively exploring factors influencing recruitment and retention to trials generally, and specifically in relation to health anxiety and related disorders.

Nested qualitative research in RCTs can facilitate a deeper, contextual understanding of quantitative findings, providing an important background or context in which to interpret findings. The PhD explored the views of both service providers and service users, and in doing so, it offers a holistic approach to understanding factors associated with recruitment and retention to DHI in both routine clinical practice and in research settings, by exploring it from the position of the service provider and the recipient of the intervention. By including these two stakeholder groups, this doctoral study provides novel

and important insights into the individual differences, which drive recruitment and retention into a trial.

The study found the way in which trial information was communicated to service providers and service users was integral in determining whether they decided to participate in the trial. When deciding to participate in the trial, psychosocial barriers were more important to service users than barriers specifically related to the DHI, such as technological competence or the functionality of the DHI, although this may be because all the participants who were interviewed decided to participate in the trial.

Despite the novel contribution of this thesis, it is however important to note some limitations which should be considered when interpreting the findings of this study. Service users who were discouraged from participating in a DHI may have also chosen not to participate in the trial and therefore, their views may be under-represented. This however is not a limitation restricted to this work, but to all research studies undertaken.

All participants who declined to participate in the Urgent Care trial were invited to be interviewed for the thesis. They however either declined this invitation or did not respond. Thus, the study participants represent a treatment-seeking sample, and the present findings may therefore be prone to selection bias. The participants interviewed were people who agreed to participate in a qualitative study, from a group that had already consented to participate in the Urgent Care trial, and who were regularly accessing unscheduled health care services for their symptoms. Therefore, this group was likely to be more open to participate in research consisting of a DHI for treating health anxiety and may have been different from those who did not wish to participate in research. This is evident in the reported emphasis placed on research value as an important reason for completing therapy or outcome measures. However, a strength of the thesis is that the interview sample consisted of service users who had not completed the intervention, or outcome measures or who had withdrawn from the intervention or the trial, which allowed for an exploration of the barriers for individuals who do not persist with the treatment or trial. Future research would benefit from

interviewing participants who declined trial participation from the outset to understand their reasons for doing so.

The sampling strategy employed was purposive due to the nested nature of the research within the wider trial, whereas a more theoretical sampling strategy may have led to different observations. Nevertheless, the purposive sampling approach was considered appropriate for this piece of pragmatic applied health services research, which was not focussed on 'theory building' but more generally, designed to mirror delivery in routine care should the intervention ever be adopted into care services. By employing a purposive sampling approach, the thesis aimed to achieve variation in the ages, geographical locations and adherence levels of study participants. While participants were recruited from sites across in the East Midlands, ethnic minorities were underrepresented when compared to regional statistics on population characteristics (Khunti et al., 2009). The sample was predominantly female and from a White background. This is consistent with the trial population, suggesting the doctoral study sample is representative of the wider trial. Had it been possible to include the views of individuals from different ethnic backgrounds, this may have contributed substantially to informing culturally relevant and sensitive care, which was something highlighted in interviews with service providers. This criticism is increasingly offered to much of health care research (Khunti et al., 2017, Willis et al., 2021) and why approaches such as building in equality and diversity issues into research practice has recently come to the fore in the Equality, Diversity and Inclusion Strategy 2022-2027 (Authority, 2022) Finally, there were some minor differences between the interview and the trial samples. A slightly older age was observed in the RCBT interview sample, and a higher rate of unemployment for both service user groups. The interview sample may therefore not be fully representative of those who took part in the trial and may suggest that research engagement is also associated with capacity and availability to participate.

Being both the main trial researcher responsible for conducting baseline and follow-up assessments, and the doctoral researcher conducting qualitative interviews with service users presented some logistical challenges that had

to be built into the research management. Due to risk of unblinding the trial participants, the doctoral study interviews took place twelve months after the service user participants had participated in the trial, and after the final follow-up assessment had been collected. This meant that that interviews relied on participants' recollections and memories of their decision-making processes to participate in the trial and their experiences of trial participation. Participants may have struggled to recall reasons for recruitment and retention and were likely influenced by their present situation in making sense of their experiences retrospectively.

Another potential limitation linked to this dual role was that most of the service user participants interviewed (n=20) had completed baseline and follow-up assessments with me, and this may have influenced their responses. However, it is also possible that this familiarity in fact had a positive influence, as it built rapport given that I was known to them, and that this existing research-based relationship facilitated participants' willingness to discuss their experiences. The varied views expressed by the interviewees go some way to negating this concern about the dual aspect of my role, as do the similarities in responses from participants with whom I had no prior contact. While there was a potential risk of compromising objectivity, the establishment of a semi-structured interview topic guide, coupled with discussions involving three supervisors and collaboration with PPI/E representatives, instils confidence in the analytical rigor.

Nesting a qualitative exploration of service provider views within this trial enabled the PhD to gain a critical insight into the potential challenges faced by service providers when deciding to become involved in a trial and refer patients. Embedding a nested study within the Urgent Care trial enabled exploration of service providers actual experiences of being involved in and referring patients to the trial rather than questioning them about hypothetical challenges to recruitment of patients. Nonetheless, there are some issues inherent in the doctoral study that may have influenced the nature of the data that were collected. Firstly, there was a time lag of over 24 months between the end of participant recruitment and the start of service provider interviews. This may have resulted in recall bias influencing the data, especially when

discussing the specific detail regarding involvement in the trial and referring patients. As previously discussed, my role as the lead researcher on the Urgent Care trial may have influenced service providers willingness to discuss their thoughts regarding the trial openly. Although this may have influenced the discussions in some cases, it is unlikely to have had a significant impact upon the data; several service providers were explicit about negative aspects of their experiences. The sample consisted of service providers from primary and secondary care and of those who did and did not refer patients to the trial ensuring that a range of views were represented. Some service providers had limited time available, with some interviews lasting 20 minutes resulting in less rich data. Despite the lack of depth, however, some interesting and unexpected findings came out of the interview data which enables the contribution of novel knowledge to the current literature and evidence base. The thesis conclusions therefore are reasonably transferable to other primary and secondary care-based trials involving not only patients with anxiety symptoms but are also likely be relevant to trials in other areas of medicine. Generic trial strength and limitations highlighted by service providers could apply to primary care and secondary care trials such as clinical workload and randomisation and need not only be limited to mental health.

Whilst this doctoral study explored factors affecting recruitment and retention to the Urgent Care trial from a service provider and service user perspective, I did not systematically try to apply a specific model or approach to implementation or use an existing theoretical to inform data collection or analysis. It could be argued that a formal process evaluation method, or applying an existing theory may have offered a greater or different insight into the findings, but I took this approach because as discussed in Chapter Five, I wished to adopt an inductive data collection approach, while also being restricted in terms of available resources and timescales.

Original/Unique contribution to knowledge

One purpose of a PhD is to provide a unique or novel contribution to knowledge in a given field of work. This doctoral study meets this objective in several nuanced ways. The studies in this thesis span the fields of recruitment and retention into health care trials, and their relation to DHIs and health anxiety. This thesis presents contemporary evidence relating to the decision-making processes involved in participating and remaining in a trial from the perspective of service providers and service users. Previous studies have described barriers and facilitators to recruitment to clinical trials and user experience of DHIs. However, none have explored recruitment and retention or qualitative experiences of DHIs in relation to health anxiety, as demonstrated by no studies being identified in the systematic review (Chapter Four). Furthermore, there have not been any new qualitative studies published in relation to health anxiety and DHIs since the review was originally conducted. This doctoral study therefore provides an in-depth of insight into the experiences of service providers and service user participation that has not been provided elsewhere.

This doctoral study demonstrates the interplay of factors influencing recruitment and retention from a service provider and service user perspective, and sheds light on the role of the research team in mediating these factors. The findings indicate that recruitment and retention should not be viewed as individual entities, but that aspects influencing recruitment can in turn impact upon retention.

The theoretical contribution of the doctoral study is that it provides support for the contemporary relevance of Rogers's Diffusion of Innovation theory, and Sekhon's TFA framework. Both offer value and analytical insight in considering the role of the characteristics of the service providers and service users, and the perceived characteristics of the intervention involved in a trial and its impact on the decision to participate in a trial (recruitment) and continuing to engage with it (retention). They also highlight the role of interpersonal relationships and how this can be mediated by the trial research team.

Although the doctoral study highlights the potential barriers and facilitators to recruitment and retention, it is important to emphasise that the Urgent Care trial was deemed to be a success. The trial achieved its recruitment target, with a high retention rate, and the intervention was also found to be clinically and cost effective. Therefore, it is possible that the findings from this doctoral study may have been different had the trial been considered unsuccessful, as this would likely have yielded different views from participants. This begs the question: what constitutes as being a successful trial? Is a trial considered successful only if its intervention is found to be clinically and cost-effective, or is a trial deemed to be successful if it reaches its target recruitment and retention rates? Can a trial still be successful and of value if the intervention is not found to be effective, but the participants express that they benefitted from trial participation? This doctoral study highlights the benefits of trial participation and its therapeutic benefits, in particular for the TAU group. Despite the TAU group not receiving the intervention, they reported benefits from participating in the trial. This included aspects such as the therapeutic benefits of completing outcome assessments and receiving regular contact from a researcher. This highlights the placebo or non-specific effects and how the rituals of participating in a trial can be beneficial and therapeutic in and of themselves.

It is important too to acknowledge that the Urgent Care trial completed recruitment and that data collection for the doctoral study commenced prior to the Covid-19 pandemic. Since the Covid-19 pandemic, there have been changes to practice with an increase in the use of remotely delivered interventions. Service providers and psychological treatment therapists now offer a large part of health care remotely, with videoconferencing being an important form of delivery of GP treatment and even more so of psychological treatment which poses additional engagement challenges. As a result of this normalisation of remotely delivered health care, it is even more important than ever to ensure that the ‘human’ relational element of research trials is maximised for their potential effect on recruitment and retention activities. Furthermore, given that most trials still necessitate health care providers to identify and approach appropriate patients, the results of

this doctoral research are likely to be even more relevant to current trials than to those conducted in the past.

Overall recommendations

Communication of trial information

Study research teams need to recognise the way in which trial information is communicated to referring sites and potential participants, and how this plays a key role in determining study participation.

1) To recruit service providers research teams should build rapport and trust, maintain existing relationships, and publicise the research and rapport to ensure that sites engage in the trial, and actively participate by referring patients to the research.
2) It is important that research teams recognise the importance of engaging sites and factor this into the planning stage.
3) When explaining a trial, it is important to consider the intended audiences (e.g. potential participants, clinicians, regulators, ethics committees, the public) and tailor the information appropriately. Consideration of aspects such as: what does this audience already know about the research area, what information is most likely to be of interest and relevant to them and what sort of language and format are appropriate to communicate with the intended audience.
4) There also needs to be focus on the informed consent process and how this could be sought to avoid overloading potential participants with unnecessary information, but also ensuring that the information provided is sufficient to enable them to make an informed decision about trial participation.
5) Research teams may want to produce a FAQ's video for recruiting sites and potential participants to explain the trial rather than the provision of written information which can be overwhelming.
6) Regular communication between sites and the trial teams is integral, it may help to allocate research members to different sites so that site teams have a dedicated person to contact with any queries.

7) Recruitment from sites may be facilitated by holding healthy competition between sites, this could be in the form of league tables or offering incentives such as prize draws.
8) Arrange regular meetings and written updates for everyone involved in the trial, including referring sites, CRN teams and other researchers.

Collaborative working with all stakeholders – going beyond PPI/E

The findings highlighted that in health care research, recruitment of service user participants is a two-stage process, firstly involving the recruitment of service providers who then inform service users about ongoing trials. Therefore, service providers are key in providing access thereby facilitating recruitment of trial participants.

1) Prior to commencing a trial, it is important to involve service providers in your project proposal and design so that any initial perceived barriers can be addressed.
2) By working in collaboration with service providers, optimal recruitment strategies can be devised which are likely to yield better uptake and engagement from service providers.
3) Likewise, the importance of PPI/E in designing and delivering RCTs is increasingly recognised and should be considered essential. Involving PPI/E representatives as early as possible involving them from the inception of trial through to dissemination is essential. PPI/E involvement can support researchers by helping to ensure that research is acceptable to participants and in a format and language that is accessible to participants. that can be easily understood.

Offering training and support to service providers/recruiting sites

Data analysis illustrated that service providers varied in their perceived ease or difficulty of approaching patients about the trial. This was related to their understanding of the Urgent Care trial and remembering to introduce the trial, clinical perceived relevance of the trial and their perceived patient readiness. The value of research in improving understanding and treatment of illness needs to be highlighted and prioritised, but it also important to

consider the care context into which the research is being conducted in and ask if it is the right place for that research.

1) Service provider trial participation and likelihood of referring patients may be enhanced through improved knowledge of the trial, trial criteria, knowing how to introduce the study and what to say to patients.
2) Research teams should offer training and offer advice on how to introduce research into consultations as it can be particularly difficult in consultations for mental health problems.
3) Additional training may also enable service providers to accurately provide information about trials, because initial expectations about the trial may be misunderstood by service users resulting in non-participation or participating for the incorrect reasons.
4) Additional time to conduct research also needs to be considered because at present there is not protected times for research related activities which may improve patient outcomes. The Department of Health, the General Medical Council (GMC) and other professional bodies could implement policies, for example using the QoF or GMC guidance on conduct and training, that could significantly influence the culture surrounding research participation in the UK.

Future research

Rogers' Diffusion of Innovation model (Rogers, 2003) and the TFA framework proposed by Sekhon et al (Sekhon et al., 2017) provides some insight into how the five stages in the innovation decision process can influence recruitment and retention. Addressing some of these aspects could result in improved recruitment and retention rates. This could benefit research and improve trial participation and needs to be developed further to aid recruiters. Further research in several areas would be beneficial:

1) The five characteristics of the innovation determined to be most influential for the adoption of an innovation as proposed by Rogers are: relative advantage, compatibility, complexity, trialability, and

observability need further exploration. The influence of interpersonal communication and relationships also needs to be further explored.

2) The constructs of the TFA framework need further exploration in terms of how each construct impacts on acceptability, and the extent to which this determines recruitment and retention rates from a service provider and service user perspective. It would also be useful to explore the concepts of anticipated and experienced acceptability and whether research teams could influence anticipated acceptability and the impact this has on recruitment and retention.
3) A trial testing different ways of communicating trial information could be explored. This could include written information and the use of videos to explain trial information to service providers and service users. This would have the potential to identify if certain formats influence recruitment. This would allow trialists to identify what approaches work best when recruiting participants to trials.
4) Further research into the development of specific training for service providers on communicating the research to potential participants and identification of the most appropriate format for this training.
5) Research teams should consider building in additional qualitative research during trial set-up. Ethnographic research including interviews and observations could be used to gain a contextual understanding of how recruiting sites usually work in practice and anticipate the challenges to being involved in research. This would also enable the designing in of 'real-world' utilisation into trial, and aid future implementation and usage of the intervention if it proves clinically effective. Research teams should also consider building in time to reflect on findings from qualitative research conducted during an internal pilot phase of the research, and to implement any changes required. Inclusion of process evaluations in trials may facilitate this.

Chapter summary

Research in health care is critical to evidence-based practice as it enables the establishment of early access to treatments and prevention strategies.

Randomised Controlled Trials (RCTs) are widely regarded as the most powerful research design. However, recruitment to RCTs is often a challenge with only just over half of trials recruiting to within 80% of their target. Low recruitment and high attrition rates continue to be common in RCTs, particularly in primary and secondary care studies. Recruitment in primary and secondary care poses additional challenges due to the characteristics of health care staff, patients, and the nature of the care settings.

Health anxiety is a debilitating condition that can impact on an individual and their family. Treatment for health anxiety consists of psychological treatment and medication. Despite the effectiveness of CBT for the treatment of health anxiety, it is not easily accessible due to long waiting times. Aspects such as stigma of accessing psychological treatment can also deter individuals from accessing talking therapies. DHIs can be overcome these barriers, but there is currently an absence of qualitative research available that provides an understanding of the experiences of DHI trials in individuals with health anxiety.

The evidence from the RCT element of the Urgent Care trial showed that RCBT can be effective in the treatment of health anxiety, resulting in a reduction in health anxiety, depression and anxiety and health care service utilisation. The trial showed that 33% of those referred from primary care and 21% referred from secondary care participated in the trial, indicating that there are clear recruitment barriers at service provider and service user levels. In addition, the trial illuminated that even after the decision to take part in a trial is made there may be retention barriers at service provider and service user level. The qualitative findings shed light on the facilitators and barriers to recruitment and retention and provide a deeper insight into the reasons for why service providers and service users may decide not to engage in a trial consisting of a digital health intervention.

The recruitment of adequate numbers of participants is a challenge faced by many trials. This seems to be especially problematic in primary and secondary care. This thesis has provided evidence that supports the existing

literature and has also identified additional factors that have not been considered before. The Urgent Care trial completed recruitment in 2016. Post Covid-19, most psychological therapy is offered online using videoconferencing. Service providers and service users are more familiar and accustomed to using remote consultations in health care. There is also greater choice in terms of the videoconferencing platforms such as Microsoft Teams and Zoom, both of which are widely used by health care professionals, service users and researchers.

However, most health care trials in primary and secondary care settings still require service providers to identify and refer patients, which means that the findings of this thesis remain relevant to trials being carried out today. Furthermore, the findings highlight that many of the factors that impact on recruitment and retention into DHI trials can be applied to both face-to-face and remotely delivered health care intervention trials. Future research should take these into account.

References

ABIMBOLA, S., PATEL, B., PEIRIS, D., PATEL, A., HARRIS, M., USHERWOOD, T. & GREENHALGH, T. 2019. The NASSS framework for ex post theorisation of technology-supported change in healthcare: worked example of the TORPEDO programme. *BMC medicine,* 17**,** 233-233.

ABSHIRE, M., DINGLAS, V. D., CAJITA, M. I. A., EAKIN, M. N., NEEDHAM, D. M. & HIMMELFARB, C. D. 2017. Participant retention practices in longitudinal clinical research studies with high retention rates. *BMC Medical Research Methodology,* 17**,** 30.

ADHABI, E. & ANOZIE, C. B. 2017. Literature review for the type of interview in qualitative research. *International Journal of Education,* 9**,** 86-97.

ADVOCAT, J. & LINDSAY, J. 2010. Internet-based trials and the creation of health consumers. *Soc Sci Med,* 70**,** 485-492.

ALBERTS, N. M., HADJISTAVROPOULOS, H. D., SHERRY, S. B. & STEWART, S. H. 2016. Linking Illness in Parents to Health Anxiety in Offspring: Do Beliefs about Health Play a Role? *Behav Cogn Psychother,* 44**,** 18-29.

AMERICAN PSYCHIATRIC ASSOCIATION, D. & ASSOCIATION, A. P. 2013. *Diagnostic and statistical manual of mental disorders: DSM-5*, American psychiatric association Washington, DC.

ANDERSSON, G. & CUIJPERS, P. 2009. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. *Cogn Behav Ther,* 38**,** 196-205.

ANDERSSON, G. & HEDMAN, E. 2013. Effectiveness of Guided Internet-Based Cognitive Behavior Therapy in Regular Clinical Settings. *Verhaltenstherapie,* 23**,** 140-148.

AROMATARIS, E. & MUNN, Z. 2020. JBI systematic reviews. *The Joanna Briggs Institute*.

ASMUNDSON, G. J. G., ABRAMOWITZ, J. S., RICHTER, A. A. & WHEDON, M. 2010. Health Anxiety: Current Perspectives and Future Directions. *Current Psychiatry Reports,* 12**,** 306-312.

ASSOCIATION, A. P. 2000. Diagnostic and statistical manual of mental disorders. *Text revision*.

ATKINS, L., FRANCIS, J., ISLAM, R., O'CONNOR, D., PATEY, A., IVERS, N., FOY, R., DUNCAN, E. M., COLQUHOUN, H., GRIMSHAW, J. M., LAWTON, R. & MICHIE, S. 2017. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implement Sci,* 12**,** 77.

AUTHORITY, N. I. E. 2022. Equality Action Plan.

AXELSSON, E., ANDERSSON, E., LJÓTSSON, B., BJÖRKANDER, D., HEDMAN-LAGERLÖF, M. & HEDMAN-LAGERLÖF, E. 2020. Effect of Internet vs Face-to-Face Cognitive Behavior Therapy for Health Anxiety: A Randomized Noninferiority Clinical Trial. *JAMA Psychiatry,* 77**,** 915-924.

AXELSSON, E. & HEDMAN-LAGERLÖF, E. 2019. Cognitive behavior therapy for health anxiety: systematic review and meta-analysis of

clinical efficacy and health economic outcomes. *Expert Review of Pharmacoeconomics & Outcomes Research,* 19**,** 663-676.
BAILER, J., KERSTNER, T., WITTHOFT, M., DIENER, C., MIER, D. & RIST, F. 2016. Health anxiety and hypochondriasis in the light of DSM-5. *Anxiety Stress Coping,* 29**,** 219-39.
BARNETT-PAGE, E. & THOMAS, J. 2009. Methods for the synthesis of qualitative research: a critical review. *BMC Med Res Methodol,* 9**,** 59.
BARRETT, B., TYRER, P., TYRER, H., COOPER, S., CRAWFORD, M. J. & BYFORD, S. 2012. An examination of the factors that influence costs in medical patients with health anxiety. *J Psychosom Res,* 73**,** 59-62.
BARSKY, A. J., BAILEY, E. D., FAMA, J. M. & AHERN, D. K. 2000. Predictors of remission in DSM hypochondriasis. *Compr Psychiatry,* 41**,** 179-83.
BARSKY, A. J., ETTNER, S. L., HORSKY, J. & BATES, D. W. 2001. Resource utilization of patients with hypochondriacal health anxiety and somatization. *Med Care,* 39**,** 705-15.
BARSKY, A. J., FAMA, J. M., BAILEY, E. D. & AHERN, D. K. 1998. A prospective 4- to 5-year study of DSM-III-R hypochondriasis. *Arch Gen Psychiatry,* 55**,** 737-44.
BARSKY, A. J., WYSHAK, G., KLERMAN, G. L. & LATHAM, K. S. 1990. The prevalence of hypochondriasis in medical outpatients. *Soc Psychiatry Psychiatr Epidemiol,* 25**,** 89-94.
BEATTIE, A., SHAW, A., KAUR, S. & KESSLER, D. 2009. Primary-care patients' expectations and experiences of online cognitive behavioural therapy for depression: a qualitative study. *Health Expect,* 12**,** 45-59.
BENDELIN, N., HESSER, H., DAHL, J., CARLBRING, P., NELSON, K. Z. & ANDERSSON, G. 2011. Experiences of guided Internet-based cognitive-behavioural treatment for depression: A qualitative study. *BMC Psychiatry,* 11**,** 107.
BERGE, L. I., SKOGEN, J. C., SULO, G., IGLAND, J., WILHELMSEN, I., VOLLSET, S. E., TELL, G. S. & KNUDSEN, A. K. 2016. Health anxiety and risk of ischaemic heart disease: a prospective cohort study linking the Hordaland Health Study (HUSK) with the Cardiovascular Diseases in Norway (CVDNOR) project. *BMJ Open,* 6**,** e012914.
BOCHNER, A. P. 2000. Criteria against ourselves. *Qualitative inquiry,* 6**,** 266-272.
BORGHOUTS, J., EIKEY, E., MARK, G., DE LEON, C., SCHUELLER, S. M., SCHNEIDER, M., STADNICK, N., ZHENG, K., MUKAMEL, D. & SORKIN, D. H. 2021. Barriers to and Facilitators of User Engagement With Digital Mental Health Interventions: Systematic Review. *J Med Internet Res,* 23**,** e24387.
BOWER, P., BRUETON, V., GAMBLE, C., TREWEEK, S., SMITH, C. T., YOUNG, B. & WILLIAMSON, P. 2014. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials,* 15**,** 399.
BOWER, P., WALLACE, P., WARD, E., GRAFFY, J., MILLER, J., DELANEY, B. & KINMONTH, A. L. 2009. Improving recruitment to health research in primary care. *Fam Pract,* 26**,** 391-7.
BRAUN, V. & CLARKE, V. 2006. Using thematic analysis in psychology. *Qualitative research in psychology,* 3**,** 77-101.

BRAUN, V. & CLARKE, V. 2019. Reflecting on reflexive thematic analysis. *Qualitative research in sport, exercise and health,* 11**,** 589-597.
BRAUN, V. & CLARKE, V. 2021. *Thematic Analysis: A Practical Guide*, SAGE Publications.
BREWER, M. B. & CRANO, W. D. Research Design and Issues of Validity. 2000.
BRITTEN, N. 1995. Qualitative research: qualitative interviews in medical research. *Bmj,* 311**,** 251-253.
BRITTEN, N., CAMPBELL, R., POPE, C., DONOVAN, J., MORGAN, M. & PILL, R. 2002. Using meta ethnography to synthesise qualitative research: a worked example. *J Health Serv Res Policy,* 7**,** 209-15.
BURR, V. & DICK, P. 2017. Social constructionism. *The Palgrave handbook of critical social psychology***,** 59-80.
CANE, J., O'CONNOR, D. & MICHIE, S. 2012. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science,* 7**,** 37.
CASP, U. 2018. CASP qualitative review checklist. Oxford: CASP UK.
CHAPPELL, A. S. 2018. Toward a Lifestyle Medicine Approach to Illness Anxiety Disorder (Formerly Hypochondriasis). *Am J Lifestyle Med,* 12**,** 365-369.
CHARMAZ, K. 2006. *Constructing grounded theory: A practical guide through qualitative analysis*, sage.
CHAUDHARI, N., RAVI, R., GOGTAY, N. J. & THATTE, U. M. 2020. Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspect Clin Res,* 11**,** 64-69.
CHRISTENSEN, H., GRIFFITHS, K. M. & FARRER, L. 2009. Adherence in internet interventions for anxiety and depression. *J Med Internet Res,* 11**,** e13.
CLAYTON, D., DE VRIES, K., CLIFTON, A., COUSINS, E., NORTON, W. & SEIMS, M. 2023. 'like an unbridled horse that runs away with you': A study of older and disabled people during the covid-19 pandemic and their use of digital technologies. Taylor & Francis.
CONLON, C., TIMONEN, V., ELLIOTT-O'DARE, C., O'KEEFFE, S. & FOLEY, G. 2020. Confused About Theoretical Sampling? Engaging Theoretical Sampling in Diverse Grounded Theory Studies. *Qualitative Health Research,* 30**,** 947-959.
COOPER, K., GREGORY, J. D., WALKER, I., LAMBE, S. & SALKOVSKIS, P. M. 2017. Cognitive Behaviour Therapy for Health Anxiety: A Systematic Review and Meta-Analysis. *Behav Cogn Psychother,* 45**,** 110-123.
COOPER, S., CRAWFORD, M., DUPONT, S., LAZAREVIC, V., NOURMAND, S., PHILIP, A., TYRER, P., TYRER, H. & WANG, D. 2021. Sustained benefit of cognitive behaviour therapy for health anxiety in medical patients (CHAMP) over 8 years: a randomised-controlled trial. *Psychological Medicine,* 51**,** 1714-1722.
CRESWELL, J. W. & CRESWELL, J. D. 2018. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*, SAGE Publications.
CRESWELL, J. W., HANSON, W. E., CLARK PLANO, V. L. & MORALES, A. 2007. Qualitative Research Designs:Selection and Implementation. *The Counseling Psychologist,* 35**,** 236-264.

DAHLBERG, K. & EKEBERGH, M. 2008. To use a method without being ruled by it: Learning supported by drama in the integration of theory with healthcare practice. *Indo-pacific journal of phenomenology,* 8**,** 1-20.
DEALE, A. 2007. Psychopathology and treatment of severe health anxiety. *Psychiatry,* 6**,** 240-246.
DICICCO-BLOOM, B. & CRABTREE, B. F. 2006. The qualitative research interview. *Med Educ,* 40**,** 314-21.
DIEFENBACH, T. 2009. Are case studies more than sophisticated storytelling?: Methodological problems of qualitative empirical research mainly based on semi-structured interviews. *Quality & Quantity,* 43**,** 875-894.
DINGWALL, R. & MILLER, G. E. 1997. Context and method in qualitative research. *Context and method in qualitative research***,** 1-240.
DINGWALL, R., MURPHY, E., WATSON, P., GREATBATCH, D. & PARKER, S. 1998. Catching goldfish: quality in qualitative research. *Journal of Health Services Research & Policy,* 3**,** 167-172.
DIXON-WOODS, M., AGARWAL, S., JONES, D., YOUNG, B. & SUTTON, A. 2005. Synthesising qualitative and quantitative evidence: a review of possible methods. *J Health Serv Res Policy,* 10**,** 45-53.
DONKIN, L. & GLOZIER, N. 2012. Motivators and motivations to persist with online psychological interventions: a qualitative study of treatment completers. *J Med Internet Res,* 14**,** e91.
EILENBERG, T., FINK, P., JENSEN, J. S., RIEF, W. & FROSTHOLM, L. 2016. Acceptance and commitment group therapy (ACT-G) for health anxiety: a randomized controlled trial. *Psychol Med,* 46**,** 103-15.
EILENBERG, T., FROSTHOLM, L., SCHRÖDER, A., JENSEN, J. S. & FINK, P. 2015. Long-term consequences of severe health anxiety on sick leave in treated and untreated patients: Analysis alongside a randomised controlled trial. *J Anxiety Disord,* 32**,** 95-102.
ERBE, D., EICHERT, H. C., RIPER, H. & EBERT, D. D. 2017. Blending Face-to-Face and Internet-Based Interventions for the Treatment of Mental Disorders in Adults: Systematic Review. *J Med Internet Res,* 19**,** e306.
ESCOBAR, J. I., GARA, M., WAITZKIN, H., SILVER, R. C., HOLMAN, A. & COMPTON, W. 1998. DSM-IV hypochondriasis in primary care. *Gen Hosp Psychiatry,* 20**,** 155-9.
ETZELMUELLER, A., RADKOVSKY, A., HANNIG, W., BERKING, M. & EBERT, D. D. 2018. Patient's experience with blended video- and internet based cognitive behavioural therapy service in routine care. *Internet Interv,* 12**,** 165-175.
FAIRBURN, C. G. & PATEL, V. 2017. The impact of digital technology on psychological treatments and their dissemination. *Behav Res Ther,* 88**,** 19-25.
FALLON, B. A., AHERN, D. K., PAVLICOVA, M., SLAVOV, I., SKRITSKYA, N. & BARSKY, A. J. 2017. A Randomized Controlled Trial of Medication and Cognitive-Behavioral Therapy for Hypochondriasis. *Am J Psychiatry,* 174**,** 756-764.
FALLON, B. A., PETKOVA, E., SKRITSKAYA, N., SANCHEZ-LACAY, A., SCHNEIER, F., VERMES, D., CHENG, J. & LIEBOWITZ, M. R. 2008.

A double-masked, placebo-controlled study of fluoxetine for hypochondriasis. *J Clin Psychopharmacol,* 28**,** 638-45.
FALLON, B. A., QURESHI, A. I., SCHNEIER, F. R., SANCHEZ-LACAY, A., VERMES, D., FEINSTEIN, R., CONNELLY, J. & LIEBOWITZ, M. R. 2003. An open trial of fluvoxamine for hypochondriasis. *Psychosomatics,* 44**,** 298-303.
FARRAR, N., ELLIOTT, D., HOUGHTON, C., JEPSON, M., MILLS, N., PARAMASIVAN, S., PLUMB, L., WADE, J., YOUNG, B., DONOVAN, J. L. & ROOSHENAS, L. 2022. Understanding the perspectives of recruiters is key to improving randomised controlled trial enrolment: a qualitative evidence synthesis. *Trials,* 23**,** 883.
FARZANFAR, R., FRISHKOPF, S., FRIEDMAN, R. & LUDENA, K. 2007. Evaluating an automated mental health care system: making meaning of human–computer interaction. *Computers in Human Behavior,* 23**,** 1167-1182.
FERGUS, T. A. & RUSSELL, L. H. 2016. Does cyberchondria overlap with health anxiety and obsessive-compulsive symptoms? An examination of latent structure and scale interrelations. *J Anxiety Disord,* 38**,** 88-94.
FERNÁNDEZ, R., FERNÁNDEZ-RODRÍGUEZ, C., RAFAEL, AMIGO & ISAAC, D. 2005. Characteristics and one-year follow-up of primary care patients with health anxiety. *Primary Care and Community Psychiatry,* 10**,** 81-93(13).
FINK, P., ORNBOL, E. & CHRISTENSEN, K. S. 2010. The outcome of health anxiety in primary care. A two-year follow-up study on health care costs and self-rated health. *PLoS One,* 5**,** e9873.
FINKELSTEIN, A. N., TAUBMAN, S. L., ALLEN, H. L., WRIGHT, B. J. & BAICKER, K. 2016. Effect of Medicaid Coverage on ED Use - Further Evidence from Oregon's Experiment. *N Engl J Med,* 375**,** 1505-1507.
FLEMMING, K. & NOYES, J. 2021. Qualitative Evidence Synthesis: Where Are We at? *International Journal of Qualitative Methods,* 20**,** 1609406921993276.
FLICK, U. 2009. *An introduction to qualitative research, 4th ed,* Thousand Oaks, CA, Sage Publications Ltd.
FONTANA, A. & FREY, J. H. 2005. The interview. *The Sage handbook of qualitative research,* 3**,** 695-727.
FOSTER, J. M., SAWYER, S. M., SMITH, L., REDDEL, H. K. & USHERWOOD, T. 2015. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol,* 15**,** 18.
FRAMPTON, G. K., SHEPHERD, J., PICKETT, K., GRIFFITHS, G. & WYATT, J. C. 2020. Digital tools for the recruitment and retention of participants in randomised controlled trials: a systematic map. *Trials,* 21**,** 478.
FRANCIS, J. J., O'CONNOR, D. & CURRAN, J. 2012. Theories of behaviour change synthesised into a set of theoretical groupings: introducing a thematic series on the theoretical domains framework. *Implement Sci,* 7**,** 35.
GEGA, L., SMITH, J. & REYNOLDS, S. 2013. Cognitive behaviour therapy (CBT) for depression by computer vs. therapist: patient experiences and therapeutic processes. *Psychother Res,* 23**,** 218-31.

GERHARDS, S. A., ABMA, T. A., ARNTZ, A., DE GRAAF, L. E., EVERS, S. M., HUIBERS, M. J. & WIDDERSHOVEN, G. A. 2011. Improving adherence and effectiveness of computerised cognitive behavioural therapy without support for depression: a qualitative study on patient experiences. *J Affect Disord,* 129**,** 117-25.
GLANVILLE, J., BAYLISS, S., BOOTH, A., DUNDAR, Y., FERNANDES, H., FLEEMAN, N. D., FOSTER, L., FRASER, C., FRY-SMITH, A., GOLDER, S., LEFEBVRE, C., MILLER, C., PAISLEY, S., PAYNE, L., PRICE, A. & WELCH, K. 2008. So many filters, so little time: the development of a search filter appraisal checklist. *J Med Libr Assoc,* 96**,** 356-61.
GLENTON, C., COLVIN, C. J., CARLSEN, B., SWARTZ, A., LEWIN, S., NOYES, J. & RASHIDIAN, A. 2013. Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: a qualitative evidence synthesis. *Cochrane Database of Systematic Reviews*.
GRAY, D. E. 2021. Doing research in the real world.
GREATREX-WHITE, S. 2008. Thinking about the nature of research findings: A hermeneutic phenomenological perspective. *International Journal of Nursing Studies,* 45**,** 1842-1849.
GREEN, J. & THOROGOOD, N. 2018. Qualitative methods for health research.
GREENHALGH, T., WHERTON, J., PAPOUTSI, C., LYNCH, J., HUGHES, G., A'COURT, C., HINDER, S., FAHY, N., PROCTER, R. & SHAW, S. 2017. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. *J Med Internet Res,* 19**,** e367.
GREEVEN, A., VAN BALKOM, A. J., VAN DER LEEDEN, R., MERKELBACH, J. W., VAN DEN HEUVEL, O. A. & SPINHOVEN, P. 2009. Cognitive behavioral therapy versus paroxetine in the treatment of hypochondriasis: an 18-month naturalistic follow-up. *J Behav Ther Exp Psychiatry,* 40**,** 487-96.
GREEVEN, A., VAN BALKOM, A. J., VISSER, S., MERKELBACH, J. W., VAN ROOD, Y. R., VAN DYCK, R., VAN DER DOES, A. J., ZITMAN, F. G. & SPINHOVEN, P. 2007. Cognitive behavior therapy and paroxetine in the treatment of hypochondriasis: a randomized controlled trial. *Am J Psychiatry,* 164**,** 91-9.
GRIFFIN, A. & MAY, V. 2012. Narrative analysis and interpretative phenomenological analysis. *Researching society and culture,* 3**,** 441-458.
GUBA, E. G. & LINCOLN, Y. S. 1994. Competing paradigms in qualitative research. *Handbook of qualitative research,* 2**,** 105.
GUEST, G., MACQUEEN, K. M. & NAMEY, E. E. 2012. Introduction to applied thematic analysis. *Applied thematic analysis,* 3**,** 1-21.
GUREJE, O., USTÜN, T. B. & SIMON, G. E. 1997. The syndrome of hypochondriasis: a cross-national study in primary care. *Psychol Med,* 27**,** 1001-10.
HAAS, J. W., ONGARO, G., JACOBSON, E., CONBOY, L. A., NEE, J., ITURRINO, J., RANGAN, V., LEMBO, A., KAPTCHUK, T. J. &

BALLOU, S. 2022. Patients' experiences treated with open-label placebo versus double-blind placebo: a mixed methods qualitative study. *BMC Psychol,* 10**,** 20.
HALL, W. A. & CALLERY, P. 2001. Enhancing the rigor of grounded theory: Incorporating reflexivity and relationality. *Qualitative health research,* 11**,** 257-272.
HAMMERSLEY, M. 2002. The Qualitative Researcher's Companion. Thousand Oaks

Thousand Oaks, California: SAGE Publications, Inc.
HEALY, P., GALVIN, S., WILLIAMSON, P. R., TREWEEK, S., WHITING, C., MAESO, B., BRAY, C., BROCKLEHURST, P., MOLONEY, M. C., DOUIRI, A., GAMBLE, C., GARDNER, H. R., MITCHELL, D., STEWART, D., JORDAN, J., O'DONNELL, M., CLARKE, M., PAVITT, S. H., GUEGAN, E. W., BLATCH-JONES, A., SMITH, V., REAY, H. & DEVANE, D. 2018. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership - the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. *Trials,* 19**,** 147.
HEDMAN, E., ANDERSSON, G., ANDERSSON, E., LJOTSSON, B., RUCK, C., ASMUNDSON, G. J. & LINDEFORS, N. 2011. Internet-based cognitive-behavioural therapy for severe health anxiety: randomised controlled trial. *Br J Psychiatry,* 198**,** 230-6.
HEDMAN, E., AXELSSON, E., ANDERSSON, E., LEKANDER, M. & LJÓTSSON, B. 2016. Exposure-based cognitive-behavioural therapy via the internet and as bibliotherapy for somatic symptom disorder and illness anxiety disorder: randomised controlled trial. *Br J Psychiatry,* 209**,** 407-413.
HEDMAN, E., AXELSSON, E., GORLING, A., RITZMAN, C., RONNHEDEN, M., EL ALAOUI, S., ANDERSSON, E., LEKANDER, M. & LJOTSSON, B. 2014. Internet-delivered exposure-based cognitive-behavioural therapy and behavioural stress management for severe health anxiety: randomised controlled trial. *Br J Psychiatry,* 205**,** 307-14.
HEDMAN, E., LEKANDER, M., LJOTSSON, B., LINDEFORS, N., RUCK, C., ANDERSSON, G. & ANDERSSON, E. 2015. Optimal cut-off points on the health anxiety inventory, illness attitude scales and whiteley index to identify severe health anxiety. *PLoS One,* 10**,** e0123412.
HEDMAN, E., LJÓTSSON, B. & LINDEFORS, N. 2012. Cognitive behavior therapy via the Internet: a systematic review of applications, clinical efficacy and cost-effectiveness. *Expert Rev Pharmacoecon Outcomes Res,* 12**,** 745-64.
HIND, D., O'CATHAIN, A., COOPER, C. L., PARRY, G. D., ISAAC, C. L., ROSE, A., MARTIN, L. & SHARRACK, B. 2010. The acceptability of computerised cognitive behavioural therapy for the treatment of depression in people with chronic physical disease: a qualitative study of people with multiple sclerosis. *Psychol Health,* 25**,** 699-712.
HOLLIS, C., SAMPSON, S., SIMONS, L., DAVIES, E. B., CHURCHILL, R., BETTON, V., BUTLER, D., CHAPMAN, K., EASTON, K., GRONLUND, T. A., KABIR, T., RAWSTHORNE, M., RYE, E. & TOMLIN, A. 2018. Identifying research priorities for digital technology

in mental health care: results of the James Lind Alliance Priority Setting Partnership. *Lancet Psychiatry,* 5**,** 845-854.
HOLMES, E. A., GHADERI, A., HARMER, C. J., RAMCHANDANI, P. G., CUIJPERS, P., MORRISON, A. P., ROISER, J. P., BOCKTING, C. L., O'CONNOR, R. C. & SHAFRAN, R. 2018. The Lancet Psychiatry Commission on psychological treatments research in tomorrow's science. *The Lancet Psychiatry,* 5**,** 237-286.
HOMMEL, K. A., HENTE, E., HERZER, M., INGERSKI, L. M. & DENSON, L. A. 2013. Telehealth behavioral treatment for medication nonadherence: a pilot and feasibility study. *Eur J Gastroenterol Hepatol,* 25**,** 469-73.
HOUGHTON, C., DOWLING, M., MESKELL, P., HUNTER, A., GARDNER, H., CONWAY, A., TREWEEK, S., SUTCLIFFE, K., NOYES, J., DEVANE, D., NICHOLAS, J. R. & BIESTY, L. M. 2020. Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis. *Cochrane Database Syst Rev,* 10**,** Mr000045.
HOWITT, D. 2016. *Introduction to Qualitative Research Methods in Psychology*, Pearson.
HUGHES-MORLEY, A., YOUNG, B., WAHEED, W., SMALL, N. & BOWER, P. 2015. Factors affecting recruitment into depression trials: Systematic review, meta-synthesis and conceptual framework. *J Affect Disord,* 172**,** 274-90.
HUNTLEY, A., LASSERSON, D., WYE, L., MORRIS, R., CHECKLAND, K., ENGLAND, H., SALISBURY, C. & PURDY, S. 2014. Which features of primary care affect unscheduled secondary care use? A systematic review. *BMJ Open,* 4**,** e004746.
IFLAIFEL, M., HALL, C. L., GREEN, H. R., WILLIS, A., RENNICK-EGGLESTONE, S., JUSZCZAK, E., TOWNSEND, M., MARTIN, J. & SPRANGE, K. 2023. Widening participation – recruitment methods in mental health randomised controlled trials: a qualitative study. *BMC Medical Research Methodology,* 23**,** 211.
JENSEN, G. M. 1989. Qualitative Methods in Physical Therapy Research: A Form of Disciplined Inquiry. *Physical Therapy,* 69**,** 492-500.
JOHANSSON, O., MICHEL, T., ANDERSSON, G. & PAXLING, B. 2015. Experiences of non-adherence to Internet-delivered cognitive behavior therapy: A qualitative study. *Internet Interventions,* 2**,** 137-142.
KALTENTHALER, E., PARRY, G., BEVERLEY, C. & FERRITER, M. 2008. Computerised cognitive-behavioural therapy for depression: systematic review. *Br J Psychiatry,* 193**,** 181-4.
KASENDA, B., LIU, J., JIANG, Y., GAJEWSKI, B., WU, C., VON ELM, E., SCHANDELMAIER, S., MOFFA, G., TRELLE, S., SCHMITT, A. M., HERBRAND, A. K., GLOY, V., SPEICH, B., HOPEWELL, S., HEMKENS, L. G., SLUKA, C., MCGILL, K., MEADE, M., COOK, D., LAMONTAGNE, F., TRELUYER, J. M., HAIDICH, A. B., IOANNIDIS, J. P. A., TREWEEK, S. & BRIEL, M. 2020. Prediction of RECRUITment In randomized clinical Trials (RECRUIT-IT)-rationale and design for an international collaborative study. *Trials,* 21**,** 731.
KAYLOR-HUGHES, C. J., RAWSTHORNE, M., COULSON, N. S., SIMPSON, S., SIMONS, L., GUO, B., JAMES, M., MORAN, P., SIMPSON, J., HOLLIS, C., AVERY, A. J., TATA, L. J., WILLIAMS, L.,

PANEL, R. N. L. E. A. & MORRISS, R. K. 2017. Direct to Public Peer Support and e-Therapy Program Versus Information to Aid Self-Management of Depression and Anxiety: Protocol for a Randomized Controlled Trial. *JMIR Res Protoc,* 6**,** e231.
KEARNEY, A., HARMAN, N. L., ROSALA-HALLAS, A., BEECHER, C., BLAZEBY, J. M., BOWER, P., CLARKE, M., CRAGG, W., DUANE, S., GARDNER, H., HEALY, P., MAGUIRE, L., MILLS, N., ROOSHENAS, L., ROWLANDS, C., TREWEEK, S., VELLINGA, A., WILLIAMSON, P. R. & GAMBLE, C. 2018. Development of an online resource for recruitment research in clinical trials to organise and map current literature. *Clinical Trials,* 15**,** 533-542.
KEITH, S. J. 2001. Evaluating characteristics of patient selection and dropout rates. *J Clin Psychiatry,* 62 Suppl 9**,** 11-4; discussion 15-6.
KELLNER, R., ABBOTT, P., WINSLOW, W. W. & PATHAK, D. 1987. Fears, beliefs, and attitudes in DSM-III hypochondriasis. *J Nerv Ment Dis,* 175**,** 20-5.
KHUNTI, K., BELLARY, S., KARAMAT, M., PATEL, K., PATEL, V., JONES, A., GRAY, J., SHEPHERD, P., HANIF, W. & FOUNDATION, S. A. H. 2017. Representation of people of South Asian origin in cardiovascular outcome trials of glucose-lowering therapies in type 2 diabetes. *Diabetic Medicine,* 34**,** 64-68.
KHUNTI, K., KUMAR, S. & BRODIE, J. 2009. Diabetes UK and South Asian health Foundation recommendations on diabetes research priorities for British South Asians. *London: Diabetes UK*.
KIRMAYER, L. J. & LOOPER, K. J. 2006. Abnormal illness behaviour: physiological, psychological and social dimensions of coping with distress. *Curr Opin Psychiatry,* 19**,** 54-60.
KNOWLES, S. E., ALLEN, D., DONNELLY, A., FLYNN, J., GALLACHER, K., LEWIS, A., MCCORKLE, G., MISTRY, M., WALKINGTON, P. & DRINKWATER, J. 2021. More than a method: trusting relationships, productive tensions, and two-way learning as mechanisms of authentic co-production. *Res Involv Engagem,* 7**,** 34.
KNOWLES, S. E., LOVELL, K., BOWER, P., GILBODY, S., LITTLEWOOD, E. & LESTER, H. 2015. Patient experience of computerised therapy for depression in primary care. *BMJ Open,* 5**,** e008581.
KNOWLES, S. E., TOMS, G., SANDERS, C., BEE, P., LOVELL, K., RENNICK-EGGLESTONE, S., COYLE, D., KENNEDY, C. M., LITTLEWOOD, E., KESSLER, D., GILBODY, S. & BOWER, P. 2014. Qualitative meta-synthesis of user experience of computerised therapy for depression and anxiety. *PLoS One,* 9**,** e84323.
KRZYWINSKI, M. & ALTMAN, N. 2013. Power and sample size. *Nature Methods,* 10**,** 1139-1140.
KUHN, E., GREENE, C., HOFFMAN, J., NGUYEN, T., WALD, L., SCHMIDT, J., RAMSEY, K. M. & RUZEK, J. 2014. Preliminary evaluation of PTSD Coach, a smartphone app for post-traumatic stress symptoms. *Mil Med,* 179**,** 12-8.
LACHAL, J., REVAH-LEVY, A., ORRI, M. & MORO, M. R. 2017. Metasynthesis: An Original Method to Synthesize Qualitative Literature in Psychiatry. *Frontiers in Psychiatry,* 8.

LARGENT, E. A. & LYNCH, H. F. 2017. Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward. *Yale journal of health policy, law, and ethics,* 17**,** 61.
LEE, R. P., HART, R. I., WATSON, R. M. & RAPLEY, T. 2014. Qualitative synthesis in practice: some pragmatics of meta-ethnography. *Qualitative Research,* 15**,** 334-350.
LILLEVOLL, K. R., WILHELMSEN, M., KOLSTRUP, N., HØIFØDT, R. S., WATERLOO, K., EISEMANN, M. & RISØR, M. B. 2013. Patients' experiences of helpfulness in guided internet-based treatment for depression: qualitative study of integrated therapeutic dimensions. *J Med Internet Res,* 15**,** e126.
LINCOLN, Y. S. & GUBA, E. G. 1985. *Naturalistic inquiry*, sage.
LISY, K. & PORRITT, K. 2016. Narrative Synthesis: Considerations and challenges. *JBI Evidence Implementation,* 14**,** 201.
LIU, Y., PENCHEON, E., HUNTER, R. M., MONCRIEFF, J. & FREEMANTLE, N. 2018. Recruitment and retention strategies in mental health trials - A systematic review. *PLoS One,* 13**,** e0203127.
LOUW, K.-A., HOARE, J. & J STEIN, D. 2014. Pharmacological treatments for hypochondriasis: a review. *Current Psychiatry Reviews,* 10**,** 70-74.
LUBORSKY, M. R. & RUBINSTEIN, R. L. 1995. Sampling in qualitative research: Rationale, issues, and methods. *Research on aging,* 17**,** 89-113.
LY, K. H., JANNI, E., WREDE, R., SEDEM, M., DONKER, T., CARLBRING, P. & ANDERSSON, G. 2015. Experiences of a guided smartphone-based behavioral activation therapy for depression: A qualitative study. *Internet Interventions,* 2**,** 60-68.
MALINS, S., BISWAS, S., PATEL, S., LEVENE, J., MOGHADDAM, N. & MORRISS, R. 2020. Preventing relapse with personalized smart-messaging after cognitive behavioural therapy: A proof-of-concept evaluation. *Br J Clin Psychol,* 59**,** 241-259.
MALTERUD, K. 2001. Qualitative research: standards, challenges, and guidelines. *The lancet,* 358**,** 483-488.
MARSHALL, M. N. 1996. Sampling for qualitative research. *Family practice,* 13**,** 522-526.
MASON, V., SHAW, A., WILES, N., MULLIGAN, J., PETERS, T., SHARP, D. & LEWIS, G. 2007. GPs' experiences of primary care mental health research: a qualitative study of the barriers to recruitment. *Fam Pract,* 24**,** 518-25.
MAY, C., FINCH, T., MAIR, F., BALLINI, L., DOWRICK, C., ECCLES, M., GASK, L., MACFARLANE, A., MURRAY, E., RAPLEY, T., ROGERS, A., TREWEEK, S., WALLACE, P., ANDERSON, G., BURNS, J. & HEAVEN, B. 2007. Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Serv Res,* 7**,** 148.
MAY, C. R., FINCH, T., BALLINI, L., MACFARLANE, A., MAIR, F., MURRAY, E., TREWEEK, S. & RAPLEY, T. 2011. Evaluating complex interventions and health technologies using normalization process theory: development of a simplified approach and web-enabled toolkit. *BMC Health Serv Res,* 11**,** 245.

MAY, C. R., MAIR, F., FINCH, T., MACFARLANE, A., DOWRICK, C., TREWEEK, S., RAPLEY, T., BALLINI, L., ONG, B. N., ROGERS, A., MURRAY, E., ELWYN, G., LEGARE, F., GUNN, J. & MONTORI, V. M. 2009. Development of a theory of implementation and integration: Normalization Process Theory. *Implement Sci,* 4**,** 29.
MAYKUT, P. & MOREHOUSE, R. 2002. *Beginning qualitative research: A philosophical and practical guide*, Routledge.
MAYS, N. & POPE, C. 1995. Qualitative research: observational methods in health care settings. *Bmj,* 311**,** 182-184.
MCLEOD, J. 2001. Qualitative Research in Counselling and Psychotherapy. London.
MCMANUS, F., SURAWY, C., MUSE, K., VAZQUEZ-MONTES, M. & WILLIAMS, J. M. 2012. A randomized clinical trial of mindfulness-based cognitive therapy versus unrestricted services for health anxiety (hypochondriasis). *J Consult Clin Psychol,* 80**,** 817-28.
MCPHERSON, S., WICKS, C. & TERCELLI, I. 2020. Patient experiences of psychological therapy for depression: a qualitative metasynthesis. *BMC Psychiatry,* 20**,** 313.
MERRIAM, S. B. 1988. *Case study research in education: A qualitative approach*, Jossey-Bass.
MERRIAM, S. B. 1998. *Qualitative Research and Case Study Applications in Education. Revised and Expanded from" Case Study Research in Education."*, ERIC.
MERTENS, D. M. 2023. *Research and evaluation in education and psychology: Integrating diversity with quantitative, qualitative, and mixed methods*, Sage publications.
MICHIE, S., JOHNSTON, M., ABRAHAM, C., LAWTON, R., PARKER, D. & WALKER, A. 2005. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care,* 14**,** 26-33.
MILLER, T. & BELL, L. 2002. Consenting to what? Issues of access, gate-keeping and 'informed'consent. *Ethics in qualitative research,* 53**,** 69.
MOGOAȘE, C., COBEANU, O., DAVID, O., GIOSAN, C. & SZENTAGOTAI, A. 2017. Internet-Based Psychotherapy for Adult Depression: What About the Mechanisms of Change? *J Clin Psychol,* 73**,** 5-64.
MOHER, D., LIBERATI, A., TETZLAFF, J. & ALTMAN, D. G. 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med,* 6**,** e1000097.
MORRISS, R., PATEL, S., MALINS, S., GUO, B., HIGTON, F., JAMES, M., WU, M., BROWN, P., BOYCOTT, N., KAYLOR-HUGHES, C., MORRIS, M., ROWLEY, E., SIMPSON, J., SMART, D., STUBLEY, M., KAI, J. & TYRER, H. 2019. Clinical and economic outcomes of remotely delivered cognitive behaviour therapy versus treatment as usual for repeat unscheduled care users with severe health anxiety: a multicentre randomised controlled trial. *BMC Medicine,* 17**,** 16.
MUNABI-BABIGUMIRA, S., GLENTON, C., LEWIN, S., FRETHEIM, A. & NABUDERE, H. 2017. Factors that influence the provision of intrapartum and postnatal care by skilled birth attendants in low- and middle-income countries: a qualitative evidence synthesis. *Cochrane Database Syst Rev,* 11**,** Cd011558.

MURPHY, E. 2017. *Qualitative methods and health policy research*, Routledge.
MURRAY, E., TREWEEK, S., POPE, C., MACFARLANE, A., BALLINI, L., DOWRICK, C., FINCH, T., KENNEDY, A., MAIR, F., O'DONNELL, C., ONG, B. N., RAPLEY, T., ROGERS, A. & MAY, C. 2010. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med,* 8**,** 63.
MUSE, K., MCMANUS, F., LEUNG, C., MEGHREBLIAN, B. & WILLIAMS, J. M. 2012. Cyberchondriasis: fact or fiction? A preliminary examination of the relationship between health anxiety and searching for health information on the Internet. *J Anxiety Disord,* 26**,** 189-96.
MYKLETUN, A., HERADSTVEIT, O., ERIKSEN, K., GLOZIER, N., ØVERLAND, S., MAELAND, J. G. & WILHELMSEN, I. 2009. Health anxiety and disability pension award: The HUSK Study. *Psychosom Med,* 71**,** 353-60.
NAKAO, M., SHINOZAKI, Y., NOLIDO, N., AHERN, D. K. & BARSKY, A. J. 2012. Responsiveness of hypochondriacal patients with chronic low-back pain to cognitive-behavioral therapy. *Psychosomatics,* 53**,** 139-47.
NEAL, R., DOWELL, A., HEYWOOD, P. & MORLEY, S. 1996. Frequent attenders: Who needs treatment? *The British Journal of General Practice,* 46**,** 131.
NEAL, R. D., HEYWOOD, P. L., MORLEY, S., CLAYDEN, A. D. & DOWELL, A. C. 1998. Frequency of patients' consulting in general practice and workload generated by frequent attenders: comparisons between practices. *Br J Gen Pract,* 48**,** 895-8.
NEWBY, J. M., HASKELBERG, H., HOBBS, M. J., MAHONEY, A. E. J., MASON, E. & ANDREWS, G. 2020. The effectiveness of internet-delivered cognitive behavioural therapy for health anxiety in routine care. *Journal of Affective Disorders,* 264**,** 535-542.
NEWBY, J. M., HOBBS, M. J., MAHONEY, A. E. J., WONG, S. K. & ANDREWS, G. 2017. DSM-5 illness anxiety disorder and somatic symptom disorder: Comorbidity, correlates, and overlap with DSM-IV hypochondriasis. *J Psychosom Res,* 101**,** 31-37.
NEWBY, J. M., SMITH, J., UPPAL, S., MASON, E., MAHONEY, A. E. J. & ANDREWS, G. 2018. Internet-based cognitive behavioral therapy versus psychoeducation control for illness anxiety disorder and somatic symptom disorder: A randomized controlled trial. *J Consult Clin Psychol,* 86**,** 89-98.
NGUNE, I., JIWA, M., DADICH, A., LOTRIET, J. & SRIRAM, D. 2012. Effective recruitment strategies in primary care research: a systematic review. *Qual Prim Care,* 20**,** 115-23.
NOBLE, H. & SMITH, J. 2015. Issues of validity and reliability in qualitative research. *Evidence Based Nursing,* 18**,** 34-35.
NOBLIT, G. & HARE, R. 1988. Meta-Ethnography. Thousand Oaks, California.
O'CONNOR, S., HANLON, P., O'DONNELL, C. A., GARCIA, S., GLANVILLE, J. & MAIR, F. S. 2016. Understanding factors affecting patient and public engagement and recruitment to digital health

interventions: a systematic review of qualitative studies. *BMC Medical Informatics and Decision Making,* 16**,** 120.
ODGAARD-JENSEN, J., VIST, G. E., TIMMER, A., KUNZ, R., AKL, E. A., SCHUNEMANN, H., BRIEL, M., NORDMANN, A. J., PREGNO, S. & OXMAN, A. D. 2011. Randomisation to protect against selection bias in healthcare trials. *Cochrane Database Syst Rev,* 2011**,** MR000012.
OLATUNJI, B. O., KAUFFMAN, B. Y., MELTZER, S., DAVIS, M. L., SMITS, J. A. & POWERS, M. B. 2014. Cognitive-behavioral therapy for hypochondriasis/health anxiety: a meta-analysis of treatment outcome and moderators. *Behav Res Ther,* 58**,** 65-74.
OLDE HARTMAN, T. C., BORGHUIS, M. S., LUCASSEN, P. L., VAN DE LAAR, F. A., SPECKENS, A. E. & VAN WEEL, C. 2009. Medically unexplained symptoms, somatisation disorder and hypochondriasis: course and prognosis. A systematic review. *J Psychosom Res,* 66**,** 363-77.
PAGET, M. A. 1983. Experience and knowledge. *Human Studies,* 6**,** 67-90.
PATEL, S., AKHTAR, A., MALINS, S., WRIGHT, N., ROWLEY, E., YOUNG, E., SAMPSON, S. & MORRISS, R. 2020. The Acceptability and Usability of Digital Health Interventions for Adults With Depression, Anxiety, and Somatoform Disorders: Qualitative Systematic Review and Meta-Synthesis. *J Med Internet Res,* 22**,** e16228.
PATEL, S., KAI, J., ATHA, C., AVERY, A., GUO, B., JAMES, M., MALINS, S., SAMPSON, C., STUBLEY, M. & MORRISS, R. 2015. Clinical characteristics of persistent frequent attenders in primary care: case-control study. *Fam Pract,* 32**,** 624-30.
PATEL, S., MALINS, S., GUO, B., JAMES, M., KAI, J., KAYLOR-HUGHES, C., ROWLEY, E., SIMPSON, J., SMART, D., STUBLEY, M., TYRER, H. & MORRISS, R. 2016. Protocol investigating the clinical outcomes and cost-effectiveness of cognitive-behavioural therapy delivered remotely for unscheduled care users with health anxiety: randomised controlled trial. *BJPsych Open,* 2**,** 81-87.
PATTON, M. Q. 1980. Qualitative evaluation methods.
PICKARD, A. J. 2013. *Research methods in information*, Facet publishing.
PILOWSKY, I. 1967. Dimensions of hypochondriasis. *Br J Psychiatry,* 113**,** 89-93.
POPAY, J., ROBERTS, H. M., SOWDEN, A. J., PETTICREW, M., ARAI, L., RODGERS, M. & BRITTEN, N. Guidance on the conduct of narrative synthesis in systematic Reviews. A Product from the ESRC Methods Programme. Version 1. 2006.
POPE, C., ZIEBLAND, S. & MAYS, N. 2000. Qualitative research in health care. Analysing qualitative data. *Bmj,* 320**,** 114-6.
POTTER, J. & HEPBURN, A. 2005. Qualitative interviews in psychology: Problems and possibilities. *Qualitative research in Psychology,* 2**,** 281-307.
POULIOT, V. 2007. “Sobjectivism”: Toward a constructivist methodology. *International studies quarterly,* 51**,** 359-384.
PROCTOR, E. K., LANDSVERK, J., AARONS, G., CHAMBERS, D., GLISSON, C. & MITTMAN, B. 2009. Implementation Research in Mental Health Services: an Emerging Science with Conceptual,

Methodological, and Training challenges. *Administration and Policy in Mental Health and Mental Health Services Research,* 36**,** 24-34.
PUGH, N. E., HADJISTAVROPOULOS, H. D., HAMPTON, A. J. D., BOWEN, A. & WILLIAMS, J. 2015. Client experiences of guided internet cognitive behavior therapy for postpartum depression: a qualitative study. *Arch Womens Ment Health,* 18**,** 209-219.
PURVES, D. G. & DUTTON, J. 2013. An exploration of the therapeutic process while using computerised cognitive behaviour therapy. *Counselling and Psychotherapy Research,* 13**,** 308-316.
PYWELL, J., VIJAYKUMAR, S., DODD, A. & COVENTRY, L. 2020. Barriers to older adults' uptake of mobile-based mental health interventions. *Digit Health,* 6**,** 2055207620905422.
RAVITCH, S. M. & CARL, N. M. 2019. *Qualitative research: Bridging the conceptual, theoretical, and methodological*, Sage Publications.
RENJITH, V., YESODHARAN, R., NORONHA, J. A., LADD, E. & GEORGE, A. 2021. Qualitative Methods in Health Care Research. *Int J Prev Med,* 12**,** 20.
RIADI, I., KERVIN, L., DHILLON, S., TEO, K., CHURCHILL, R., CARD, K. G., SIXSMITH, A., MORENO, S., FORTUNA, K. L., TOROUS, J. & COSCO, T. D. 2022. Digital interventions for depression and anxiety in older adults: a systematic review of randomised controlled trials. *Lancet Healthy Longev,* 3**,** e558-e571.
RICHARDS, D. & RICHARDSON, T. 2012. Computer-based psychological treatments for depression: a systematic review and meta-analysis. *Clin Psychol Rev,* 32**,** 329-42.
RITCHIE, J., LEWIS, J. & ELAM, G. 2003. Designing and selecting samples. *Qualitative research methods***,** 77-108.
ROBINSON, K. A., DENNISON, C. R., WAYMAN, D. M., PRONOVOST, P. J. & NEEDHAM, D. M. 2007. Systematic review identifies number of strategies important for retaining study participants. *J Clin Epidemiol,* 60**,** 757-65.
ROBINSON, K. A., DINGLAS, V. D., SUKRITHAN, V., YALAMANCHILLI, R., MENDEZ-TELLEZ, P. A., DENNISON-HIMMELFARB, C. & NEEDHAM, D. M. 2015. Updated systematic review identifies substantial number of retention strategies: using more strategies retains more study participants. *J Clin Epidemiol,* 68**,** 1481-7.
ROBSON, C. & MCCARTAN, K. 2016. Real world research: A resource for users of social research methods in applied settings.
ROBSON, S., ALMEIDA, J. & SCHARTNER, A. 2018. Internationalization at home: time for review and development? *European Journal of Higher Education,* 8**,** 19-35.
ROGERS, E. M. 2003. Diffusion of innovations/everett m. rogers. *NY: Simon and Schuster,* 576.
ROOSHENAS, L., ELLIOTT, D., WADE, J., JEPSON, M., PARAMASIVAN, S., STRONG, S., WILSON, C., BEARD, D., BLAZEBY, J. M., BIRTLE, A., HALLIDAY, A., ROGERS, C. A., STEIN, R. & DONOVAN, J. L. 2016. Conveying Equipoise during Recruitment for Clinical Trials: Qualitative Synthesis of Clinicians' Practices across Six Randomised Controlled Trials. *PLoS Med,* 13**,** e1002147.

ROWLANDS, B. H. 2005. Grounded in practice: Using interpretive research to build theory. *Electronic Journal of Business Research Methods,* 3**,** pp81-92-pp81-92.
SALKOVSKIS, P. M., RIMES, K. A., WARWICK, H. M. & CLARK, D. M. 2002. The Health Anxiety Inventory: development and validation of scales for the measurement of health anxiety and hypochondriasis. *Psychol Med,* 32**,** 843-53.
SALKOVSKIS, P. M. & WARWICK, H. M. C. 1986. Morbid preoccupations, health anxiety and reassurance: a cognitive-behavioural approach to hypochondriasis. *Behaviour Research and Therapy,* 24**,** 597-602.
SALKOVSKIS, P. M., WARWICK, H. M. C. & DEALE, A. 2003. Cognitive-Behavioral Treatment for Severe and Persistent Health Anxiety (Hypochondriasis). *Brief Treatment and Crisis Intervention,* 3**,** 353-367.
SCARELLA, T. M., BOLAND, R. J. & BARSKY, A. J. 2019. Illness Anxiety Disorder: Psychopathology, Epidemiology, Clinical Characteristics, and Treatment. *Psychosom Med,* 81**,** 398-407.
SCARELLA, T. M., LAFERTON, J. A., AHERN, D. K., FALLON, B. A. & BARSKY, A. 2016. The Relationship of Hypochondriasis to Anxiety, Depressive, and Somatoform Disorders. *Psychosomatics,* 57**,** 200-7.
SCHWANDT, T. A., LINCOLN, Y. S. & GUBA, E. G. 2007. Judging interpretations: But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. *New directions for evaluation,* 2007**,** 11-25.
SCHWIND, J., NENG, J. M., HÖFLING, V. & WECK, F. 2015. Health Behavior in Hypochondriasis. *J Nerv Ment Dis,* 203**,** 493-8.
SCHWIND, J., NENG, J. M. & WECK, F. 2016. Changes in Free Symptom Attributions in Hypochondriasis after Cognitive Therapy and Exposure Therapy. *Behav Cogn Psychother,* 44**,** 601-14.
SECKER, J., WIMBUSH, E., WATSON, J. & MILBURN, K. 1995. Qualitative methods in health promotion research: some criteria for quality. *Health Education Journal,* 54**,** 74-87.
SEIVEWRIGHT, H., SALKOVSKIS, P., GREEN, J., MULLAN, N., BEHR, G., CARLIN, E., YOUNG, S., GOLDMEIER, D. & TYRER, P. 2004. Prevalence and service implications of health anxiety in genitourinary medicine clinics. *Int J STD AIDS,* 15**,** 519-22.
SEKHON, M., CARTWRIGHT, M. & FRANCIS, J. J. 2017. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research,* 17**,** 88.
SHARROCK, M. J., MAHONEY, A. E. J., HASKELBERG, H., MILLARD, M. & NEWBY, J. M. 2021. The uptake and outcomes of Internet-based cognitive behavioural therapy for health anxiety symptoms during the COVID-19 pandemic. *J Anxiety Disord,* 84**,** 102494.
SHEIKH, A., HALANI, L., BHOPAL, R., NETUVELI, G., PARTRIDGE, M. R., CAR, J., GRIFFITHS, C. & LEVY, M. 2009. Facilitating the recruitment of minority ethnic people into research: qualitative case study of South Asians and asthma. *PLoS Med,* 6**,** e1000148.
SHENTON, A. K. 2004. Strategies for ensuring trustworthiness in qualitative research projects. *Education for information,* 22**,** 63-75.
SHERIDAN, R., MARTIN-KERRY, J., HUDSON, J., PARKER, A., BOWER, P. & KNAPP, P. 2020. Why do patients take part in research? An

overview of systematic reviews of psychosocial barriers and facilitators. *Trials,* 21**,** 259.
SILVERMAN, D. 2015. Interpreting qualitative data. *Interpreting Qualitative Data***,** 1-520.
SIM, J. & WATERFIELD, J. 2019. Focus group methodology: some ethical challenges. *Quality & Quantity,* 53**,** 3003-3022.
SMITH, J. A. 2015. Qualitative psychology: A practical guide to research methods. *Qualitative psychology***,** 1-312.
SMITS, F. T., BROUWER, H. J., TER RIET, G. & VAN WEERT, H. C. P. 2009. Epidemiology of frequent attenders: a 3-year historic cohort study comparing attendance, morbidity and prescriptions of one-year and persistent frequent attenders. *BMC Public Health,* 9**,** 36.
SØRENSEN, P., BIRKET-SMITH, M., WATTAR, U., BUEMANN, I. & SALKOVSKIS, P. 2011. A randomized clinical trial of cognitive behavioural therapy versus short-term psychodynamic psychotherapy versus no intervention for patients with hypochondriasis. *Psychol Med,* 41**,** 431-41.
SPARKES, A. C. & SMITH, B. 2013. *Qualitative research methods in sport, exercise and health: From process to product*, Routledge.
SPECKENS, A. E., SPINHOVEN, P., SLOEKERS, P. P., BOLK, J. H. & VAN HEMERT, A. M. 1996. A validation study of the Whitely Index, the Illness Attitude Scales, and the Somatosensory Amplification Scale in general medical and general practice patients. *J Psychosom Res,* 40**,** 95-104.
SPENCE, D. 2016. Bad Medicine: The worried hell. *Br J Gen Pract,* 66**,** 526.
SPEZIALE, H. S., STREUBERT, H. J. & CARPENTER, D. R. 2011. *Qualitative research in nursing: Advancing the humanistic imperative*, Lippincott Williams & Wilkins.
STEWART, P. & O'DOWD, T. 2002. Clinically inexplicable frequent attenders in general practice. *Br J Gen Pract,* 52**,** 1000-1.
SUNDERLAND, M., NEWBY, J. M. & ANDREWS, G. 2013. Health anxiety in Australia: prevalence, comorbidity, disability and service use. *Br J Psychiatry,* 202**,** 56-61.
TAYLOR, S. & ASMUNDSON, G. J. G. 2004. *Treating health anxiety: A cognitive-behavioral approach,* New York, NY, US, The Guilford Press.
TERRY, G. & HAYFIELD, N. 2020. 38. Reflexive thematic analysis. *Handbook of qualitative research in Education. Edward Elgar Publishing Limited***,** 430-441.
TONG, A., FLEMMING, K., MCINNES, E., OLIVER, S. & CRAIG, J. 2012. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Medical Research Methodology,* 12**,** 181.
TRACY, S. J. 2010. Qualitative quality: Eight “big-tent” criteria for excellent qualitative research. *Qualitative inquiry,* 16**,** 837-851.
TREWEEK, S., PITKETHLY, M., COOK, J., FRASER, C., MITCHELL, E., SULLIVAN, F., JACKSON, C., TASKILA, T. K. & GARDNER, H. 2018. Strategies to improve recruitment to randomised trials. *Cochrane Database of Systematic Reviews*.
TUDUR SMITH, C., HICKEY, H., CLARKE, M., BLAZEBY, J. & WILLIAMSON, P. 2014. The trials methodological research agenda: results from a priority setting exercise. *Trials,* 15**,** 32.

TYRER, P. 2014. A comparison of DSM and ICD classifications of mental disorder. *Advances in Psychiatric Treatment,* 20**,** 280-285.
TYRER, P., COOPER, S., CRAWFORD, M., DUPONT, S., GREEN, J., MURPHY, D., SALKOVSKIS, P., SMITH, G., WANG, D., BHOGAL, S., KEELING, M., LOEBENBERG, G., SEIVEWRIGHT, R., WALKER, G., COOPER, F., EVERED, R., KINGS, S., KRAMO, K., MCNULTY, A., NAGAR, J., REID, S., SANATINIA, R., SINCLAIR, J., TREVOR, D., WATSON, C. & TYRER, H. 2011. Prevalence of health anxiety problems in medical clinics. *J Psychosom Res,* 71**,** 392-4.
TYRER, P., COOPER, S., SALKOVSKIS, P., TYRER, H., CRAWFORD, M., BYFORD, S., DUPONT, S., FINNIS, S., GREEN, J., MCLAREN, E., MURPHY, D., REID, S., SMITH, G., WANG, D., WARWICK, H., PETKOVA, H. & BARRETT, B. 2014. Clinical and cost-effectiveness of cognitive behaviour therapy for health anxiety in medical patients: a multicentre randomised controlled trial. *Lancet,* 383**,** 219-25.
TYRER, P., COOPER, S., TYRER, H., WANG, D. & BASSETT, P. 2019. Increase in the prevalence of health anxiety in medical clinics: Possible cyberchondria. *Int J Soc Psychiatry,* 65**,** 566-569.
TYRER, P., EILENBERG, T., FINK, P., HEDMAN, E. & TYRER, H. 2016. Health anxiety: the silent, disabling epidemic. *BMJ,* 353**,** i2250.
TYRER, P., SALKOVSKIS, P., TYRER, H., WANG, D., CRAWFORD, M. J., DUPONT, S., COOPER, S., GREEN, J., MURPHY, D., SMITH, G., BHOGAL, S., NOURMAND, S., LAZAREVIC, V., LOEBENBERG, G., EVERED, R., KINGS, S., MCNULTY, A., LISSEMAN-STONES, Y., MCALLISTER, S., KRAMO, K., NAGAR, J., REID, S., SANATINIA, R., WHITTAMORE, K., WALKER, G., PHILIP, A., WARWICK, H., BYFORD, S. & BARRETT, B. 2017. Cognitive-behaviour therapy for health anxiety in medical patients (CHAMP): a randomised controlled trial with outcomes to 5 years. *Health Technol Assess,* 21**,** 1-58.
TYRER, P. & TYRER, H. 2018. Health anxiety: detection and treatment. *BJPsych Advances,* 24**,** 66-72.
VAN DEN HEEDE, K. & VAN DE VOORDE, C. 2016. Interventions to reduce emergency department utilisation: A review of reviews. *Health Policy,* 120**,** 1337-1349.
VAN DER GAAG, W. H., VAN DEN BERG, R., KOES, B. W., BOHNEN, A. M., HAZEN, L. M., PEUL, W. C., VOOGT, L., VERHAGEN, A. P., BIERMA-ZEINSTRA, S. M. & LUIJSTERBURG, P. A. 2017. Discontinuation of a randomised controlled trial in general practice due to unsuccessful patient recruitment. *BJGP Open,* 1**,** bjgpopen17X101085.
WAFFENSCHMIDT, S., KNELANGEN, M., SIEBEN, W., BÜHN, S. & PIEPER, D. 2019. Single screening versus conventional double screening for study selection in systematic reviews: a methodological systematic review. *BMC Medical Research Methodology,* 19**,** 132.
WALLER, R. & GILBODY, S. 2009. Barriers to the uptake of computerized cognitive behavioural therapy: a systematic review of the quantitative and qualitative evidence. *Psychol Med,* 39**,** 705-12.
WALTERS, S. J., BONACHO DOS ANJOS HENRIQUES-CADBY, I., BORTOLAMI, O., FLIGHT, L., HIND, D., JACQUES, R. M., KNOX, C., NADIN, B., ROTHWELL, J., SURTEES, M. & JULIOUS, S. A. 2017.

Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. *BMJ Open,* 7**,** e015276.
WECK, F., NENG, J. M., RICHTBERG, S., JAKOB, M. & STANGIER, U. 2015. Cognitive therapy versus exposure therapy for hypochondriasis (health anxiety): A randomized controlled trial. *J Consult Clin Psychol,* 83**,** 665-76.
WELLS, M. J., OWEN, J. J., MCCRAY, L. W., BISHOP, L. B., EELLS, T. D., BROWN, G. K., RICHARDS, D., THASE, M. E. & WRIGHT, J. H. 2018. Computer-Assisted Cognitive-Behavior Therapy for Depression in Primary Care: Systematic Review and Meta-Analysis. *Prim Care Companion CNS Disord,* 20.
WILHELMSEN, M., LILLEVOLL, K., RISØR, M. B., HØIFØDT, R., JOHANSEN, M.-L., WATERLOO, K., EISEMANN, M. & KOLSTRUP, N. 2013. Motivation to persist with internet-based cognitive behavioural treatment using blended care: a qualitative study. *BMC Psychiatry,* 13**,** 296.
WILLIG, C. 2013. *Introducing Qualitative Research In Psychology*, Open University Press.
WILLIS, A., ISAACS, T. & KHUNTI, K. 2021. Improving diversity in research and trial participation: the challenges of language. *Lancet Public Health,* 6**,** e445-e446.
WITTEVEEN, A. B., YOUNG, S., CUIJPERS, P., AYUSO-MATEOS, J. L., BARBUI, C., BERTOLINI, F., CABELLO, M., CADORIN, C., DOWNES, N., FRANZOI, D., GASIOR, M., JOHN, A., MELCHIOR, M., MCDAID, D., PALANTZA, C., PURGATO, M., VAN DER WAERDEN, J., WANG, S. & SIJBRANDIJ, M. 2022. Remote mental health care interventions during the COVID-19 pandemic: An umbrella review. *Behaviour Research and Therapy,* 159**,** 104226.
WOOD, E., OHLSEN, S. & RICKETTS, T. 2017. What are the barriers and facilitators to implementing Collaborative Care for depression? A systematic review. *J Affect Disord,* 214**,** 26-43.
WOODALL, A., MORGAN, C., SLOAN, C. & HOWARD, L. 2010. Barriers to participation in mental health research: are there specific gender, ethnicity and age related barriers? *BMC Psychiatry,* 10**,** 103.

Appendix 1 Full search strategy for systematic review

Appendix 1 Full search strategy for systematic review

Search strategy - Medline

1 exp TELEMEDICINE/

2 exp INVENTIONS/

3 (eHealth or ehealth* or e-health* or e health* or "electronic adj health" or e-mental health or m-mental health or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic adj psyc*) or eTherap* or e-therap* or (electronic adj therap*)).tw. (6798)

4 ("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*).tw.

5 ((intervention* or invention* or innovation*) and technolog*).tw.

6 exp Mobile Applications/

7 ((app or apps or application) adj2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software)).tw.

8 exp Video Games/

9 (gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*).tw.

10 exp Videoconferencing/

11 (videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex).tw.

12 wearable electronic devices/ or fitness trackers/

13 (smartwatch* or (wearable adj device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*).tw.

14 exp Virtual Reality/ or exp Virtual Reality Exposure Therapy/

15 ("virtual reality" or "augmented reality").tw.

16 ("interactive multimedia" or "interactive software").tw.

17 ("digital media" or "software program*").tw.

18 ((Internet or digital* or online* or on-line or web* or virtual or computer*) adj2 (deliver* or information or communication* or assisted or e-learning or support)).tw.

19 (ipad adj2 (app or apps or application or intervention*)).tw.

20 (Internet adj2 based).tw.

21 (technolog* adj2 (deliver* or information or communication*)).tw.

22 ("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*").tw.

23 *Robotics/

24 (robot or robots or robotics).tw.

25 or/1-24

26 exp DEPRESSION/

27 exp Depressive Disorder/

28 exp Anxiety Disorders/

29 exp ANXIETY/

30 exp Somatoform Disorders/

31 exp HYPOCHONDRIASIS/

32 exp Dysthymic Disorder/

33 exp Conversion Disorder/

34 exp Body Dysmorphic Disorders/

35 exp Factitious Disorders/

36 exp Stress Disorders, Post-Traumatic/

37 exp Agoraphobia/ or exp Panic Disorder/

38 exp Phobia, Social/ (

39 exp Obsessive-Compulsive Disorder/

40 exp Stress Disorders, Traumatic, Acute/

41 exp Premenstrual Dysphoric Disorder/

42 exp Mutism/

43 exp Mood Disorders/

44 exp Cyclothymic Disorder/

45 exp NEUROTIC DISORDERS/

46 exp Phobic Disorders/

47 exp Adjustment Disorders/

48 (depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or multi somat* or dysthymic disorder* or conversion disorder* or pain disorder* or hypochondria* or body dysmorphi* or factitious disorder* or panic disorder* or panic attack* or phobi* or agrophobi* or obsessive compulsive* or OCD or post traumatic stress* or PTSD or stress disorder* or disruptive mood dysregulation disorder* or body dysmorphic disorder* or premenstrual dysphoric disorder* or mutism or mood affective disorder* or mood disorder* or cyclothymi* or neurotic disorder* or adjustment disorder* or medically unexplained symptom*).tw.

49 or/26-48

50 25 and 49

51 exp QUALITATIVE RESEARCH/

52 exp INTERVIEW/

53 exp Focus Groups/

54 __(("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or self report) adj3 (interview* or discussion* or questionnaire*)).tw.

55 (focus group* or advisory group* or qualitative or ethnograph* or fieldwork or field work or key informant or thematic analy* or grounded theor* or phenomenolog* or discourse analy* or content analy* or narrative* or observational method* or open ended evaluation* or action research or inductive analy* or emic or etic or hermeneutic* or constant compar* or grounded theor* or lived experience* or life experience* or theoretical sampl* or purposive sampl* or quasi-experiment* or (case adj2 stud*)).tw.

56 exp "Surveys and Questionnaires"/

57 exp Self Report/

58 __(field note* or fieldnote* or field record* or field stud* or structured categor* or unstructured categor* or (participant* adj3 observ*) or (nonparticipant* adj3 observ*) or (non participant* adj3 observ*)).tw.

59 or/51-58

60 50 and 59

61 limit 60 to english language

Search strategy - PsycINFO

1 exp TELEMEDICINE/

2 exp Innovation/

3 __(eHealth or ehealth* or e-health* or "e health*" or "electronic adj health" or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic adj psyc*) or eTherap* or e-therap* or (electronic adj therap*)).tw.

4 __((intervention* or invention* or innovation*) and technolog*).tw.

5 __((app or apps or application) adj2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software)).tw.

6 exp Computer Games/

7 __(gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*).tw.

8 exp Teleconferencing/

9 __(videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex).tw.

10 __(smartwatch* or (wearable adj device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*).tw. (

11 exp Virtual Reality/

12 __("virtual reality" or "augmented reality").tw.

13 __("interactive multimedia" or "interactive software").tw.

14 __("digital media" or "software program*").tw.

15 __((Internet or digital* or online* or on-line or web* or virtual or computer*) adj2 (deliver* or information or communication* or assisted or e-learning or support)).tw.

16 (ipad adj2 (app or apps or application or intervention*)).tw.

17 (Internet adj2 based).tw.

18 (technolog* adj2 (deliver* or information or communication*)).tw.

19 ("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*").tw.

20 exp ROBOTICS/ (5035)

21 (robot or robots or robotics).tw.

22 or/1-21 (99258)

23 exp MAJOR DEPRESSION/

24 exp ANXIETY DISORDERS/ or exp ANXIETY/

25 exp Somatoform Disorders/

26 exp HYPOCHONDRIASIS/

27 exp Dysthymic Disorder/

28 exp Conversion Disorder/

29 exp Body Dysmorphic Disorder/

30 exp Factitious Disorders/

31 exp Posttraumatic Stress Disorder/

32 exp AGORAPHOBIA/

33 exp Panic Disorder/

34 exp Social Phobia/

35 exp Obsessive Compulsive Disorder/

36 exp Acute Stress Disorder/

37 exp Premenstrual Dysphoric Disorder/

38 exp MUTISM/

39 exp Affective Disorders/

40 exp Cyclothymic Personality/

41 exp Neurosis/

42 exp Phobias/

43 exp Adjustment Disorders/

44 (depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or multi somat* or dysthymic disorder* or conversion disorder* or pain disorder* or hypochondria* or body dysmorphi* or factitious disorder* or panic disorder* or panic attack* or phobi* or agrophobi* or obsessive compulsive* or OCD or post traumatic stress* or PTSD or stress disorder* or disruptive mood dysregulation disorder* or body dysmorphic disorder* or premenstrual dysphoric disorder* or mutism or mood affective disorder* or mood disorder* or cyclothymi* or neurotic disorder* or adjustment disorder* or medically unexplained symptom*).tw.

45 or/23-44

46 22 and 45

47 exp QUALITATIVE RESEARCH/

48 exp INTERVIEWS/

49 exp action research/

50 ((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or self report) adj3 (interview* or discussion* or questionnaire*)).tw.

51 (focus group* or advisory group* or qualitative or ethnograph* or fieldwork or field work or key informant or thematic analy* or grounded theor* or phenomenolog* or discourse analy* or content analy* or narrative* or observational method* or open ended evaluation* or action research or inductive analy* or emic or etic or hermeneutic* or constant compar* or grounded theor* or lived experience* or life experience* or theoretical sampl* or purposive sampl* or quasi-experiment* or (case adj2 stud*)).tw.

52 exp SURVEYS/

53 exp QUESTIONNAIRES/

54 exp Self-Report/

55 ((field note* or fieldnote* or field record* or field stud* or structured categor* or unstructured categor* or (participant* adj3 observ*) or (nonparticipant* adj3 observ*) or (non participant* adj3 observ*)).tw.

56 or/47-55

57 46 and 56

58 limit 57 to english language

Search strategy - EMBASE

1 telemedicine/

2 exp invention/

3 ((eHealth or ehealth* or e-health* or "e health*" or "electronic adj health" or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic adj psyc*) or eTherap* or e-therap* or (electronic adj therap*)).tw.

4 ("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*).tw.

5 ((intervention* or invention* or innovation*) and technolog*).tw.

6 exp mobile application/

7 ((app or apps or application) adj2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software)).tw.

8 exp video game/

9 (gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*).tw.

10 exp videoconferencing/

11 exp teleconsultation/

12 (videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex).tw. (4538)

13 exp activity tracker/

14 (smartwatch* or (wearable adj device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*).tw.

15 exp virtual reality/

16 ("virtual reality" or "augmented reality").tw.

17 ("interactive multimedia" or "interactive software").tw.

18 ("digital media" or "software program*").tw.

19 ((Internet or digital* or online* or on-line or web* or virtual or computer*) adj2 (deliver* or information or communication* or assisted or e-learning or support)).tw.

20 (ipad adj2 (app or apps or application or intervention*)).tw.

21 (Internet adj2 based).tw.

22 (technolog* adj2 (deliver* or information or communication*)).tw.

23 ("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*").tw.

24 exp robotics/

25 (robot or robots or robotics).tw.

26 or/1-25

27 exp depression/

28 exp anxiety disorder/

29 exp anxiety/

30 exp somatoform disorder/

31 exp hypochondriasis/

32 exp dysthymia/

33 exp conversion disorder/

34 exp body dysmorphic disorder/

35 exp factitious disease/

36 exp posttraumatic stress disorder/

37 exp agoraphobia/

38 exp social phobia/

39 exp obsessive compulsive disorder/

40 exp acute stress disorder/ or stress/

41 exp premenstrual dysphoric disorder/

42 exp mutism/

43 exp mood disorder/

44 exp cyclothymia/

45 exp neurosis/

46 exp phobia/

47 exp adjustment disorder/

48 (depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or multi somat* or dysthymic disorder* or conversion disorder* or pain disorder* or hypochondria* or body dysmorphi* or factitious disorder* or panic disorder* or panic attack* or phobi* or agrophobi* or obsessive compulsive* or OCD or post traumatic stress* or PTSD or stress disorder* or disruptive mood dysregulation disorder* or body dysmorphic disorder* or premenstrual dysphoric disorder* or mutism or mood affective disorder* or mood disorder* or cyclothymi* or neurotic disorder* or adjustment disorder* or medically unexplained symptom*).tw.

49 or/27-48

50 26 and 49

51 exp qualitative research/

52 exp interview/

53 exp questionnaire/

54 exp self report/

55 ((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or self report) adj3 (interview* or discussion* or questionnaire*)).tw.

56 (focus group* or advisory group* or qualitative or ethnograph* or fieldwork or field work or key informant or thematic analy* or grounded theor* or phenomenolog* or discourse analy* or content analy* or narrative* or observational method* or open ended evaluation* or action research or inductive analy* or emic or etic or hermeneutic* or constant compar* or grounded theor* or lived experience* or life experience* or theoretical sampl* or purposive sampl* or quasi-experiment* or (case adj2 stud*)).tw.

57 or/51-56

58 50 and 57 (

59 limit 58 to english language

Search strategy – CINAHL

S56 S45 AND S54

S55 S45 AND S54

S54 S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53

S53 TI (("field note*" or fieldnote* or "field record*" or "field stud*" or "structured categor*" or "unstructured categor*" or (participant* N3 observ*) or (nonparticipant* N3 observ*) or (non participant* N3 observ*))) OR AB (("field note*" or fieldnote* or "field record*" or "field stud*" or "structured categor*" or "unstructured categor*" or (participant* N3 observ*) or (nonparticipant* N3 observ*) or (non participant* N3 observ*)))

S52 (MH "Questionnaires+")

S51 (MH "Survey Research")

S50 TI (("focus group*" or "advisory group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "thematic analy*" or "grounded theor*" or phenomenolog* or "discourse analy*" or "content analy*" or narrative* or "observational method*" or "open ended evaluation*" or "action research" or "inductive analy*" or emic or etic or hermeneutic* or "constant compar*" or "grounded theor*" or "lived experience*" or "life experience*" or "theoretical sampl*" or "purposive sampl*" or quasi-experiment* or (case N2 stud*))) OR AB (("focus group*" or "advisory group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "thematic analy*" or "grounded theor*" or phenomenolog* or "discourse analy*" or "content analy*" or narrative* or "observational method*" or "open ended evaluation*" or "action research" or "inductive analy*" or emic or etic or hermeneutic* or "constant compar*" or "grounded theor*" or "lived experience*" or "life experience*" or "theoretical sampl*" or "purposive sampl*" or quasi-experiment* or (case N2 stud*))

S49 TI (((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or self report) N3 (interview* or discussion* or questionnaire*))) OR AB (((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or self report) N3 (interview* or discussion* or questionnaire*)))

S48 (MH "Focus Groups")

S47 (MH "Interviews+")

S46 (MH "Qualitative Studies+")

S45 S24 AND S44

S44 S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43

S43 TI ((depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or "multi somat*" or "dysthymic disorder*" or "conversion disorder*" or "pain disorder*" or hypochondria* or "body dysmorphi*" or "factitious disorder*" or "panic disorder*" or "panic attack*" or phobi* or agrophobi* or "obsessive compulsive*" or OCD or "post traumatic stress*" or PTSD or "stress disorder*" or "disruptive mood dysregulation disorder*" or "body dysmorphic disorder*" or "premenstrual dysphoric disorder*" or mutism or "mood affective disorder*" or "mood disorder*" or cyclothymi* or "neurotic disorder*" or "adjustment disorder" or "medically unexplained symptom*")) OR AB ((depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or "multi somat*" or "dysthymic disorder*" or "conversion disorder*" or "pain disorder*" or hypochondria* or "body dysmorphi*" or "factitious disorder*" or "panic disorder*" or "panic attack*" or phobi* or agrophobi* or "obsessive compulsive*" or OCD or "post traumatic stress*" or PTSD or "stress disorder*" or "disruptive mood dysregulation disorder*" or "body dysmorphic disorder*" or "premenstrual dysphoric disorder*" or mutism or "mood affective disorder*" or "mood disorder*" or cyclothymi* or "neurotic disorder*" or "adjustment disorder" or "medically unexplained symptom*"))

S42 (MH "Adjustment Disorders+")

S41 (MH "Neurotic Disorders+")

S40 (MH "Cyclothymic Disorder")

S39 (MH "Affective Disorders+")

S38 (MH "Mutism+")

S37 (MH "Premenstrual Dysphoric Disorder")

S36 (MH "Obsessive-Compulsive Disorder+")

S35 (MH "Phobic Disorders+")

S34 (MH "Agoraphobia") OR (MH "Panic Disorder")

S33 (MH "Stress Disorders, Post-Traumatic+")

S32 (MH "Factitious Disorders+")

S31 (MH "Body Dysmorphic Disorder")

S30 (MH "Dysthymic Disorder")

S29 (MH "Hypochondriasis")

S28 (MH "Somatoform Disorders+")

S27 (MH "Anxiety+") OR (MH "Generalized Anxiety Disorder")

S26 (MH "Anxiety Disorders+")

S25 (MH "Depression+")

S24 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23

S23 TI ((robot or robots or robotics)) OR AB ((robot or robots or robotics))

S22 (MH "Robotics+")

S21 TI (("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*")) OR AB (("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*"))

S20 TI ((technolog* N2 (deliver* or information or communication*))) OR AB ((technolog* N2 (deliver* or information or communication*)))

S19 TI (Internet N2 based) OR AB (Internet N2 based)

S18 TI ((ipad N2 (app or apps or application or intervention*))) OR AB ((ipad N2 (app or apps or application or intervention*)))

S17 TI (((Internet or digital* or online* or on-line or web* or virtual or computer*) N2 (deliver* or information or communication* or assisted or e-learning or support))) OR AB (((Internet or digital* or online* or on-line or web* or virtual or computer*) N2 (deliver* or information or communication* or assisted or e-learning or support)))

S16 TI (("digital media" or "software program*")) OR AB (("digital media" or "software program*"))

S15 TI (("interactive multimedia" or "interactive software")) OR AB (("interactive multimedia" or "interactive software"))

S14 TI (("virtual reality" or "augmented reality")) OR AB (("virtual reality" or "augmented reality"))

S13 (MH "Virtual Reality Exposure Therapy") OR (MH "Virtual Reality+")

S12 TI ((smartwatch* or (wearable N device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*)) OR AB ((smartwatch* or (wearable N device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*))

S11 (MH "Wearable Sensors+") OR (MH "Accelerometers")

S10 TI ((videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex)) OR AB ((videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex))

S9 (MH "Videoconferencing+")

S8 TI ((gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*)) OR AB ((gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*))

S7 (MH "Video Games+")

S6 TI (((app or apps or application) N2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software))) OR AB (((app or apps or application) N2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software)))

S5 (MH "Mobile Applications")

S4 TI (((intervention* or invention* or innovation*) and technolog*)) OR AB (((intervention* or invention* or innovation*) and technolog*))

S3 TI (("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*)) OR AB (("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*))

S2 TI ((eHealth or ehealth* or e-health* or "e health*" or "electronic N health" or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic N psyc*) or eTherap* or e-therap* or (electronic N therap*))) OR AB ((eHealth or ehealth* or e-health* or "e health*" or "electronic N health" or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic N psyc*) or eTherap* or e-therap* or (electronic N therap*)))

S1 (MH "Telemedicine+") OR (MH "Telepsychiatry") OR (MH "Telehealth+")

Search strategy – Web of Science

26

#24 AND #19
Refined by: LANGUAGES: (ENGLISH)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

25

#24 AND #19

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

24

#23 OR #22 OR #21 OR #20

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

23

TOPIC: (("field note*" or fieldnote* or "field record*" or "field stud*" or "structured categor*" or "unstructured categor*" or (participant* NEAR/3 observ*) or (nonparticipant* NEAR/3 observ*) or (non participant* NEAR/3 observ*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

22

TOPIC: ((case NEAR/2 stud*))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

21

TOPIC: (("focus group*" or "advisory group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "thematic analy*" or "grounded theor*" or phenomenolog* or "discourse analy*" or "content analy*" or narrative* or "observational method*" or "open ended evaluation*" or "action research" or "inductive analy*" or emic or etic or hermeneutic* or "constant compar*" or "grounded theor*" or "lived experience*" or "life experience*" or "theoretical sampl*" or "purposive sampl*" or quasi-experiment*))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

20

TOPIC: ((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or "follow up" or "self report") NEAR/3 (interview* or discussion* or questionnaire*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

19

#18 AND #17

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

18

TS=((depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or "multi somat*" or "dysthymic disorder*" or "conversion disorder*" or "pain disorder*" or

hypochondria* or "body dysmorphi*" or "factitious disorder*" or "panic disorder*" or "panic attack*" or phobi* or agrophobi* or "obsessive compulsive*" or OCD or "post traumatic stress*" or PTSD or "stress disorder*" or "disruptive mood dysregulation disorder*" or "body dysmorphic disorder*" or "premenstrual dysphoric disorder*" or mutism or "mood affective disorder*" or "mood disorder*" or cyclothymi* or "neurotic disorder*" or "adjustment disorder*"or "medically unexplained symptom*"))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#17

#16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#16

TOPIC: (((robot or robots or robotics)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#15

TOPIC: (((("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*")))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#14

TOPIC: (((technolog* NEAR/2 (deliver* or information or communication*))))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#13

TOPIC: (((Internet NEAR/2 based)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#12

TOPIC: (((ipad NEAR/2 (app or apps or application or intervention*))))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#11

TS=((((Internet or digital* or online* or on-line or web* or virtual or computer*) NEAR/2 (deliver* or information or communication* or assisted or e-learning or support))))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#10

TOPIC: ((("digital media" or "software program*")))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#9

TOPIC: ((("interactive multimedia" or "interactive software")))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#8

TOPIC: ((("virtual reality" or "augmented reality")))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#7

TOPIC: (((smartwatch* or (wearable NEAR device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#6

TOPIC: (((videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#5

TOPIC: (((gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#4

TOPIC: ((((app or apps or application) NEAR/2 (smartphone* or smart-phone or mobile* or phone* or sensor* or software))))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#3

TOPIC: *((((intervention* or invention* or innovation*) and technolog*)))*
Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#2

TOPIC: ((("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele

med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*)))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

#1

TOPIC: (((eHealth or ehealth* or e-health* or "e health*" or "electronic NEAR health" or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic NEAR psyc*) or eTherap* or e-therap* or (electronic NEAR therap*))))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC
Timespan=All years

Search strategy- scopus

(((((KEY ((ehealth OR ehealth* OR e-health* OR "e health*" OR mhealth* OR m-health* OR "mobile health*" OR "m health" OR epsych* OR e-psych* OR etherap* OR e-therap*))) OR (KEY ((electronic W/2 (health OR psyc* OR therap*)))) OR (KEY (("telebehavio?ral health" OR "tele care" OR telecare OR "tele coaching" OR telecoaching OR telecomm* OR tele-comm*))) OR (KEY (("tele conference*" OR teleconference* OR "tele consultation" OR teleconsultation OR "tele health care" OR "tele health*" OR telehealth* OR tele-health OR "tele management" OR telemanagement))) OR (KEY (("tele med*" OR tele-med* OR "tele mental health*" OR "telemental health*" OR telemetry OR tele-monitor* OR telemonitor* OR telepractice OR "tele practice" OR tele-psych* OR telepsych* OR "tele speech" OR telespeech OR "tele therap*" OR tele-therap*))) OR (KEY (teletherap*))) OR ((KEY (((intervention* OR invention* OR innovation*) AND technolog*))) OR (KEY (((app OR apps OR application) W/2 (smartphone* OR smart-phone OR mobile* OR phone* OR sensor* OR software)))) OR (KEY ((gaming OR gamification OR videogam* OR computer AND gam* OR video AND gam* OR electronic AND gam*))) OR (KEY ((videoconferenc* OR "video conferenc*" OR videoconsultation* OR "video consultation*" OR "video technolog*" OR "video model*" OR skype* OR facetime OR webex))) OR (KEY ((smartwatch* OR (wearable W/1 device*) OR wearables OR "real-time monitoring device*" OR actigraphy OR accelerometer*)))) OR ((KEY (("virtual reality" OR "augmented reality"))) OR (KEY (("virtual reality" OR "augmented reality"))) OR (KEY (("interactive multimedia" OR "interactive software"))) OR (KEY (("digital media" OR "software program*"))) OR (KEY (((internet OR digital* OR online* OR on-line OR web* OR virtual OR computer*) W/2 (deliver* OR information OR communication* OR assisted OR e-learning OR support)))) OR (KEY ((ipad W/2 (app OR apps OR application OR intervention*))))) OR ((KEY ((internet W/2 based))) OR (KEY ((technolog* W/2 (deliver* OR information OR communication*)))) OR (KEY (("interactive technolog*" OR "wearable technolog*" OR "mHealth technolog*" OR "mobile technolog*" OR "sensor technolog*"))) OR (KEY ((robot OR robots OR robotics)))))) AND (KEY (depress* OR anxiety OR anxieties OR anxious OR gad OR somatiz* OR somatis* OR somatic OR somatoform* OR multisomat* OR "multi somat*" OR "dysthymic disorder*" OR "conversion disorder*" OR "pain disorder*" OR hypochondria* OR "body dysmorphi*" OR "factitious disorder*" OR "panic disorder*" OR "panic attack*" OR phobi* OR agrophobi* OR "obsessive compulsive*" OR ocd OR "post traumatic stress*" OR ptsd OR "stress disorder*" OR "disruptive mood dysregulation disorder*" OR "body dysmorphic disorder*" OR "premenstrual dysphoric disorder*" OR mutism OR "mood affective disorder*" OR "mood disorder*" OR cyclothymi* OR "neurotic disorder*" OR "adjustment disorder" OR "medically unexplained symptom*"))) AND ((KEY ("field note*" OR fieldnote* OR "field record*" OR "field stud*" OR "structured categor*" OR "unstructured categor*" OR (participant* W/3 observ*) OR (nonparticipant* W/3 observ*) OR (non AND participant* W/3 observ*))) OR (KEY ("focus group*" OR "advisory group*" OR qualitative OR ethnograph* OR fieldwork OR "field work" OR "key informant" OR "thematic analy*" OR "grounded theor*" OR phenomenolog* OR "discourse analy*" OR "content analy*" OR narrative* OR "observational method*" OR "open ended evaluation*" OR "action research" OR "inductive analy*" OR emic OR etic OR hermeneutic* OR

"constant compar*" OR "grounded theor*" OR "lived experience*" OR "life experience*" OR "theoretical sampl*" OR "purposive sampl*" OR quasi-experiment* OR (case W/2 stud*))) OR (KEY (("semi-structured" OR semistructured OR unstructured OR informal OR "in-depth" OR indepth OR "face-to-face" OR structured OR guide OR guides OR "follow up" OR "self report") W/3 (interview* OR discussion* OR questionnaire*)))) AND (LIMIT-TO (LANGUAGE , "English"))

Search strategy: Cochrane library Cochrane Central Register of Controlled Trials

(CENTRAL)

#1 MeSH descriptor: [Telemedicine] explode all trees

#2 MeSH descriptor: [Inventions] explode all trees

#3 (eHealth or ehealth* or e-health* or e health* or "electronic next health" or e-mental health or m-mental health or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic next psyc*) or eTherap* or e-therap* or (electronic next therap*)):ti or (eHealth or ehealth* or e-health* or e health* or "electronic adj health" or e-mental health or m-mental health or mhealth* or m-health* or "mobile health*" or "m health" or ePsych* or e-Psych* or (electronic next psyc*) or eTherap* or e-therap* or (electronic next therap*)):ab

#4 ("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*):ti or ("telebehavio?ral health" or "tele care" or telecare or "tele coaching" or telecoaching or telecomm* or tele-comm* or "tele conference*" or teleconference* or "tele consultation" or teleconsultation or "tele health care" or "tele health*" or telehealth* or tele-health or "tele management" or telemanagement or "tele med*" or tele-med* or "tele mental health*" or "telemental health*" or telemetry or tele-monitor* or telemonitor* or telepractice or "tele practice" or tele-psych* or telepsych* or "tele speech" or telespeech or "tele therap*" or tele-therap* or teletherap*):ab

#5 ((intervention* or invention* or innovation*) and technolog*):ti or ((intervention* or invention* or innovation*) and technolog*):ab

#6 MeSH descriptor: [Mobile Applications] explode all trees

#7 ((app or apps or application) next (smartphone* or smart-phone or mobile* or phone* or sensor* or software)):ti or ((app or apps or application) next (smartphone* or smart-phone or mobile* or phone* or sensor* or software)):ab

#8 MeSH descriptor: [Video Games] explode all trees

#9 (gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*):ti or (gaming or gamification or videogam* or computer gam* or video gam* or electronic gam*):ab

#10 MeSH descriptor: [Videoconferencing] explode all trees

#11 (videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex):ti or (videoconferenc* or "video conferenc*" or videoconsultation* or "video consultation*" or "video technolog*" or "video model*" or Skype* or facetime or webex):ab

#12 MeSH descriptor: [Wearable Electronic Devices] explode all trees

#13 MeSH descriptor: [Fitness Trackers] explode all trees

#14 (smartwatch* or (wearable next device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*):ti or (smartwatch* or (wearable next device*) or wearables or "real-time monitoring device*" or actigraphy or accelerometer*):ab 2404

#15 MeSH descriptor: [Virtual Reality] explode all trees

#16 MeSH descriptor: [Virtual Reality Exposure Therapy] explode all trees

#17 ("virtual reality" or "augmented reality" or "interactive multimedia" or "interactive software" or "digital media" or "software program*"):ti or ("virtual reality" or "augmented reality" or "interactive multimedia" or "interactive software" or "digital media" or "software program*"):ab

#18 ((Internet or digital* or online* or on-line or web* or virtual or computer*) next (deliver* or information or communication* or assisted or e-learning or support)):ti or ((Internet or digital* or online* or on-line or web* or virtual or computer*) next (deliver* or information or communication* or assisted or e-learning or support)):ab

#19 (ipad next (app or apps or application or intervention*)):ti or (ipad next (app or apps or application or intervention*)):ab

#20 (technolog* next (deliver* or information or communication*)):ti or (technolog* next (deliver* or information or communication*)):ab

#21 ("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*"):ti or ("interactive technolog*" or "wearable technolog*" or "mHealth technolog*" or "mobile technolog*" or "sensor technolog*"):ab

#22 MeSH descriptor: [Robotics] explode all trees

#23 (robot or robots or robotics):ti or (robot or robots or robotics):ab

#24 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23

#25 MeSH descriptor: [Depression] explode all trees

#26 MeSH descriptor: [Depressive Disorder] explode all trees

#27 MeSH descriptor: [Anxiety Disorders] explode all trees

#28 MeSH descriptor: [Anxiety] explode all trees

#29 MeSH descriptor: [Somatoform Disorders] explode all trees

#30 MeSH descriptor: [Hypochondriasis] explode all trees

#31 MeSH descriptor: [Dysthymic Disorder] explode all trees

#32 MeSH descriptor: [Conversion Disorder] explode all trees

#33 MeSH descriptor: [Body Dysmorphic Disorders] explode all trees

#34 MeSH descriptor: [Factitious Disorders] explode all trees

#35 MeSH descriptor: [Stress Disorders, Post-Traumatic] explode all trees

#36 MeSH descriptor: [Agoraphobia] explode all trees

#37 MeSH descriptor: [Panic Disorder] explode all trees

#38 MeSH descriptor: [Phobia, Social] explode all trees

#39 MeSH descriptor: [Obsessive-Compulsive Disorder] explode all trees

#40 MeSH descriptor: [Stress Disorders, Traumatic] explode all trees

#41 MeSH descriptor: [Premenstrual Dysphoric Disorder] explode all trees

#42 MeSH descriptor: [Mutism] explode all trees

#43 MeSH descriptor: [Mood Disorders] explode all trees

#44 MeSH descriptor: [Cyclothymic Disorder] explode all trees

#45 MeSH descriptor: [Neurotic Disorders] explode all trees

#46 MeSH descriptor: [Phobic Disorders] explode all trees

#47 MeSH descriptor: [Adjustment Disorders] explode all trees

#48 (depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or "multi somat*" or "dysthymic disorder*" or "conversion disorder*" or "pain disorder*" or hypochondria* or "body dysmorphi*" or "factitious disorder*" or "panic disorder*" or "panic attack*" or phobi* or agrophobi* or "obsessive compulsive*" or OCD or "post traumatic stress*" or PTSD or "stress disorder*" or "disruptive mood dysregulation disorder*" or "body dysmorphic disorder*" or "premenstrual dysphoric disorder*" or mutism or "mood affective disorder*" or "mood disorder*" or cyclothymi* or "neurotic disorder*" or "adjustment disorder" or "medically unexplained symptom*"):ti or (depress* or anxiety or anxieties or anxious or GAD or somatiz* or somatis* or somatic or somatoform* or multisomat* or "multi somat*" or "dysthymic disorder*" or "conversion disorder*" or "pain disorder*" or hypochondria* or "body dysmorphi*" or "factitious disorder*" or "panic disorder*" or "panic attack*" or phobi* or agrophobi* or "obsessive compulsive*" or OCD or "post traumatic stress*" or PTSD or "stress disorder*" or "disruptive mood dysregulation disorder*" or "body dysmorphic disorder*" or "premenstrual dysphoric disorder*" or mutism or "mood affective disorder*" or "mood disorder*" or cyclothymi* or "neurotic disorder*" or "adjustment disorder" or "medically unexplained symptom*"):ab

#49 #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48

#50 #24 and #49

#51 MeSH descriptor: [Qualitative Research] explode all trees

#52 MeSH descriptor: [Interview] explode all trees

#53 MeSH descriptor: [Focus Groups] explode all trees

#54 (("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or "self report") next (interview* or discussion* or questionnaire*)):ti or (("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides or follow up or "self report") next (interview* or discussion* or questionnaire*)):ab

#55 ("focus group*" or "advisory group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "thematic analy*" or "grounded theor*" or phenomenolog* or "discourse analy*" or "content analy*" or narrative* or "observational method*" or "open ended evaluation*" or "action research" or "inductive analy*" or emic or etic or hermeneutic* or "constant compar*" or "grounded theor*" or "lived experience*" or "life experience*" or "theoretical sampl*" or "purposive sampl*" or quasi-experiment* or (case near/2 stud*)):ti or ("focus group*" or "advisory group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "thematic analy*" or "grounded theor*" or phenomenolog* or "discourse analy*" or "content analy*" or narrative* or "observational method*" or "open ended evaluation*" or "action research" or "inductive analy*" or emic or etic or hermeneutic* or "constant compar*" or "grounded theor*"

Appendix 2 Service provider interview topic guides

Appendix 2 Service provider interview topic guide

Interview guides for Service Providers

Interview guide (does not take part) – completed over the phone, approx. 10-15 minutes

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis of the Participation Information Sheet.
- Explain Information Sheet will be posted out to them.
- Read out the bullet points from the Participant Consent Form and ask them if they agree with each item.
- Ask them to confirm consent "I consent to being interviewed".

Their thoughts on the reasons patients access urgent care

Experience of being involved in research studies

Can they tell you about their reasons for choosing not to take part in the study?

Is there anything that would have made them want to participate?

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (Does take part in the study but does not refer many patients) – over the phone or in person, approx. 15-30 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally or in writing depending on where interview takes place

Their thoughts on the reasons patients access urgent care

Experience of being involved in research studies

What their thoughts were when they first heard that the study was going to be carried out at their hospital/practice

Experiences of being involved in the study

Their thoughts on why they feel not many patients have been referred to the study

Anything else they would like to share in relation to the study

Interview guide (Does take part in the study and refers many patients) – over the phone or in person, approx. 15-30 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally or in writing depending on where interview takes place

Their thoughts on reasons patients access urgent care

Experience of being involved in research studies

What their thoughts were when they first heard that the study was going to be carried out at their hospital/practice

Experiences of being involved in the study

Their thoughts on why they and their team referred patients to the study

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Appendix 3 Service user participant interview topic guides

Appendix 3 Service user interview topic guide

Interview Guide for Service Users

Interview guide (withdraws from the study RCBT and TAU arm) - completed over the phone approx. 15 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis of the Participation Information Sheet. Explain Information Sheet will be posted out to them if they wish.
- Read out the bullet points from the Participant Consent Form and ask them if they agree with each item.
- Ask them to confirm consent "I consent to being interviewed".

How they came to take part in the study.

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study

How they found it completing the questionnaires and their reasons for deciding to withdraw from the study and completion of questionnaires

Is there anything we could have done that might have encouraged them to remain in the study?

Anything else they would like to share in relation to the study

Anything else they would like to share in relation to the study.

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (Does not commence/complete treatment – but DOES complete outcome measures) – over the phone or in person, approx. 30-45 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained as part of trial).

How they came to take part in the study.

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Their experience of being in the study

Can they please tell me their reasons for not starting/completing therapy?

Is there anything we could have done that might have encouraged them to start/complete therapy?

How they found it completing the questionnaires and their reasons for completing them.

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (Does not commence/complete treatment – and does NOT complete outcome measures) – over the phone or in person, approx. 30-45 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained as part of trial).

How they came to take part in the study

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study

Can they please tell me their reasons for not starting/completing therapy?

Is there anything we could have done that might have encouraged them to start/complete therapy?

How they found it completing the questionnaires and what made them decide not to complete them

Is there anything we could have done that might have encouraged them to complete questionnaires

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (Completes treatment – and completes outcome measures) – over the phone or in person, approx. 1 hour

Confirm participant happy to be audio recorded.

- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained).

How they came to take part in the study

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study

How they found the therapy and what were their reasons for completing therapy are

How they found it completing questionnaires and what made them decide to complete them.

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (Completes treatment BUT does NOT complete outcome measures) – over the phone or in person, approx. 1 hour

Confirm participant happy to be audio recorded.

- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained).

How they came to take part in the study

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study

How they found it completing the therapy and what their reasons for completing therapy are

How they found it completing questionnaires and reasons why they didn't complete them

Is there anything we could have done that might have encouraged them to complete questionnaires

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (TAU - includes those who do complete outcome measures) – over the phone or in person, approx. 30-45 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained)

How they came to take part in the study

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study – ask what it was like being in TAU and no intervention

How they found it completing questionnaires and reasons for completing them

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Interview guide (TAU - those who do NOT complete outcome measures) – over the phone or in person, approx. 30-45 minutes.

- Confirm participant happy to be audio recorded.
- Explain purpose of the study and provide synopsis/copy of the Participation Information Sheet. Explain Information Sheet will be posted out to them if interview is over the phone.
- Ask them to confirm consent verbally (written consent has already been obtained).

How they came to take part in the study

Can they tell you about what they hoped to get out of the study?

How things have been for them since I/colleague met with them

Who were they seeing before they took part in the study/who are they seeing now

Their experience of being in the study– ask what it was like being in TAU and no intervention

How they found it completing questionnaires and reasons why they didn't complete them

Is there anything we could have done that might have encouraged them to complete questionnaires

Anything else they would like to share in relation to the study

- Thank participant for their time and ask if they have any questions
- End interview

Appendix 4 NHS HRA Ethical approval letters

NHS
Health Research Authority
NRES Committee London - Riverside
Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1391

23 June 2015

Shireen Patel
Research Assistant and Study Coordinator
NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) East Midlands
C Floor Institute of Mental Health Building
University of Nottingham
Innovation Park Triumph Road
Nottingham NG7 2TU

Dear Shireen Patel,

Study title:	**Helping Urgent Care Users Cope with Distress about Physical Complaints: A Randomised Controlled Trial**
REC reference:	**14/LO/1102**
Protocol number:	**14056**
Amendment number:	**Substantial Amendment 1, May 2015 - add two doctoral research projects**
Amendment date:	**01 May 2015**
IRAS project ID:	**150153**

The above amendment was reviewed at the meeting of the Sub-Committee held on 19 June 2015.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study flyer Helping Urgent Care Users cope with distress about physical complaints v2.0 28.1.15]	2.0	28 January 2015
Interview schedules or topic guides for participants [Sudden Gains Service User Interviews Topic Guide Helping Urgent Care Users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015
Interview schedules or topic guides for participants [sudden gains therapist interview topic guide helping urgent care users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015

study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [study flyer Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Covering letter on headed paper [Letter with submission to ethics]		03 June 2014
Covering letter on headed paper		23 July 2014
Covering letter on headed paper [Emergency Department Recruitment of participants]	1.0	23 July 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2013 Clinical Trials Evidence of Insurance Letter]		31 July 2013
GP/consultant information sheets or letters [GP letter Helping Urgent Care Users cope with distress about physical complaints v.1.0 29.5.14]	1.0	29 May 2014
GP/consultant information sheets or letters [GP eligibility checklist sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
GP/consultant information sheets or letters [Research Nurse Eligibility Checklist Sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Interview schedules or topic guides for participants [Staff Qualitative Interview Guide]	1.0	29 May 2014
Interview schedules or topic guides for participants [Staff Qualitative Interview Guide]	1.0	29 May 2014
Interview schedules or topic guides for participants [Service User Qualitative Interviews Topic Guide Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 29.5.14]	1.0	29 May 2014
Interview schedules or topic guides for participants [Staff Qualitative Interviews Topic Guide Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 29.5.14]	1.0	29 May 2014
Interview schedules or topic guides for participants [Staff Qualitative Interviews Topic Guide Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 29.5.14]	1.0	29 May 2014
IRAS Checklist XML [Checklist_06062014]		06 June 2014
IRAS Checklist XML [Checklist_24072014]		24 July 2014
IRAS Checklist XML		24 July 2014
Letter from sponsor [14056 Sponsor letter signed]		04 June 2014

Letters of invitation to participant [GP letter of invite Helping urgent care users cope with distress about physical complaints v1.029.5.14]	1.0	29 May 2014
Letters of invitation to participant [Emergency department letter of invite Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Other [CBT info_sheet Helping Urgent Care Users cope with distress about physical complaints v1.1 1 23.7.14]	1.1	23 July 2014
Other [Participant Consent Form Helping Urgent Care Users cope with distress about physical complaints v1.1 23.7.14]	1.1	23 July 2014
Other [GP Recruitment of Participants covering letter]	1.0	23 July 2014
Other [REC response letter Helping Urgent Care Users cope with distress about physical complaints 23.7.14]		23 July 2014
Other [Emergency Department Recruitment of Participants Cover Letter Helping Urgent Care Users cope with distress about physical complaints v1. 0 23.7.14]	1.0	23 July 2014
Other [GP Eligibility Checklist]	1.1	23 July 2014
Other [Participant Remote CBT intervention letter Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Other [GP Eligibility Checklist Helping Urgent Care Users cope with distress about physical complaints v1.1 23.7.14]	1.1	23 July 2014
Other [Research Nurse checklist Helping Urgent Care Users cope with distress about physical complaints v1.1 23.7.14]	1.1	23 July 2014
Other [CBT Info sheet]	1.1	23 July 2014
Other [Participant TAU treatment allocation letter Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Other [Participant information sheet Helping Urgent Care Users cope with distress about physical complaints v1.1 23.7.14]	1.1	23 July 2014
Other [GP Recruitment of Participants Cover Letter Helping Urgent Care Users cope with distress about physical complaints v1.0 23.7.14]	1.0	23 July 2014
Other [Research Nurse Checklist]	1.1	23 July 2014
Participant consent form [Consent_to_contact_form Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Participant consent form [Staff Consent Form Helping Urgent Care Users cope with distress about physical complaints v1.029.5.14]	1.0	29 May 2014
Participant consent form	1.1	23 July 2014
Participant consent form [Participant Consent Form Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Participant information sheet (PIS) [CBT info_sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Participant information sheet (PIS) [Qualitative Participant Information Sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Participant information sheet (PIS) [Participant information sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014

Participant information sheet (PIS)	1.1	23 July 2014
Participant information sheet (PIS) [Staff Participant Information Sheet Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 29.5.14]	1.0	29 May 2014
REC Application Form [REC_Form_04062014]		04 June 2014
Referee's report or other scientific critique report [Initial EM SC review_Proj 5 Health Anxiety Prof Morriss v1.0 Date 03.1.14]		03 January 2014
Referee's report or other scientific critique report [Reply to initial EM SC review_Proj 5_Health Anxiety_Prof Morriss reply v1.0 Date 23.01.14]	1.0	23 January 2014
Referee's report or other scientific critique report [Final EM SC Proj 5 review - Health Anxiety - Prof Richard Morriss v1.0 date 4.3.14]	1.0	04 March 2014
Research protocol or project proposal [PROTOCOL Helping Urgent Care Users cope with distress about physical complaints v1 0 29 5 14]	1.0	29 May 2014
Response to Request for Further Information		
Summary CV for Chief Investigator (CI) [Professor Richard Morriss CV]		
Validated questionnaire [Baseline assessment Helping Urgent Care Users cope with distress about physical complaints v1.0_29.5.14]	1.0	29 May 2014
Validated questionnaire [Eligibility Screening Assessment Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Validated questionnaire [Treatment satisfaction questionnaire Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Validated questionnaire [follow up booklet 6 and 12 months Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Validated questionnaire [SCID Question Sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Validated questionnaire [follow up booklet 3and 9 months Helping Urgent Care Users cope with distress about physical complaints v1.0 29.5.14]	1.0	29 May 2014
Validated questionnaire [SCID Scoring sheet Helping Urgent Care Users cope with distress about_physical complaints v1.0 29.5.14]	1.0	29 May 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/1102	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Sabita Uthaya
Chair

Email: nrescommittee.london-riverside@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Angela Shone*
Ms Shirley Mitchell, Head of Research Management and Governance

NHS
Health Research Authority
NRES Committee London - Riverside
Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1391

23 June 2015

Shireen Patel
Research Assistant and Study Coordinator
NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) East Midlands
C Floor Institute of Mental Health Building
University of Nottingham
Innovation Park Triumph Road
Nottingham NG7 2TU

Dear Shireen Patel,

Study title:	**Helping Urgent Care Users Cope with Distress about Physical Complaints: A Randomised Controlled Trial**
REC reference:	**14/LO/1102**
Protocol number:	**14056**
Amendment number:	**Substantial Amendment 1, May 2015 - add two doctoral research projects**
Amendment date:	**01 May 2015**
IRAS project ID:	**150153**

The above amendment was reviewed at the meeting of the Sub-Committee held on 19 June 2015.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study flyer Helping Urgent Care Users cope with distress about physical complaints v2.0 28.1.15]	2.0	28 January 2015
Interview schedules or topic guides for participants [Sudden Gains Service User Interviews Topic Guide Helping Urgent Care Users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015
Interview schedules or topic guides for participants [sudden gains therapist interview topic guide helping urgent care users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015

Interview schedules or topic guides for participants [Interview guides for Service Users Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Interview schedules or topic guides for participants [Interview guides for Service Providers Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Notice of Substantial Amendment (non-CTIMP) [Notice of amendment REC ref 14 LO 1102]		01 May 2015
Other [Session by session ratings Helping Urgent Care Users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015
Other [Hopes and Thoughts questionnaire Helping Urgent Care Users cope with distress about physical complaint v1.0 27.4.15]	1.0	27 April 2015
Other [Telephone Therapy resources Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Other [WebEx guide Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Other [Contingency planning Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Other [Baseline assessment Helping Urgent Care Users cope with distress about physical complaints v2.0 23.1.15]	2.0	23 January 2015
Other [follow up booklet 6 months Helping Urgent Care Users cope with distress about physical complaints v2.0 23.1.15]	2.0	23 January 2015
Other [follow up booklet 12 months Helping Urgent Care Users cope with distress about physical complaints v2.0 23.1.15]	2.0	23 January 2015
Other [CBT manual Helping Urgent Care Users Cope with Distress about Physical Complaints v2.0 Date 12.5.2015]	2.0	12 May 2015
Participant consent form [Public Involvement Consent form Helping Urgent Care Users cope with Distress about Physical Complaints v1.0 6.5.15]	1.0	06 May 2015
Participant consent form [Therapist Consent Form Helping Urgent Care Users cope with distress about physical complaints v1.0 27.1.15]	1.0	27 January 2015
Participant consent form [Participant Consent Form Helping Urgent Care Users cope with distress about physical complaints v2.0 27.4.15]	2.0	27 April 2015
Participant consent form [Decline-withdraw Participant Consent form Helping Urgent Care Users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015
Participant consent form [Staff Consent Form Helping Urgent Care Users cope with distress about physical complaints v2.0 27.4.15]	2.0	27 April 2015
Participant information sheet (PIS) [Participant information sheet Helping Urgent Care Users cope with distress about physical complaints v2.0 27.4.15]	2.0	27 April 2015
Participant information sheet (PIS) [Service User sudden gains Participant Information Sheet Helping Urgent Care users cope with Distress about Physical Complaints v1.0 27.4.15]	1.0	27 April 2015
Participant information sheet (PIS) [Therapist Sudden gains Participant Information Sheet Helping Urgent Care Users Cope with Distress about Physical Complaints v1.0 27.4.15]	1.0den gains Participant Information Sheet Helping Urgent Care Users Cope with Distress abo	27 April 2015
Participant information sheet (PIS) [Decline Withdraw Participant Information Sheet Helping Urgent Care Users cope with distress about physical complaints v1.0 27.4.15]	1.0	27 April 2015

Participant information sheet (PIS) [Qualitative Participant Information Sheet Helping Urgent Care Users cope with distress about physical complaints v2.0 27.4.15]	2.0	27 April 2015
Participant information sheet (PIS) [Staff Participant Information Sheet Helping Urgent Care Users Cope with Distress about Physical Complaints v2.0 27.4.15]	2.0	27 April 2015
Research protocol or project proposal [PROTOCOL Helping Urgent Care Users cope with distress about physical complaints v2.0 27.4.15]	2.0	27 April 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/1102:	**Please quote this number on all correspondence**

Yours sincerely

Pp

Margaret Jones
Vice Chair

E-mail: nrescommittee.london-riverside@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Fanny Mitchell,*
Professor Richard Morriss, University of Nottingham
Ms Angela Shone

Appendix 5 Service provider participant information sheet

Collaboration for Leadership in Applied Health Research and Care East Midlands

The University of Nottingham UNITED KINGDOM · CHINA · MALAYSIA

NHS National Institute for Health Research

Appendix 5 Staff Participant Information Sheet

Staff Participant Information Sheet (Version 2.0 Date: 27.4.15)

Helping Urgent Care Users Cope with Distress about Physical Complaints

We would like to invite you to take part in our research study. Before you decide you we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of this study?

(1) We want to arrive at a better understanding of the needs of patients who use unscheduled/urgent care

Each year many people make use of emergency services, such as going to the A & E department, walk in centre or making an urgent same day appointment with their GP. This is termed 'unscheduled/urgent care'.

Many patients have had to attend one of these emergency services more than once in the past year but the doctors have been unable to tell them what exactly is causing their symptoms.

These symptoms can be painful and cause distress if they are not able to be treated, yet repeated investigation may not establish the cause.

(2) We want to find out if providing CBT via video calling/over the telephone is acceptable and effective in improving physical and emotional health

It may be possible to reduce the pain and discomfort using a talking therapy called Cognitive Behavioural Therapy (CBT) which can be delivered via a video calling system (similar to Skype) or the telephone.

CBT aims to teach you individuals how best to cope when they get distressed. It will also help them understand their body's responses better and how to manage them.

To find out whether CBT is effective we will carry out a "randomised controlled trial" in which we make comparisons between two groups. Half of the people we interview will be offered CBT as well as their usual care and the other half will continue to receive their usual care only. For statistical reasons, each patient is put into a group by chance (randomly).

In addition to the above we would also like to know:

An important part of the research is to find out how this intervention might continue after this project is completed. To do this, we would like to hear the views of those who would be involved in the future uptake and implementation of this intervention, to find out what they think might help and hinder its implementation in the long term. To do this we need to explore the views of services users, health professionals and other experts and researchers.

Why have I been invited?

You are being invited to take part because you are involved with the management of care and/or delivery of care of patients who access unscheduled/urgent care services. Because of the level of your involvement, you will be able to provide information on the enablers and barriers to implementing this intervention.

Do I have to take part?

No, it is up to you to decide. We will describe the study and go through this information sheet which we will then give to you. If you decide to take part, we will ask you to sign a consent form to show that you have agreed. You are free to withdraw at any time, without giving a reason. If you withdraw then the information that has already been collected from you cannot be erased and may still be used in the final analysis.

What will happen to me if I take part?

If you agree to take part, a member of the study team (Shireen Patel) will contact you and arrange a time for an interview. The interview will take approximately 15-30 minutes to complete. This may be a group interview with other members of your team. With your permission, we would like to record the conversation so we can refer back to it later on.

What are the possible disadvantages and risks of taking part?

Taking part in the project will take up some of your time.

What are the possible benefits of taking part?

The interviews will allow you to reflect on your part in delivery of care as well as, in a broader sense, the value and availability of health services for people who attend urgent care services. Your participation in the study may help to improve the delivery of care and possibly, the implementation of a new service.

What happens when the research study stops?

We will provide a summary of our findings and its implications when the study is completed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the study researcher, the Clinical Trials Manager or the Chief Investigator who will do their best to answer your questions. Their contact details are given at the end of this information sheet.

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence at all times.

All information which is collected about you during the course of the research will be kept **strictly confidential** stored in a secure and locked office, and on a password protected database**.** Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

All research data will be kept securely for seven years in accordance with the University of Nottingham regulations. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

We will write reports on our findings that will be published in journals and presented at conferences, but these reports will describe all of the data together - particular care will be taken to ensure that neither you nor your specific views are able to be identified.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw from the study at any time, without giving any reason, and without your legal rights being affected. If you decide to withdraw from the study, any information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results will be publicised through the extensive arrangements for dissemination locally within the University and local NHS services (through road shows, websites, and conferences) as well as publication in peer reviewed journals, local, national and international scientific conferences. These reports will describe all of the data together - particular care will be taken to ensure that neither you nor your specific views are able to be identified.

Who is organising and funding the research?

This study is funded by National Institute for Health Research (NIHR) and matched funding from local partner organisations as part of a research and implementation centre called CLAHRC

East Midlands, one of 13 such research centres in the country. The Chief Investigator and researchers you will meet are based at the University of Nottingham.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by National Research Ethics Service (NRES) London-Riverside Committee.

Further information and contact details:

If you have any queries or would like to talk more about the study you can contact:

Study Researcher
Shireen Patel
Tel: 0115 82314 34/25
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Clinical trials Manager
Dr Catherine Kaylor-Hughes
Tel: 0115 8232478
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Principal Investigator
Professor Richard Morriss
Professor of Psychiatry
Tel: 0115 8230427
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Appendix 6 Service provider participant consent form

The University of Nottingham
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Collaboration for Leadership in Applied Health Research and Care East Midlands

NHS National Institute for Health Research

TIC:

APPENDIX 6 Service provider participant consent form

STAFF CONSENT FORM
(Version 2.0)

Helping Urgent Care Users Cope with Distress about Physical Complaints

REC ref: 14/LO/1102

Name of Chief Investigator: Professor Richard Morriss

Name of Participant:

	Please Initial box
1. I confirm I have read and understand the information sheet (Staff Participant Information Sheet Version 2.0 dated 27.4.15) for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis	☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.	☐
4. I understand that the interview will be recorded and transcribed and that anonymous direct quotes from the interview may be used in the study reports.	☐
5. I agree to take part in the above study.	☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

2 copies: 1 for participant and 1 for the project notes

Appendix 7 Service user participant qualitative interview participant information sheet

Collaboration for Leadership in Applied Health Research and Care East Midlands

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Appendix 7 : Service User Qualitative Interview Participant Information Sheet

Helping Urgent Care Users Cope with Distress about Physical Complaints

Name of Researcher: Shireen Patel

We would like to invite you to take part in our research study

- Before you decide we would like you to understand why the research is being done and what it would involve for you.
- One of our team will go through the information sheet with you and answer any questions you have.
- Talk to others about the study if you wish.
- Ask us if there is anything that is not clear.

1 What is the purpose of the study?

Thank you for taking part in our study titled *"Helping Urgent Care Users Cope with Distress about Physical Complaints."* One of the aims of our study was to find out if providing CBT via video calling or over the telephone is acceptable and effective in improving physical and emotional health

We also want to find out :

What is the best way to deliver this treatment and put it into practice?

An important part of the research is to find out how talking therapy delivered via video calling systems (similar to Skype) or the telephone might continue after this project is completed.

To do this, we would like to hear the views of those who would be involved in the future uptake and implementation of this intervention. We would like to find out what they think might help and hinder its implementation in the long term.

To do this we need to explore the views of services users, health professionals and other experts and researchers.

We would like to hear your views about the study and what aspects you found helpful and unhelpful.

Contents

If you have any questions about this study, please talk to study researcher Shireen Patel on **0115 8231434**

2 Why have I been invited?

We are asking some people who have taken part in the study and provided consent to be interviewed again. This interview will allow you to talk about your thoughts about the being involved in the study.

3 Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked if you are happy to be interviewed. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

4 What will happen to me if I take part?

If you agree to take part, a member of the study team you and arrange a time for an interview. The interview will take approximately 30-45 minutes to complete. With your permission, we would like to record the conversation so we can refer back to it later on.

5 Expenses and payments

To thank you for completing the interview and for your time, you will be given a £10 High Street Voucher at the end of this interview. You can also claim travel expenses for any visits incurred as a result of participation.

6 What are the possible disadvantages and risks of taking part?

Some of the questions we will be asking might lead you to talk about your emotions such as feeling anxious or low. Whilst most people do not mind answering these questions, some people may feel upset. It is important that we ask these questions and find out if treatment can improve these symptoms. Many people find talking about or sharing concerns in a safe and confidential way can be helpful.

7 What are the possible benefits of taking part?

By taking part you may receive treatment which helps with your symptoms. The interview you complete as part of the research will allow you to reflect on your symptoms and emotions and how these have changed over the research period.

We cannot promise the study will help you but the information we get from this study may help patients in the future to get treatment that helps them manage their difficulties, and cope better with their pain or associated symptoms.

8 What happens when the research study stops?

Your care will not change as a result of taking part in the study. If you are interested in finding out the results of the study we can keep your contact details and inform you of results when the study is completed.

9 What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers or the Clinical Trials Manager who will do their best to answer your questions. Their contact details are given at the end of this information sheet. f you remain unhappy you may contact the Patient Advice Liaison Service (PALS) [0115 924 9924 ext: 63187] and if you wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

10 Will my taking part be kept confidential?

- We will follow ethical and legal practice and all information about you will be handled in confidence at all times.
- If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. Data may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.
- All information which is collected about you during the course of the research will be kept **strictly confidential** stored in a secure and locked office, and on a password protected database**.** Any information about you which leaves the hospital or GP practice will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.
- The only time that we would break confidentiality is if we felt that we need to share information to protect your safety or the safety of others.
- Your personal data (address, telephone number) will be kept for twelve months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for seven years in accordance with the University of Nottingham regulations. . After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

11 What will happen to me if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw from the study at any time, without giving any reason, and without your legal rights being affected. If you decide to withdraw from the study, any information collected so far cannot be erased and this information may still be used in the project analysis.

12 Involvement of the General Practitioner/Family GP

With your written consent, we have sent a letter to your usual doctor informing them that you are taking part in this study. We will not be informing them of your participation in this interview unless we need to share information to protect your safety or the safety of others.

13 What will happen to the results of the research study?

The results will be publicised through the extensive arrangements for dissemination locally within the University and local NHS services (through road shows, websites, and conferences) as well as publication in peer reviewed journals, local, national and international scientific conferences. We will also send all participants a summary of the findings. The results will be published at the end of the study which is expected to be the end of 2018.

14 Who is organising and funding the research?

This study is funded by National Institute for Health Research (NIHR) and matched funding from local partner organisations as part of a research and implementation centre called CLAHRC East Midlands, one of 13 such research centres in the country.

15 Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by National Research Ethics Service (NRES) London-Riverside Committee.

16. Further information and contact details

If you have any queries or would like to talk more about the study you can contact:

Study researchers

Shireen Patel/Michelle Stubley
Tel: 0115 82314 34/25
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Clinical Trials Manager

Dr Catherine Kaylor-Hughes
Tel: 0115 8232478
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Chief Investigator

Professor Richard Morriss
Tel: 0115 8230427
CLAHRC EM
IMH Building
University of Nottingham
Nottingham
NG7 2TU

Appendix 8 Service user participant consent form

The University of Nottingham
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Collaboration for Leadership in Applied Health Research and Care East Midlands

NHS National Institute for Health Research

Local letter head to be added

TIC:

Appendix 8 Service user participant consent form

PARTICIPANT CONSENT FORM
(Version 1.1)

Helping Urgent Care Users Cope with Distress about Physical Complaints

REC ref:

Name of Chief Investigator: Professor Richard Morriss

Name of Participant:

	Please Initial box
1. I confirm I have read and understand the information sheet (Participant Information Sheet Version 1.1 dated 23.7.14) for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.	☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study.	☐
4. I agree to my GP being informed of my participation in this study.	☐
5. I give permission for my treatment sessions to be audio/video recorded. I understand that any quotes used in publications, reports or training materials will be anonymous and I will not be identified.	☐
6. I agree to being contacted in the event that the research team wish to carry out a further interview.	☐
7. I understand that if I agree to a further interview it will be recorded and transcribed and that anonymous direct quotes from the interview may be used in the study reports.	☐
8. I agree to take part in the above study.	☐

Name of Participant	**Date**	**Signature**
_____	_____	_____
Name of Researcher	**Date**	**Signature**

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

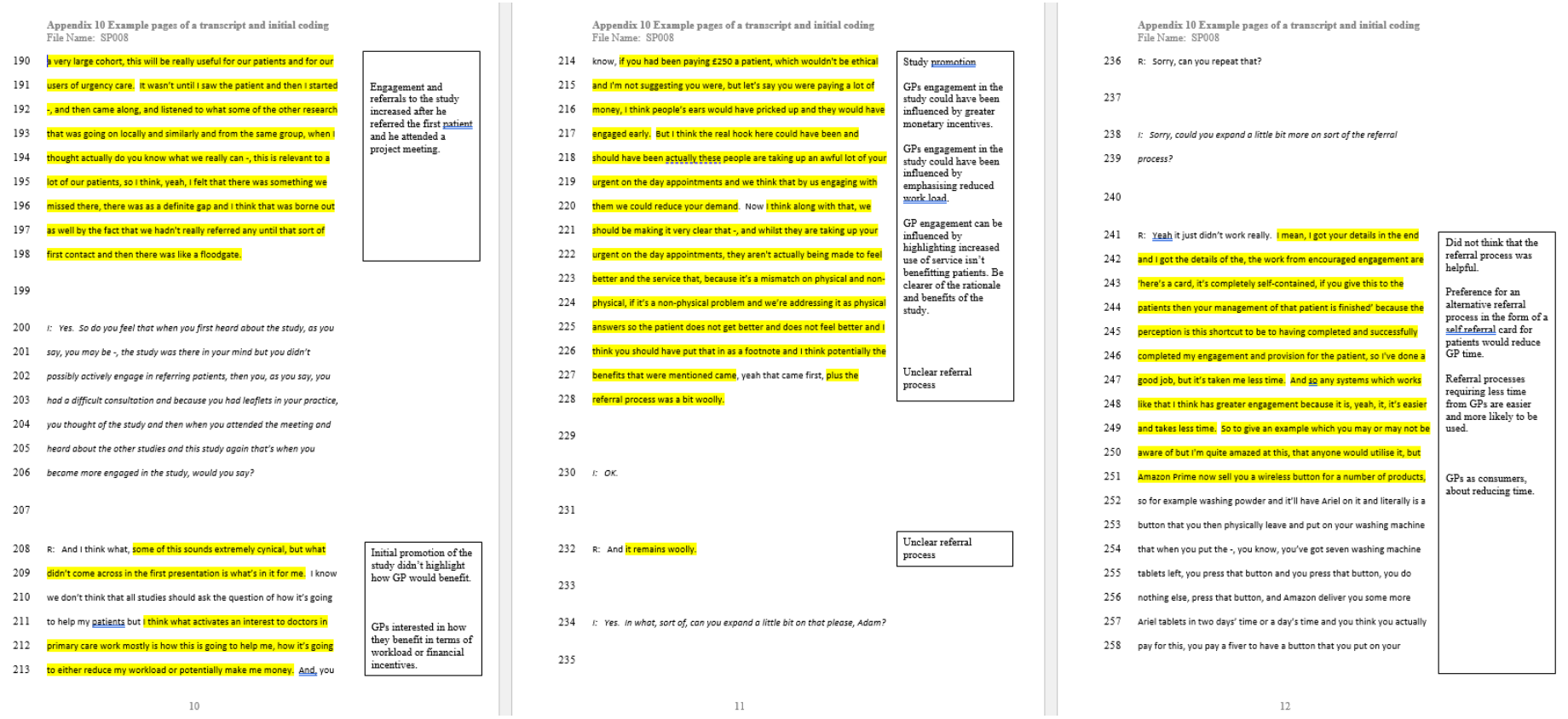
Appendix 9 A 15-Point checklist criteria for good Thematic Analysis process (Braun and Clarke, 2006)

Appendix 9 A 15-Point Checklist of Criteria for Good Thematic Analysis Process (Braun and Clarke, 2006)

Transcription	1.	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'.
Coding	2.	Each data item has been given equal attention in the coding process.
	3.	Themes have not been generated from a few vivid examples (an anecdotal approach) but, instead, the coding process has been thorough, inclusive and comprehensive.
	4.	All relevant extracts for all each theme have been collated.
	5.	Themes have been checked against each other and back to the original data set.
	6.	Themes are internally coherent, consistent, and distinctive.
Analysis	7.	Data have been analysed rather than just paraphrased or described.
	8.	Analysis and data match each other – the extracts illustrate the analytic claims.
	9.	Analysis tells a convincing and well-organised story about the data and topic.
	10.	A good balance between analytic narrative and illustrative extracts is provided.
Overall	11.	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly.
Written report	12.	The assumptions about ThA are clearly explicated.
	13.	There is a good fit between what you claim you do, and what you show you have done – ie, described method and reported analysis are consistent.
	14.	The language and concepts used in the report are consistent with the epistemological position of the analysis.
	15.	The researcher is positioned as *active* in the research process; themes do not just 'emerge'.

(Braun and Clark, 2006, p37)

Appendix 10 Example pages of a transcript and initial coding carried out



Appendix 10 Example pages of a transcript and initial coding
File Name: SP008

190 a very large cohort, this will be really useful for our patients and for our
191 users of urgency care. It wasn't until I saw the patient and then I started
192 -, and then came along, and listened to what some of the other research
193 that was going on locally and similarly and from the same group, when I
194 thought actually do you know what we really can -, this is relevant to a
195 lot of our patients, so I think, yeah, I felt that there was something we
196 missed there, there was as a definite gap and I think that was borne out
197 as well by the fact that we hadn't really referred any until that sort of
198 first contact and then there was like a floodgate.
199
200 *I: Yes. So do you feel that when you first heard about the study, as you*
201 *say, you may be -, the study was there in your mind but you didn't*
202 *possibly actively engage in referring patients, then you, as you say, you*
203 *had a difficult consultation and because you had leaflets in your practice,*
204 *you thought of the study and then when you attended the meeting and*
205 *heard about the other studies and this study again that's when you*
206 *became more engaged in the study, would you say?*
207
208 R: And I think what, some of this sounds extremely cynical, but what
209 didn't come across in the first presentation is what's in it for me. I know
210 we don't think that all studies should ask the question of how it's going
211 to help my patients but I think what activates an interest to doctors in
212 primary care work mostly is how this is going to help me, how it's going
213 to either reduce my workload or potentially make me money. And, you

Engagement and referrals to the study increased after he referred the first patient and he attended a project meeting.

Initial promotion of the study didn't highlight how GP would benefit.

GPs interested in how they benefit in terms of workload or financial incentives.

10

Appendix 10 Example pages of a transcript and initial coding
File Name: SP008

214 know, if you had been paying £250 a patient, which wouldn't be ethical
215 and I'm not suggesting you were, but let's say you were paying a lot of
216 money, I think people's ears would have pricked up and they would have
217 engaged early. But I think the real hook here could have been and
218 should have been actually these people are taking up an awful lot of your
219 urgent on the day appointments and we think that by us engaging with
220 them we could reduce your demand. Now I think along with that, we
221 should be making it very clear that -, and whilst they are taking up your
222 urgent on the day appointments, they aren't actually being made to feel
223 better and the service that, because it's a mismatch on physical and non-
224 physical, if it's a non-physical problem and we're addressing it as physical
225 answers so the patient does not get better and does not feel better and I
226 think you should have put that in as a footnote and I think potentially the
227 benefits that were mentioned came, yeah that came first, plus the
228 referral process was a bit woolly.
229
230 *I: OK.*
231
232 R: And it remains woolly.
233
234 *I: Yes. In what, sort of, can you expand a little bit on that please, Adam?*
235

Study promotion

GPs engagement in the study could have been influenced by greater monetary incentives.

GPs engagement in the study could have been influenced by emphasising reduced work load.

GP engagement can be influenced by highlighting increased use of service isn't benefitting patients. Be clearer of the rationale and benefits of the study.

Unclear referral process

Unclear referral process

11

Appendix 10 Example pages of a transcript and initial coding
File Name: SP008

236 R: Sorry, can you repeat that?
237
238 *I: Sorry, could you expand a little bit more on sort of the referral*
239 *process?*
240
241 R: Yeah it just didn't work really. I mean, I got your details in the end
242 and I got the details of the, the work from encouraged engagement are
243 'here's a card, it's completely self-contained, if you give this to the
244 patients then your management of that patient is finished' because the
245 perception is this shortcut to be to having completed and successfully
246 completed my engagement and provision for the patient, so I've done a
247 good job, but it's taken me less time. And so any systems which works
248 like that I think has greater engagement because it is, yeah, it, it's easier
249 and takes less time. So to give an example which you may or may not be
250 aware of but I'm quite amazed at this, that anyone would utilise it, but
251 Amazon Prime now sell you a wireless button for a number of products,
252 so for example washing powder and it'll have Ariel on it and literally is a
253 button that you then physically leave and put on your washing machine
254 that when you put the -, you know, you've got seven washing machine
255 tablets left, you press that button and you press that button, you do
256 nothing else, press that button, and Amazon deliver you some more
257 Ariel tablets in two days' time or a day's time and you think you actually
258 pay for this, you pay a fiver to have a button that you put on your

Did not think that the referral process was helpful.

Preference for an alternative referral process in the form of a self-referral card for patients would reduce GP time.

Referral processes requiring less time from GPs are easier and more likely to be used.

GPs as consumers, about reducing time.

12

Appendix 11 Generating initial codes table for service user recruitment themes

Appendix 11 Generating initial codes table – service user recruitment

Clusters/candidate themes	Codes (S=semantic, L=latent)	Participant number and quotes
Initial perceptions and its impact on motivation to participate **Hope for improvement** **Developing techniques to manage symptoms** **Gaining personal ownership and control**	Hope that the intervention could help with symptoms and pain management (L) Intervention would provide coping techniques to help manage anxiety (L) Wanting to get better (L) Being open to anything that might help (S) Finding a cure (S) Desperation Reduce anxieties (S) Feeling empowered (L)	01016 She hoped to be able to manage her long term condition and pain. 01019 He hoped that study participation would help by providing him techniques to manage his anxiety. He hoped to develop ways to manage his worries (174-179). 01015 She hoped to see how it would help her (71-72) She was open to anything that would help her to get her better (80-81). 01007 She hoped to reduce her anxiety. She was in a bad place with her personal life and she thought why not (80-82). 01008 He hoped to get a cure. He hoped to wake up one day and not worry (72-75). He knew that it may/may not help. But in his mind he was looking for a cure (79-81). 01024 She was pleased when she heard about the study. Because she wanted to try anything that would help (97-98).

Appendix 11 Generating initial codes table – service user recruitment

		Prior to participating they didn't think about whether the therapy would work or not. It was just about being offered help and even making a slight improvement (352-357). 01066 He hoped to receive advice on how to reduce his anxiety and low mood (135-136). At the time he was really keen to receive help from someone to manage his stress, anxiety and depression (162-166). 02001 He hoped to improve himself. He was out of work at the time and wanted to do something (113-114). 04001 At the baseline assessment her thoughts were that study participation might benefit (108-113). Her reason for study participation was that she was prepared to try anything to help reduce or help her understand her pain and what was causing it (87-94).
Curiosity, ambivalence, apprehensions about study participation **Perceived relevance/usefulness of the intervention** **Concerns regarding trial suitability**	Uncertainty about study expectations (L) Curiosity (S) Uncertainty about study relevance Scepticism about relevance of talking therapy for their symptoms (L)	01015 Initially she felt apprehensive about the study. Uncertain about what to expect (65-66) 03012 His understanding of the study was that it was to help people access the care they required. He was experiencing unexplained fatigue symptoms. He didn't really understand what the GP was suggesting but he agreed to be referred out of curiosity (84-90). 04001

Appendix 11 Generating initial codes table – service user recruitment

	Anxiety related to study participation (S)	Initially she felt sceptical about the study. She did not think talking would help. She thinks her pain is medical (75-78). She thought it was an underlying medical problem rather than something psychological. She thought it may be stress related but she was not totally convinced (81-84). After speaking to the researcher she considered giving it a try but still wasn't convinced about it (103-104). 01019 Initially he had mixed feelings, he was nervous but knew it was something he had to do (153-159).
Opportunity to access treatment **Improved accessibility and convenience of the intervention being offered** Participation in the research as a means of gaining access to services	Access to services (L) The intervention improved accessibility because it reduced logistical barriers Reduced long waiting times Current experiences of trying to access services could be challenging Participation seen as an opportunity to access treatment	01002 She hoped to get experience of therapy (71) 01008 He has had health anxieties for so long and he just wanted some hope, and he was prepared to access anything that might help (339-340). 01014 She hoped to get some therapy (73) 01018 He hoped to receive the remotely delivered therapy (95-98) 01040 Dr referred him to the study. It was a smooth process. The Doctor didn't ask him to self-refer which is what he has had to do in the past. He suggested that it was as additional opportunity to try (796-801). 01043

Appendix 11 Generating initial codes table – service user recruitment

		He understands that the internet is not always the right place to seek health information but it is hard to access support because of the demand. Getting access to support is difficult which put him off seeking any help in the past (342-355). 01055 He decided to take part because he thought that any help offered was a good thing (73-74). He saw therapy as complimentary to other services he was accessing (104-106).He saw it as another step in the right direction. 01046 She doesn't think NHS have the resources to provide CBT. Previously she was paying £80 an hour for private sessions (127-135). 01051 RCBT was a good option for her because she didn't have to rely on others to take her for therapy (108-109). Her initial thoughts were of excitement. She had been waiting long time for CBT and was struggling to find a solution for her condition. Before seeing the Dr she felt like she wasn't getting anywhere. Now she had help (126-131). 01082 She wanted to get better and was willing to try CBT regardless of how it was offered (138-139). Therapy is not readily available and there can be anxiety around what it might entail (365-374). She was on a waiting list to received CBT through her Uni (217). 01015

Appendix 11 Generating initial codes table – service user recruitment

		Time was short because she was due to go abroad. She wanted therapy quickly (81-83). She was keen to hear more about the study. It felt like chance and fate. She was given the opportunity to participate and not everybody does so she wanted to take it (101-106.) At the time she was extremely anxious and so she was excited about the possibility of receiving some additional therapy. She was nervous about the possibility of being in the TAU. She really wanted therapy (68-73). 03012 He wanted to see if the study could help him (102-103). He hoped to get some answers and see if he could receive counselling or have further investigations to help him receive a diagnosis or understanding about his symptoms (113-117). 03002 After speaking to the researcher, she hoped to get randomised into the intervention group (192-193)
Seeing the value of the research **altruism** **Benefit to self and others** **Increased awareness of mental health conditions and improving knowledge and current services**	Desire to help others (S) Advancing knowledge (S) Improving services in the future (S) Reducing misconceptions about anxiety (L)	01016 She hoped to be able to help people like her manage long term conditions and pain. She hoped for there to be resources because currently there is a long delay of people living with a condition without support. She wanted to know if there was a way to help people (92-101). 01043 He hoped to help other people, not personal gain. The vouchers were a bonus (488-489).

Appendix 11 Generating initial codes table – service user recruitment

	Value of participating in research (L) Making a difference (S) Perceptions about relevance of the study (L) Understanding the need/value of research (L) Overcoming misconceptions of health anxiety and mental health (L)	He hopes other people can benefit from the study because there is a need for greater awareness and resources because there are misconceptions about anxiety (493-502). 03004 Her initial thoughts about participating was to do anything to help others (64) Her main hopes about the study was to be able to provide information that could help other people (91-92). 03005 Her hopes were to improve awareness for people with anxiety and mental illness because currently it is lacking. She hoped her participation could help others. (221-227). 01082 Taking part in the study would mean she could potentially find information that could help others in the future (138-141). 01015 She didn't expect anything from the study. She hoped she would be useful to the study team (167-168) She didn't expect to gain anything from it (171-172). 01066 He had some free time and thought it would be great if the study could help someone (76-78) 01082 She is open minded in terms of participating in studies. The study sounded like a good idea (122-124).

Appendix 11 Generating initial codes table – service user recruitment

		01015 She didn't want her participation to be a waste of someone else doing it (170-171). 03005 She was pleased to be referred to the study because mental illnesses such as anxiety and depression are not discussed enough. She was grateful to be referred as she always welcomes receiving information (79-82). 03002 After the researcher met with her she relayed her initial thoughts about the study and decided to participate because the study seemed relevant and interesting (128-130).
Impact of others in influencing trial participation **Communication of trial information** **Understanding of trial and processes involved**	Relationship with service providers (L) Relationship with researchers/rapport building (L) Trust (L) How trial is explained and how they felt about it (S) Not being believed (S)	01077 After talking to the researcher she thought that the study was interesting and that through expressing her thoughts others could be helped (130-131 01015 She was referred by chance, she was diagnosed with PTSD and anxiety. Her GP had some leaflets about an anxiety study and suggested it to her (58-62). Her GP did not really explain the study. He just gave her a leaflet about it (95-97). She had a supportive network of friends who encouraged her to participate and this helped her to decide to take part (106-115) 03002 After talking to the researcher she understood that there was the possibility of being randomised to receive CBT and develop coping mechanisms to manage long term health conditions (169-172).

Appendix 11 Generating initial codes table – service user recruitment

		03002 After speaking to the researcher, she analysed herself and realised that CBT may benefit her. Prior to that she hadn't realised that she needed CBT (188-191). 03004 After speaking to the researcher her understanding of the study was that it was primarily about her mental health (69 03005 The researcher explained the study really well and explained the different formats of assessment completion. It was helpful that the researcher could go to her home. (97-101). 01051 When the researcher contacted her about the study she felt really elated to know she may get help with her condition. Her condition was having a huge impact on her life (211-219). The information the researcher provided about the study process was clear and precise (247-248). 01043 Engaging with services is easier when you have guidance/direction. His condition makes it harder for him to take speak to people and self-refer (814-827). It felt like the GP was concerned and suggested a different avenue to what he was used to such as medication or having to contact other services (104-107). 01082 She went to see her GP to access any type of help. When the GP suggested the study and that she might need therapy she thought why not (63-73)

Appendix 11 Generating initial codes table – service user recruitment

		01077 She felt devastated to be referred and that nobody believed her and thought she was wasting their time (88-94). She decided to take part in the study to shut the referrers up for thinking it was all her in head. She felt pressured into taking part (105-111).She was told her pain was in her head and that they would ask the research team to deal with her (73-78).Dr who referred her to the study was very rude, he told her the pain was in her head and that she needed help (292-294) 01023 Her Neurologist referred her. He thought she would be suitable for it (92-94) 01023 Her Neurologist referred her. He thought she would be suitable for it (92-94) 01046 Her neurologist did not perceive her to be a time waster. He recognised that she needed additional help for her problems (785-789). She hoped to be able to express her feelings without being looked down on. Somebody who could understand her feelings (115-117) 04001 She was referred by the nurse for undiagnosed longstanding scalp pain. She has since been referred to neurology. Her nurse thought that the study might be beneficial to her (44-49). 01051 Her Consultant suggested that the study would help other people. His main reason for referring her was because she had been on a waiting list for CBT for a long time.

Appendix 11 Generating initial codes table – service user recruitment

		He Asked her if she would be interested in doing CBT via skype as this would be helpful because she had transport issues (99-104). 01019 After speaking to the researcher he felt calmer knowing what it would involve and wanted to do it more (133-135) 01015 She was referred by chance, she was diagnosed with PTSD and anxiety. Her GP had some leaflets about an anxiety study and suggested it to her (58-62). Her GP did not really explain the study. He just gave her a leaflet about it (95-97). She had a supportive network of friends who encouraged her to participate and this helped her to decide to take part(106-115) 03002 He usually saw a nurse but she referred him to a doctor for second opinion. He felt like the doctor came in with a pre-existing assumption and that the doctor was forcing the study on to him which made him dubious (259-265) 01077 She felt devastated to be referred and that nobody believed her and thought she was wasting their time (88-94). She decided to take part in the study to shut the referrers up for thinking it was all her in head. She felt pressured into taking part (105-111). She was told her pain was in her head and that they would ask the research team to deal with her (73-78). Dr who referred her to the study was very rude, he told her the pain was in her head and that she needed help (292-294
Awareness and understanding of health anxiety	Acknowledging and accepting that symptoms	01018 Deep down he always knew he might have health anxiety so when the GP suggested the study he agreed to being referred (75-80).

Appendix 11 Generating initial codes table – service user recruitment

Acceptance of health anxiety and psychological treatment	were related to anxiety and worries about health (S/L) Health state at time of referral (L) Wanting to understand his anxieties better (S) To be listened to and understood (S)	01019 Initially he was nervous about the study because it was the first time that he was acknowledging he had anxiety. He knew it may cause him more anxiety but he knew he needed to he needed to seek help to manage his anxieties (120-128). His health worries were impacting on his life and he was panicking, He knew he needed to gain better understanding of it (165-168) 01045 He wanted to take part. He was going through a difficult time so to be able to talk to somebody would be good (84-86). He hoped to gain satisfaction, to feel listened to and understood (86-90) 01082 She knew she had health worries so she felt that the study was suitable and relevant (124-128). She had experienced some difficult life situations, her friend had been murdered and this had triggered anxiety and panic attacks. She needed help to deal with it (158-162). She wanted to access CBT to learn how to understand and manage her worries and get on with her life (166-168) 01007 Referred by her GP after she had a panic attack at the surgery about removing her implant. Her GP recommended her based on her anxiety around health issues (55-61) 01046 Referred by neurologist for severe health anxiety. She thought she had a brain tumour (99-110). She knew she had health anxiety. 03012

Appendix 11 Generating initial codes table – service user recruitment

		He usually saw a nurse but she referred him to a doctor for second opinion. He felt like the doctor came in with a pre-existing assumption and that the doctor was forcing the study on to him which made him dubious (259-265).
Stigma of health anxiety Stigma of seeking help Feeling a sense of connectedness from trial participation	Trust/relationships with GPs consultants influenced how study was perceived (L) Feeling pressured to participate (S) Symptoms were imagined (S) Shared experience (L) Stigma of receiving help for health anxiety (L)	01018 He was fine about being diagnosed with health anxiety he understands it is a common thing ,so he is not embarrassed by it (85-86). 01019 When the doctor referred him for anxiety, he was scared of the label but if being referred would help him get a better understanding and control that was more important. 01082 Some doctors are good at helping her to feel calm but other doctors have made her feel like she is imagining her pain (480-489). It's reassuring to know that there are others like her who have worries about their health (493-497). Doctors can sometimes misdiagnose and attribute pain to anxiety but it can be wrong (507-517). The study has reassured her that doctors are used to dealing with people anxieties (535-537). 03005 She was pleased to be referred to the study because mental illnesses such as anxiety and depression are not discussed enough. She was grateful to be referred as she always welcomes receiving information (79-82).
Understanding the study purpose and trial processes	Study understanding (L)	01016

Appendix 11 Generating initial codes table – service user recruitment

	How information about the study was provided (S) Understanding what study participation would involve (S) Misunderstanding study aims and process (L) Understanding of RCTs (L)	GP didn't really explain the study. She would have liked to have received more information about the study from her GP (82-86). Talking to the researcher changed her mind about participating because the researcher spent time explaining the study rationale and reasons for an RCT. The study interested her (72-76) 03002 His understanding of the study was that it was to help people access the care they required. He was experiencing unexplained fatigue symptoms. He didn't really understand what the GP was suggesting but he agreed to take part out of curiosity (84-90). 01012 Her GP told her that she would receive CBT as part of the study – but she didn't (82-84). She agreed to be referred to the study because she thought she would receive CBT through it as this is what her doctor told her (90-96). She was not told that she had a 50% chance she was advised that she would definitely receive CBT (101-102).She can't recall if the researcher Provided information about the study being a RCT (115) 01066 His understanding of study participation was that it would counselling sessions which would be face to face (107-112). He hoped to speak to someone f2f and receive support and information about coping with stress (122-126) 03002 She self-referred because she was dissatisfied with the NHS and the doctors as she had not been diagnosed. She wanted to take part in the study to express her dissatisfaction with the NHS and her treatment in terms of not getting a diagnosis (91-97). Her initial hopes about the study was to express her frustrations with the

Appendix 11 Generating initial codes table – service user recruitment

		NHS's inability to diagnose. She thought the study was looking at supporting people from a medical point of view. She did not think it was related to the psychological impact of having a chronic issue 148-156). She didn't fully understand the study, if she had known she would not have signed up to be contacted (72-73). It is hard to say what her initial expectations about the study were because her study understanding was wrong (162-163). 01082 She understood she may not get therapy but knew she would be able to access it via a different route (103-10.

Appendix 12 Finalised themes and potential quotes to include for service user participants interviews related to recruitment

Appendix 12: Finalised themes and potential quotes to include for service user interviews recruitment

Theme	Sub-theme	Potential quotes to include
Initial perceptions and its impact on motivation to participate	Communication of trial information	*I can't remember what I had at the time, I think it was a brain tumour I thought I had, and he said that basically I'd got nothing neurologically wrong with me, but he thought I'd got severe health anxiety, which I knew I'd got anyway, and he suggested I went on this study and wrote to yourselves (01046/F/RCBT).* *It sounded like a good idea, I felt like I was pretty similar had a lot of worries about my health so the study made a lot of sense for me to be a part of and it sounded like a sensible study (01082/F/TAU).* *One of his main reasons for doing it, is I've been on the waiting list for quite a long time to CBT and he said would you be interested in doing one via Skype (01051/F/RCBT).* *It was a bit more like he was kind of concerned that there's this different avenue that he's going to recommend instead of just putting me on medication or telling me to call different services basically (01043/M/RCBT).* *I don't really truly understand what he was trying to get at and I just kind of allured out of curiosity (03012/M/TAU).* *Basically, they turned round to me (laughs) and told me I was going to get cognitive behavioural therapy out of it but I didn't (0112/F/TAU).* *It was good, it was very clear, very precise as to what was going to be happening um so that was kind of good (01051/F/CBT)* *She explained it really well and she gave me options of you know, I could do it on my own or she could do it over the phone or she could even come to the house and do it (03005/F/TAU).*

Appendix 12: Finalised themes and potential quotes to include for service user interviews recruitment

		It probably would have helped yeah if I'd have sort of known exactly what I was going to, as it stands it would – experience it was fine. But I think having done research myself that it's not got a very good uptake. People don't follow things through very well. So, they might perhaps be more participants if they'd known more initially (01016/F/TAU). *I didn't fully understand (laughs)! And had I have known what the study actually was, I wouldn't have signed up for it (03002/F/RCBT)* *He didn't overly explain it actually (01015/F/RCBT).* *she was very helpful, bless her, no she was lovely (01015/F/RCBT).* *They didn't tell me I'd have a 50% chance, they said that I'd definitely get it (01012/F/RCBT).* *He didn't really explain anything he was getting a piece of paper erm, erm, it was only like I think an A4 piece of it was quite a while ago. So like an A4 sheet of paper saying you know 'you'd be good at this study (01016/F/TAU)* *I think once I spoke to you it cleared up what it would entail and I was a lot more calm about it and I was a lot more, erm I felt I wanted to do it a lot more because I wanted to do it a lot more because I felt it would be useful in helping me with my anxiety (01019/M/TAU).* *The doctor recommended me based on my anxiety around health issues (01007/F/RCBT)* *They said something about there's some courses coming up, well not a course but like um, um where you'd be like asked questions about your anxiety. It might help, it might not but it might be worth something considering, some people could get benefits from it. It works for some, some it don't. I thought you know, anyhow it's worth a go. So basically that's why I tried (01008/M/RCBT).*

		Very little he just said that it was taking place and would I be interested and he gave it a very basic description. I think he, he mentioned, I think he mentioned health anxiety, I think he mentioned symptoms with no medical explanation and said you know would I be interested and explained that you know, it would be a form of therapy (01055/M/RCBT).
	Perceived relevance of the Urgent Care trial	*I was quite pleased really because anxiety and depression and stuff, mental illnesses aren't talked about as much as I think they should be so for my GP to bring it up at all, I was quite grateful really, because I don't think you can ever have too much information (03005/F/TAU).* *It's nice to know that there are other people out there who are doing it as well who are a little bit crazy because we've got such bad anxiety and our mental health is a mess but at least we're worrying about it together (01082/F/TAU).* *I think in the back of my head I realised it was health anxiety all along but obviously when you're in that situation there's half of you telling you that and then the other half thinking the worst. So, when he did say 'look, you probably need this sort of thing', obviously I took it and waited to see what was going to happen (01018/M/TAU).* *I think I was nervous at first. It was still my first sort of foray into acknowledging what I had, that I had like anxiety and I was still nervous about the whole process so I was scared of I guess what it would entail and if I would, you know – I think partly it was maybe that it would cause some extra anxiety but I knew that I needed to get involved in something and I knew that needed to get a handle on what I had because it was causing me problems so I knew it was important for me to seek these sort of things outs (01019/M/TAU).* *I thought it was more of a medical... underlying medical problem rather than a psychological... it very could be down to stress, you know, it's at the root of a lot of things that we don't quite understand but I didn't, you know, I wasn't totally convinced (04001/F/RCBT).*

Appendix 12: Finalised themes and potential quotes to include for service user interviews recruitment

		I was really, really anxious and so I had this excitement of would this be able to help me in addition to other therapies that I'm trying. So I think I was actually nervous that what if I you know have the opportunity to receive a treatment and I don't get selected? I was nervous about that I really wanted it (01015/F/RCBT). *I just didn't think that talking about the problem would help. I do think it's a medical problem (04001/F/RCBT).*
	Hope for recovery and improvement of symptoms	*I hoped that it would help and that it would you know help me come to terms and help me understand more and you know provide me techniques with which I could handle my anxiety (01019/M/TAU).* *To help work through, coping mechanisms and when you're having to deal with the longer-term health condition. In particular, things like pain and that kind of thing, learning how to self-manage better during the process (03002/F/RCBT).* *Anything to try and help coz I've just gone from one person to another to another and it's, you know, no help or offer of help so when he said about this, it was just, you know, nice to, you know, go somewhere where I could be helped a bit really, rather than the door always being shut (01024/F/RCBT).* *Frankly at that time my view was that any help offered was a good thing to do really, was a good thing to accept (01055/M/CBT).* *I think I wanted to get better, like honestly if like the CBT was going to help me no matter what way I accessed it through (01082/F/TAU).* *I hoped that it would help people be able to like me manage long term conditions, particularly pain, erm to be able to find some sort of resource that can help people because at the moment in health you sort of have diagnostics, you then find out what's wrong and then there's just a long period of you live with something (01016/F/TAU).*

		It's interesting to know that other people were going through the same thing and that you're not on your own and hope, you know I was hoping that it would help me to deal with the anxiety (01001/F/RCBT). *I was hoping it would be a cure but obviously it's not but I think that was just me just dwelling on that on that you know, 'cause that's what I was hoping, just to make you know, that I could wake up one day without having to worry (01008/M/RCBT)* *I actually felt quite excited about it to be honest, because I feel I've been waiting for such a long time for a CBT um, so I actually, because I was getting to the stage with my condition where we were struggling to find any solution (01051/F/RCBT).*
Perceived credibility of the intervention over existing treatment pathways	Improved access to treatment and services	*See with the NHS I don't think they've got resources to actually do it for you, so that was a big, you know, bonus as well (01046/F/RCBT).* *I was open to anything and everything to get me better. I didn't have a lot of time to get better you see um because I was going abroad, so anything that might speed up the process (01015/F/RCBT).* *To be honest with you, it's so hard to get even an appointment or to get a foot in the door, (01043/M/TAU).* *Part of the problem was when I first started with this condition I couldn't get out. So the fact that I could do it from home and I wasn't relying on people to take me was brilliant (1051/F/RCBT).* *I just hoped to get like a, um, any experience of therapy and things like that and see how it would help me and things (01002/F/TAU).*

Appendix 12: Finalised themes and potential quotes to include for service user interviews recruitment

	Value of research and its potential benefit to other people	*Well I hoped that it would help people be able to like me manage long term conditions, particularly pain, erm to be able to find some sort of resource that can help people (01016/F/TAU).* *I had some free time so I thought why not, just give some time to someone, it might, that study, help someone else, that would be great. That's why I took part (01066/M/RCBT).* *My hopes were that the generalised, you know, treatment for anxiety and you know, the awareness of everybody, everyday people were having mental illnesses, would improve, 'cause I do find it's not brill and you know but I'm not the only one that suffers with it so therefore I wasn't just thinking of it from my point of view, I was just thinking of it from a whole that it needs to improve generally and if this can help then I'm happy to partake (03005/F/TAU).* *I'm in support of anything that tries to improve you know, help for depression and mental health issues, so yeah. (03005/F/TAU).* *I think just to help other people really and personally no gain at all. Marks and Spencers vouchers were just a bonus (01043/M/TAU).* *I was hoping to get some therapy but um (laughs), and just to, well help other people I suppose yeah (01014/F/RCBT).*

Appendix 13 Extracts from research diary

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03/02/2016

This is my second service user interview and the first interview with a participant from the TAU group. At the time of interviewing, we are still recruiting participants to the Urgent Care trial. I had carried out the baseline assessment for this participant over 12 months ago and I recall that she had been keen to receive the therapy. When I asked her about how she initially felt about being allocated to the TAU she expressed feeling a little upset not to receive therapy but that she chose to continue because she understands that we needed data from both groups. This made me understand that for service users despite trial participation being influenced by the desire to receive therapy participants would continue to complete questionnaire because they recognised the importance of data. She also explained that she continues to complete questionnaires because she has an interest in the study and enjoys doing questionnaires. This is an interesting finding and something I want to explore in further interviews with participants allocated to the TAU group. It also made me feel sad because being a researcher on a trial can be challenging because we know that participants have a 50% chance of receiving the intervention. When we talk to participants, and we carry out the baseline assessments it can be emotionally difficult knowing that participants are likely not to receive their treatment preference but that in RCTs this is necessary. A code that comes to mind is understanding the importance of research and data regardless of not receiving the intervention and something I want to explore in further interviews with participants from the TAU group.

11/05/2017

This is my seventh interview with a service provider and the fourth interview with a GP. This GP is from the surgery who referred and recruited the most participants. Initially this GP surgery did not engage with the study and had not referred any patients to the trial despite the study team meeting with them in May 2015. It was only after the GP attended a project meeting that he became actively engaged in the Urgent Care trial and started referring patients to the trial, with the first participant recruited from this surgery in April 2016. Ultimately, they recruited 32 participants to the trial becoming the top recruiting site. Between October 2016 and December 2016, they recruited 24 participants to the trial enabling the Urgent Care trial to meet its recruitment target. I wanted to understand this, so I asked him what his initial thoughts were about the study when we first attended a practice meeting to talk about the study. He expressed that his initial thoughts were that the way in which the Urgent Care trial was promoted was weak and he was unsure about how he would refer patients. He could not see the relevance of the trial, and this is why initially he did not refer patients. He explained that it was only after he attended a research meeting that he understood the relevance of the trial and identify the gap it filled. After this he referred a lot of patients. He also talked about the fact that when GP surgeries decide whether to participate in a study their main reason will be if they are gaining anything from participating in terms of reduction in their workload and if it would benefit them financially. This made me think about several aspects that may be facilitators/barriers to trial participation from a service provider perspective. Firstly, how information about a study is explained seems important and highlighting how the study is relevant to them. It is also important to highlight how the study would benefit their surgery. I recognised that aspects such as benefits and costs of participating in terms of time/workload/understanding study processes had started to come up in GP interviews and needed further exploration.