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An Asynchronous Peer Support Intervention for Men experiencing Unipolar Depression; Development of a Complex intervention

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Abstract

This study set out to develop a complex intervention, delivered in a community pharmacy setting that can support men prescribed antidepressants for depression.

Depression is a common and potentially long-term mental disorder. It can be debilitating for both individuals and society. Men experiencing depression can be considered a unique population of interest based on their different profiles; particularly their expression of depression, their risk profiles in depression, and how they navigate the healthcare system.

Antidepressants can be effective for treating depression, but there are barriers to their practical application. These may include psychosocial issues such as self-stigma, and information issues such as mismatched expectations on treatment duration. It has been suggested that gender, and views of masculinity, can underpin some negative attitudes.

Holding negative beliefs about taking prescribed antidepressants and poor health literacy has been linked with poorer treatment outcomes. Increasing treatment engagement, however, can improve outcomes.

Community pharmacists are accessible healthcare professionals, with expertise on medication and who have good mental health literacy. They can potentially support these patients, yet little is known about what these male patients see as the role of the community pharmacist in their treatment journey. No interventions exist for these patients within a community pharmacy setting.

Guided by the Medical Research Councils guidance on developing and evaluating a complex intervention, this thesis takes a research through design approach, underpinned by qualitative methods to develop a complex intervention. Research through design is a relatively underdeveloped approach in healthcare, but it focuses research on preferred future states, supports incorporation of stakeholders in the design process of a complex problem, and presents design as a research contribution.

There are several key areas where this study makes an original contribution to knowledge. The first is qualitatively exploring men's views of antidepressants, and the community pharmacist's role. Thematic analysis of qualitative interviews found men in their depressed state are not seeking to get advice or support from the community pharmacist. The COM-B behaviour model has been used to help organise these findings. Men did, however, reflect on some unmet needs and that there could be a role for the community pharmacist in their care.

The second contribution is the development of a complex intervention. Findings from the above study and literature were used to support a theory-based approach to development. This work was built on by involving stakeholders in the design process. In the designed intervention, asynchronous communication is used to enable people newly prescribed antidepressants to ask questions of peers with more experience, either through

audio or video, with facilitation by a community pharmacist. This intervention had a task focused mechanism of interaction and was designed to be gender sensitive.

This was modelled in its real setting. Acceptability was measured using qualitative interviews and findings organised by the theoretical framework of acceptability. Overall the intervention was acceptable.

The final knowledge contribution is a methodological one, where the appropriateness of integrating the Medical Research Council guidance with research through design is discussed.

Further work should involve evaluation, feasibility, and implementation studies, particularly addressing how this intervention links within a wider healthcare system, and exploring cost effectiveness.

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Contents

Abstract	2
Acknowledgments.....	4
Contents.....	5
Index of Tables.....	9
Index of Figures	11
Abbreviations and Acronyms.....	12
Chapter 1: Introduction to Thesis	13
1.1. Introducing the study and research aims.....	13
1.2. Organization of the study.....	13
1.3. A focus on men – what does that mean?	14
1.4. Impact of Covid-19 pandemic on the research.....	15
Chapter 2: Background to the problem of interest	16
2.1. Depression, and depression in men	16
2.2. Men’s navigation of healthcare	19
2.3. Men’s risk profiles.....	20
2.4. Gender, Hegemonic masculinity, and its relevance in men’s depression	20
2.5. Treatment for depression; a focus on antidepressants	25
2.6. Community pharmacists and their role in supporting men prescribed antidepressants; a problem focused perspective	29
2.7. Overall conclusion	31
Chapter 3: Methodology and methods used in developing a complex intervention	32
3.1. The research paradigm.....	32
3.2. Medical Research Council Guidance on Complex Interventions.	34

3.3. Orientation to core research chapters in thesis	43
3.4. Qualitative Methods for Chapter 4 and Chapter 7 (Primary Research studies)	44
3.5. Methodological considerations for Semi-structured Interviews	46
3.6. Data Analysis Methods and Theory introduction (Chapter 4 and 7)	48
3.7. Methodology for intervention design (Chapter 6).....	53
3.8. Introduction to Research through Design	57
3.9. Research through Design as a design approach in this thesis	60
3.10. Ethical approval and considerations	60
 Chapter 4: A thematic analysis of qualitative interviews to explore men’s views of antidepressants for the treatment of their depression, and the role of community pharmacy in their treatment journey.	62
4.1. Introduction and aims.....	62
4.2. Ethics and Methods	63
4.3. Results and Thematic analysis; generating themes and presenting participant characteristics.	69
4.4. Thematic analysis of results discussed; five defined themes.	71
4.5. Discussion	81
4.6. Strengths and limitations.....	87
4.7. Conclusion	89
 Chapter 5: Develop theory, and explore evidence base for a solution.	91
5.1. Identify evidence base	91
Decision to not conduct a systematic review as part of the literature search	94
5.2. Initial Literature search	95
5.3. Literature review: Community Pharmacy Interventions targeted at Men treating Depression with Antidepressants.....	98
5.4. Typology of relevant interventions.....	99

5.5. Community pharmacy and depression interventions.....	103
5.6. Depression interventions for men experiencing depression, or targeting men’s mental wellbeing.....	112
5.7. Interventions that target people experiencing depression of any gender. .	115
5.8. Findings from men’s health	118
5.9. Summary of typology findings.	119
5.10. A focus on peer support in depression.	120
5.11. Summary.....	124
Chapter 6: Design Rationale for the Complex Intervention.....	125
6.1. Introduction.....	125
6.2. Applying the Behaviour Change Wheel in the design process.....	126
6.3. Stage 2: Identify intervention options	137
6.4. Stage 3: Identify content options.....	140
6.5. Conclusion following the behaviour change wheel:	145
6.6. Lessons learned from rejected approaches; intervention mapping and its contribution to this thesis.	146
6.7. Phase 1: Pre-pilot sensitizing study using iterative modelling and thinking aloud method; the design decisions and learning points.	149
Chapter 7: Modelling, Evaluating and Refining the Complex Intervention	159
7.1. . Introduction and aims.....	159
7.2. Participants recruitment.....	160
7.3. Overview of method	163
7.4. Intervention Overview:.....	166
7.5. Ethics	169
7.6. Data analysis.....	170
7.7. Qualitative interviews - Results and Discussion.....	171
7.8. Content Analysis – Results and Discussion.	209

7.9. A focused example; introducing bias through cognitive distortion.....	243
7.10. Program theory and overall conclusion.....	249
7.11. Strengths and limitations of study.....	251
Chapter 8: : Reflexivity, overall discussion, and conclusion.....	254
8.1. Introduction and reflexivity.....	254
8.2. Further work.....	259
8.3. Does RtD integrate with the MRC guidelines on developing and evaluating complex interventions?.....	262
8.4. Conclusion.....	265
Chapter 9: : References.....	267
Appendices.....	316
Appendix 1: GUIDED 14 point checklist.....	316
Appendix 2 Standards for Reporting Qualitative Research (SRQR), and where covered in this thesis.....	318
Appendix 3 Interview Schedules for chapter 4 study.....	320
Appendix 4 Interview Schedule for Chapter 7 study (Peer/Pharmacist participants).....	322
Appendix 5 Patient Information Sheet for Peer participants research.....	324
Appendix 6 Pharmacist Participation Information Sheet.....	330
Appendix 7 Participation Information Sheet for chapter 6.....	336
Appendix 8 Consent Forms for all research studies.....	339

Index of Tables

Table 1: Definitions of change points in depression.	18
Table 2: Questions for researchers adapted from MRC guidance on complex intervention development	36
Table 3: Core domains actions in developing healthcare interventions.	40
Table 4: Data collection phases in the design, modelling, and evaluation domains	43
Table 5: Key constructs of acceptability based on the framework of acceptability	52
Table 6: Link between COM-B components and potential intervention functions	56
Table 7: Ten characteristic definitions of Wicked Problems.	58
Table 8: Inclusion and Exclusion Criteria for study.	65
Table 9: Characteristics of Participants	70
Table 10: Key concepts in search strategy	96
Table 11: Search concepts in chapter 5.5-5.8.	101
Table 12: Typology of core interventions for depression interventions in community pharmacy setting	103
Table 13: Quality appraisal of studies	108
Table 14: Typology of interventions targeting men with depression or their mental wellbeing	112
Table 15: Typology of interventions that target persons experiencing depression.	115
Table 16: Defining the problem in behavioural terms	127
Table 17: Analysis and scoring of potential target behaviours	129
Table 18: Specifying the target behaviour.	132
Table 19: Identifying what needs to change, using the COM-B framework.	134
Table 20: Matrix of links between COM-B and intervention functions,	138
Table 21: Evaluation of potential intervention functions judged using APEASE criteria.	139
Table 22: Chosen behaviour change techniques to underpin intervention design	141
Table 23 Consideration of mode of delivery for a peer support service in a community pharmacy setting.	143

Table 24: Matrix of objectives. .	147
Table 25: Design ideas modelled out in study	150
Table 26: Key learnings linked to design prototypes	155
Table 27: Mapping the key learning points to design decisions:	156
Table 28: Eligibility criteria for Peer Participants.	161
Table 29: Eligibility criteria for Pharmacist Participants.	162
Table 30: Outline of intervention using the TIDieR template	166
Table 31: Participant details, and media files.	170
Table 32: Summary of findings for Affective Attitude theme	172
Table 33: Summary of findings for Burden theme	175
Table 34: Summary of findings for Perceived Effectiveness theme	180
Table 35: Findings for ethicality theme	193
Table 36 Findings for Intervention coherence theme:	198
Table 37: Findings for Opportunity Cost theme	201
Table 38: Findings for Self-efficacy	205
Table 39: Responses of panel member participants to question 1	211
Table 40: Number of panel member's media responses theme from Table 39	214
Table 41: Responses of panel member participants to question 2	215
Table 42: Number of panel member's media responses from Table 41	218
Table 43; Responses of panel member participants to question 3	219
Table 44: Number of panel member's media responses from Table 43	222
Table 45: Coding of panel member's response media for supportive responses	223
Table 46: Number of panel member's media responses from Table 45.	227
Table 47: Coding panel members' media responses for personal insights	228
Table 48: Number of panel member's media responses from Table 47.	232
Table 49: Coding panel members' media responses for medical advice.	233
Table 50: Number of panel member's media responses from Table 49	239
Table 51: Data analysis of Lawrence's media response to James with comments	244
Table 52: Data analysis showing emergent themes	246

Index of Figures

Figure 1: Key elements for researchers developing and evaluating complex intervention	35
Figure 2: Schematic used to map overall thesis structure	42
Figure 3: Photograph of the 'one sheet of paper' being used in data analysis	49
Figure 4: The COM-B system, a framework for understanding behaviour	53
Figure 5: The Behaviour Change Wheel	54
Figure 6: Criteria for prioritizing behaviours that could be targeted in an intervention	55
Figure 7: Introduction to chapter 4;	62
Figure 8 : Information power and the components.	67
Figure 9: Hub and Spoke model	71
Figure 10: Hierarchy of themes in terms of importance.	72
Figure 11: COM-B model	84
Figure 12: COM-B model linked to Chapter 4 study	85
Figure 13: Schematic showing an overview of chapter 5	91
Figure 14: Schematic identifying and organising interventions	93
Figure 15: Flow diagram (based on PRISMA flow diagram)	97
Figure 16: Adaption of Figure 14 for section 5.5 search	111
Figure 17: Adaption of Figure 14 for section 5.6 search	114
Figure 18: Adaption of Figure 14 for section 5.7 search	118
Figure 19: Peer Support and levels of Formality.	120
Figure 20: Introduction to chapter 6;	125
Figure 21: Stages of the Behaviour Change Wheel	126
Figure 22: Generation of ideas for potential target behaviours while considering systems of behaviours	128
Figure 23: Introduction to chapter 7;	159
Figure 24: Storyboard of intervention for Phase 2	164
Figure 25: Introduction to chapter 8;	254
.Figure 26: MRC updated guidelines for complex development and evaluation.	260

Abbreviations and Acronyms

DSM-V	The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
GPhC	General Pharmaceutical Council
GP	General Practitioner
HCI	Human-Computer Interaction
HRA	Health Research Authority
IRAS	Integrated Research Application System
IT	Information Technology
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PHQ-9	Patient Health Questionnaire-9 questions.
PIS	Patient Information Sheet
PPI	Patient Public Involvement
RCT	Randomised Control Trial
REC	Research Ethics Committees
SRQR	Standards for Reporting Qualitative Research
SSRI	Selective Serotonin Reuptake Inhibitors
TFA	Theoretical Framework of acceptability
UK	United Kingdom
USA	United States of America

Chapter 1: Introduction to Thesis

1.1. Introducing the study and research aims

This study explores how community pharmacy can better support men who have had a diagnosis of depression and have been prescribed antidepressants to treat this condition. Specifically it looks at the development of a complex intervention for use in this setting.

To do this the study aims to understand the perspectives and experiences of men who are taking antidepressants, in relation to their treatment, and the role of the pharmacist in their treatment. The study builds on these findings, taking a theory-based approach to intervention development. It involves stakeholders throughout the design and development process and seeks to understand intervention acceptability and program theory.

The desired outcome of this complex intervention is to support men, who have been diagnosed and prescribed an antidepressant for unipolar depression. In particular, this intervention seeks to increase access to information and support and improve recovery-orientated outcomes such as empowerment and sense of hope.

An additional aim of this study is to make a methodological contribution and to explore how design can be addressed in the development of a complex intervention.

1.2. Organization of the study

This study is divided into eight chapters. This current chapter (chapter 1) introduces the research, the aims, and orientation of the study.

Chapter 2 explores the background to the population and setting of interest. It makes the case for why men with depression should be considered a unique population for healthcare delivery, and how community pharmacists could be a resource to support these patients, and explores the current problems.

Chapter 3 firstly discusses the research paradigm and overall approach for complex intervention development research. Then follows a section focusing on methodological considerations and explaining that this thesis takes a Research through Design (RtD) approach, underpinned by qualitative methods. Methodological choices are justified in this chapter and issues such as reliability and trustworthiness are discussed.

Chapter 4 is a qualitative research study which seeks to gain a deeper understanding of the experiences of men's who are taking antidepressants to treat depression within the context of community pharmacy practice. The findings are discussed, as well as what these findings mean for community pharmacy practice. The behaviour change model COM-B

(capacity, opportunity, motivation - behaviour) is used to help map findings to behavioural change theory.

Chapter 5 presents a narrative literature review that focuses on identifying relevant interventions and understanding what might be key active components that underpin how these interventions work. Chapter 5 also explores what outcomes have been evaluated in previous work. For the identified interventions, typologies are created. Each typology is assessed for its evidence base, and to identify outcomes have been measured, and what program theory exists. Peer support interventions are focused on due to having one of the most extensive discussions around mechanisms of effect and program theory.

Chapter 6 builds on the work of chapter 4 and 5. It is focused on the design domain and presents this as a research contribution. A RtD approach and the behavioural change wheel are used to help make design decisions on modes of deliveries, procedures, and activities for the complex intervention that will be further explored in chapter 7, and to describe if any rationale, theory, or elements could be essential to the intervention design.

Chapter 7 is a qualitative research study that pilots the intervention designed in chapter 6 within a community pharmacy setting. Community pharmacists' and service users' views on intervention acceptability pre and post intervention were explored using thematic analysis. Media responses within the peer support scheme were analysed using content analysis to summarise consultation foci and enable comparisons between different peer responses to the same questions. Finally, a case study was also purposefully sampled to illustrate the concept of 'introducing bias through cognitive distortion'. Key findings are presented, as well as a discussion of the studies' strengths and weaknesses, and suggestions for further intervention refinements.

Chapter 8 completes the thesis by providing a reflexive review of the research in this study, discussing further work and provides an overall conclusion on the study. The conclusion brings together all the research work within this thesis and highlights the significance and the contribution this work has made to knowledge.

1.3. A focus on men – what does that mean?

In this study men are focused on. There can be differences between one's assigned birth sex and their current sex. In this thesis the male inclusion criteria for the research studies (chapter 4, 6 and 7) are defined as those who are born as male sex and currently identify as being male. It feels important to introduce some definitions, and to justify this inclusion criteria decision at the start of this thesis.

Sex refers to the inherent biological differences e.g. different anatomies, different hormone levels etc., which typically, but not always will be one of two binaries; 'male' or 'female'.

Gender is determined by a human perception of one's gender. It refers to cultural, social or society influences or behaviours that maybe acquired, or be operating, depending on one's gender. It is often classed as being 'male' or 'female', but can be a spectrum, with some identifying as being non-binary.

The term men in this thesis is defined by sex, and when used it refers to men as a population. Another term discussed in this thesis is masculinity. Masculinity refers to a set of personality characteristics most strongly associated with men, but where each person can have a mixture of masculine and feminine characteristics.

The decision for the definition of 'male' used for the participant inclusion purposes is based on the research and theory used to underpin core arguments made in this thesis. One core argument made in chapter 2 is how men's depression as a population has differences to female depression, and as such men's depression can be considered as a distinct research population. The evidence underpinning this argument discusses men as a population. It is known that some transgender men can have unique mental health concerns relating to their gender. As this was not the focus of this thesis this in part justifies the inclusion criteria definition. A second justification is that hegemonic masculinity (introduced in chapter 2) is a theory that this thesis argues is important in men's depression. Hegemonic masculinity is suggested to be influential over lifespans, and there is a suggestion that the impact of hegemonic masculinity on one's juvenile years can particularly impact mental health and wellbeing. Therefore, this research focuses on males who are born as male sex and currently identify as being male.

1.4. Impact of Covid-19 pandemic on the research

This thesis is a part time study that occurred between 2014-2022 (excluding 1 year maternity leave). Around February 2020 there were significant changes to public health due to the COVID-19 global pandemic. In March 2020 there were lockdowns in the United Kingdom (UK). There has since been three national lockdowns, various local lockdowns and numerous restrictions due to the global pandemic. Other countries have followed similar practices. This affected lives, healthcare, and employment practices worldwide (ONS 2021). COVID-19 will have had an impact on statistical public health data, and as such this data needs to be interpreted within the context of the pandemic.

Chapter 2: Background to the problem of interest

2.1. Depression, and depression in men

Community pharmacy, as a profession, is striving to provide better support for people experiencing mental health problems, such as depression (RPS England 2018).

Depression is a common and potentially long-term mental disorder (Metrics and Evaluation 2019). It can be debilitating for both individuals and society (Wang, Simon et al. 2003). Depression has consistently been ranked in the leading causes of global disability since 1990 (Murray, Aravkin et al. 2020), and has been further exacerbated by the COVID-19 pandemic (Santomauro, Herrera et al. 2021). Major depressive disorder accounted for 49.4 million disability-adjusted life-years globally in 2020 (Santomauro, Herrera et al. 2021), and it is estimated that over 4.5 million adults in the UK were diagnosed with depression in 2017-18 (NHS Digital 2019).

Depression can also worsen treatment outcomes for co-morbid conditions (Moussavi, Chatterji et al. 2007, Kang, Kim et al. 2015). For example, there is a large body of evidence showing depression has a causal link to poor ischemic heart disease outcomes, (Jünger, Schellberg et al. 2005, Van der Kooy, van Hout et al. 2007, Baxter, Page et al. 2011, Sherwood, Blumenthal et al. 2011, Carney and Freedland 2017), possibly due to a combination of behavioural and physiological mechanisms (Sherwood, Blumenthal et al. 2011, Lossnitzer, Feisst et al. 2020). Depression has also shown to worsen other physical co-morbidities (Moussavi, Chatterji et al. 2007) such as chronic obstructive pulmonary disease (Cuijpers, Vogelzangs et al. 2014), diabetes (Renn, Feliciano et al. 2011), and cancer (Pinquart and Duberstein 2010), although the evidence is inconsistent (Cuijpers, Vogelzangs et al. 2014, Ferrari, 2013).

Substance misuse disorders and depression as comorbidities are common (Rush and Koegl 2008, Saha, Lim et al. 2021). A systematic review estimates a six-fold elevated risk for substance misuse in those with mood disorders, including depression (Saha, Lim et al. 2021). Substance use disorders with depression are linked to worsening outcomes (McKay, Pettinati et al. 2002, Stepankova, 2017, Richardson, Robb et al. 2021), and co-occurrence can complicate the treatment of both conditions (Pirkola, Pelkonen et al. 2011, Hesse, 2009). Similarly, depression and anxiety can frequently co-occur, which, when in combination can also increase suicide risk (Nock, Hwang et al. 2010).

Depression overall is a significant risk factor for suicide (Ribeiro, Huang et al. 2018), and particularly suicide ideation (Nock, Hwang et al. 2010). The risk of suicide in depression can be increased by depression severity (Hawton, Casañas i Comabella et al. 2013).

Core symptoms of depression are persistent low mood and/or loss of pleasure in general activities. While depression can be a long-term condition, it can have change points (de

Zwart, Jeronimus et al. 2019). These change points are highlighted in Table 1.

It is estimated that only 20% of those with depression will recover without a relapse or a recurrence. Previous depression episodes are a risk factor for recurrence (Wojnarowski, Firth et al. 2019) and depression can be considered a long-term condition.

This thesis is particularly focused on depression experienced in men. There are statistically significant differences in depression profiles between men and women. This has led to the term male-type depression, and the advice to focus on men's mental health as a distinct research population (Smith, Mouzon et al. 2018). In particular, it is the expression of symptoms, the navigation of depression (Cochran and Rabinowitz 2000) and the risk profiles, rather than severity or duration (Gili, Castro et al. 2014, Otten, Tibubos et al. 2021, Addis 2008, Smith, Mouzon et al. 2018) that makes men's depression, as a population, distinctly different to women, and with an overall consequence of men having worse outcomes in depression (Ryan, Carriere et al. 2008, Cuijpers, Vogelzangs et al. 2014, Gilman, Sucha et al. 2017, Das-Munshi, Chang et al. 2019, Otten, Tibubos et al. 2021).

Table 1: Definitions of change points in depression. Taken and adapted from (Bockting, Hollon et al. 2015)

Term	Definition
Index Episode	Major Depressive Episode as defined by a diagnostic system e.g. DSM-V lasting at least 2 weeks.
Response	A reduction in symptom severity relative to baseline status.
Remission	A period (often defined as two months or longer) when symptoms have normalised, and the patient can be thought of as well. (Note that remission precedes both recovery and recurrence).
Stable remission	A sustained interval in which depressive symptoms are absent or minimal.
Unstable/partial remission	An interval during which some levels of depressive symptoms are present (partial) or only sporadic (unstable).
Recovery	The end of the index episode following an extended period of remission (e.g., 6–12 months).
Relapse	The re-emergence of depression symptoms (presumably part of the index episode) following some level of remission but preceding recovery.
Recurrence	The onset of a new episode of depression following an extended period of remission of sufficient duration to assume that recovery had occurred.

Men can experience both internalising and externalising symptoms in depression. As a population they are more likely to exhibit externalising behaviours. For example anger, emotional suppression, avoidance and substance misuse (Moller-Leimkuhler, Bottlender et al. 2004, Rochlen, Paterniti et al. 2010, Martin, Neighbors et al. 2013, Rice, Fallon et al. 2015, Cavanagh, Wilson et al. 2017). These symptoms are often used by men as a way to cover up their depression, rather than to address their depression (Scholz, Crabb et al. 2017, Farmer et al., 2012, Rochlen et al., 2010). However, these strategies can be maladaptive coping strategies (Brownhill, Wilhelm et al. 2005, Nolen-Hoeksema 2012, Scholz, Crabb et al. 2013). For example, substance misuse in men with depression nearly doubled their overall mortality risk (Das-Munshi, Chang et al. 2019). Suppressing feelings has been linked to worsening pathology in men's depression (Hoy 2012) and the link between emotional suppression and worsening depression is more relevant for men than for women when experiencing depressive symptoms (Flynn, Hollenstein et al. 2010).

2.2. Men's navigation of healthcare

Regardless of race or age, men as a population are less likely to seek lay or professional help for depression (Addis and Mahalik 2003, Yousaf, Grunfeld et al. 2015). Gender is considered to be an important concept underpinning help-seeking in males for depression and depression treatment, and this is discussed further in "Gender, Hegemonic masculinity, and its relevance in men's depression."

As well as help-seeking, some men's preference for treatment may not fit into how mainstream healthcare is offered within the UK and other westernized countries. It has been suggested that some men prefer more action based and informal approaches to mental health healing, and that this is not easily or readily offered within a formal healthcare system (Whitley 2021).

Men are also more likely to present within the healthcare system at crisis points, rather than at points of preventative care (Dryden, Williams et al. 2012, Yousaf, Grunfeld et al. 2015).

Men's lack of help-seeking could have a confounding effect. Previous help-seeking experiences can result in greater willingness to seek help in the future (Rickwood, Deane et al. 2005), although this has not been shown in all studies (Rice, Aucote et al. 2017). It may be that men's lack of help-seeking makes subsequent help-seeking harder. Overall men have shown to have lower mental health literacy compared to women, and this has been linked to reduced help-seeking (Wei, McGrath et al. 2015).

Men, as a population are also less likely to be familiar with healthcare systems, having used them less. Greater familiarity with healthcare systems can increase one's likelihood to use them (Möller-Leimkühler 2002). Healthcare systems have been criticized for being unwelcoming and unengaging for men (Hawkes and Buse 2013, Whitley 2021), and there have been calls to try and address this (WHO 2018).

2.3. Men's risk profiles

Men have different risk profiles in depression, and this has been linked to worse outcomes in depression (Das-Munshi, Chang et al. 2019). The reasons for men's different risk profiles in depression is also complex and multi-causative. However the interplay of how men navigate depression, the healthcare systems, and the display of externalising symptoms do largely explain their increased risk profile.

Men are significantly more likely to commit suicide. Over the past ten years, suicide has been around three times higher in men compared to women (WHO 2018). Although not all these suicides can be linked to depression, it is known that depression is a risk factor for suicide.

Adaptions need to be made for men's different risk profiles to provide appropriate care and support for those experiencing depression (Robertson, Bagnall et al. 2015). When this has not occurred, it puts men experiencing depression at risk of worse care. For example, it is suggested that men are underdiagnosed for depression due to their different expression of symptoms (Borowsky, Rubenstein et al. 2000). Men tend to underreport some of the symptoms of depression that are included in the diagnostic criteria for depression, such as depressed mood and appetite disturbance, whereas many externalising symptoms such as anger are not diagnostic markers for depression (Uebelacker, Strong et al. 2009, Cavanagh, Wilson et al. 2017). Another example is that men typically are less articulate and less comfortable in discussing their emotions and mental health, which has been linked to disengagement in healthcare and increased risk profiles (Robertson, Bagnall et al. 2015, Struszczyk, Galdas et al. 2019).

Although the reasons for the different population profiles of depression experienced in men compared to women are complex, it is widely thought that the gendered dimension of this phenomenon is important.

It is also worth mentioning that within the wider context of men's health similar patterns are found, with men utilizing healthcare differently to women, and having worse mortality in non-sex specific disease, and that gender is considered an important phenomenon in partly explaining this (White, de Sousa et al. 2011, WHO 2018).

2.4. Gender, Hegemonic masculinity, and its relevance in men's depression

Both sex and gender have a role in explaining the state of men's health relating to depression, and why this population should be considered a unique population of interest. Yet it is gender that is regarded as particularly impactful and may help guide researchers on directions that could lead to preferred states, both for future healthcare interventions (Robertson, Bagnall et al. 2015) and future research (Smith, Mouzon et al. 2018).

It is important to note that sex and gender can be mutually shaped, and therefore an

assumption that these are binary terms is problematic (Krieger 2003, Lohan 2007, Springer, Hankivsky et al. 2012). Consequently, this research uses these definitions, but with the understanding that they are not true binaries, and this is managed by considering intersectionality. Intersectionality is a useful concept to introduce because it advances our understanding of heterogeneity. It encourages the researcher to consider the man and the multiple attributes that affect an individual health status and potential health inequalities. It encourages the researcher to consider the interplay of those factors (Hankivsky and Cormier 2011, Bauer 2014). How to practice an intersectional approach is complex and there are no developed methods that ensure intersectionality is addressed or adjusted for within research (Dhamoon 2011, Muntaner and Augustinavicius 2019). This research does aspire to take an intersectional approach, yet this must be manageable. Arguably being reflexive and acknowledging impacting factors from social categories is a way of practicing intersectionality (Hankivsky and Cormier 2011, Bauer 2014). Therefore, a reflexive approach will be taken. This is in line with some academics guidance on practicing intersectionality (Hancock 2007, Cole 2008, Dhamoon 2011), but pragmatically does not go to the depth that some academics suggest intersectionality analysis should go to (Winker and Degele 2011). In summary gender has an important focus in this thesis; it is acknowledged that men are not a homogenous group, and that multiple factors can intersect and interplay to influence the phenomena of health.

Masculinity, particularly hegemonic masculinity, is widely accepted to be an important influence in men's mental health, and can partly explain how some men express and navigate depression, and their risk profiles (Courtenay 2000, Conrad and White 2010, White, De Sousa et al. 2011). Hegemonic masculinity is a pattern of practices enacted (mainly by men) to demonstrate or protect one's masculine status (Connell and Messerschmidt 2005). Hegemonic masculinity is exemplified by both the practicing of desirable behaviours and the discouragement (subordination (Messerschmidt 2019)) of undesirable behaviours (Courtenay 2000, Connell and Messerschmidt 2005). What is considered as desirable, or undesirable, is culturally and contextually determined (Connell and Messerschmidt 2005, McVittie, Hepworth et al. 2017, Messerschmidt 2019).

In western societies, stoicism, strength, control, and restricted emotionality are traits typically characteristic of hegemonic masculinity (Courtenay 2000, Connell and Messerschmidt 2005, Addis, Mansfield et al. 2010). Examples of undesirable traits are weakness, vulnerability, unregulated emotions (except for anger), and unnecessary help-seeking (Addis and Mahalik 2003, Connell and Messerschmidt 2005, McVittie, Hepworth et al. 2017, Messerschmidt 2019).

Masculinity is dynamic, and men are 'active players' within this social construct (Connell and Messerschmidt 2005, Messerschmidt 2019). One's masculinity is not assumed, fixed, nor passively ascribed (Connell and Messerschmidt 2005, McVittie, Hepworth et al. 2017). It involves continuous re-creation, and this is not always a conscious practice (de Visser, McDonnell 2013). Masculinity can occur at both an individual level and societal level (Robertson, Williams et al. 2016). It is possible that a man who does not subscribe to

masculine norms at an individual level may still be influenced by, and have to navigate masculine norms within his social world (Valkonen and Hänninen 2013).

Hegemonic masculinity, and masculinity, can have both negative and positive effects in depression and can impact on several aspects relevant in the phenomena of men's depression. For clarity, these aspects are grouped below as risk factor for depression, help-seeking and expression of depression, and depression treatment. However, all these aspects are strongly interconnected.

Risk factor for depression

Adhering to hegemonic masculinity is a risk factor for depression and reduced wellbeing (de Visser and McDonnell 2013, Vandello and Bosson 2013). Hegemonic masculinity is a conceptual ideal, and one that, for most men, is unattainable. Despite this it can still be seen as a normative standard for some men to prescribe to or be judged against. The payout is that men will require repeated demonstration of an arguably unobtainable and precarious status (Courtenay 2000, Vandello and Bosson 2013). Deviations from accepted masculine norms can cause stress (Taylor 2014), partially due to the individual predicting or experiencing judgment from other men (Vandello and Bosson 2013, Rummell and Levant 2014). A study by Syzdek and Addis (Syzdek and Addis 2010) found that unemployed men who were more likely to endorse hegemonic masculine ideals were also more likely to develop depression symptoms. In this study masculinity was positioned as an objective measure, using the validated conformity to masculine norms inventory (Mahalik, Talmadge et al. 2005). Qualitative studies also support the same finding; a meta synthesis of qualitative studies on men's understanding of their depression found that many believed the pressure they felt to "be a man" underpinned their depression (Mckenzie, Jenkin et al. 2016). What may be a particularly damaging aspect of hegemonic masculinity is emotional restrictions ('restricted emotionality'), which has been linked to increased depression and increased stress in men (Seidler, Dawes et al. 2016, Carlton, Harrison et al. 2020).

Help-seeking and expression of depression

Restricted emotionality, and overall hegemonic masculinity, is also connected to delayed help-seeking in some men experiencing depression (Addis and Mahalik 2003, Seidler, Dawes et al. 2016). Seeking help may be perceived as a threat to desired traits such as being stoic and is juxtaposed to strength (Murray, Aravkin et al. 2020). As Richards et al. highlight, to accept help for depression requires an acknowledgement that one is unable to cope, which may further compound feelings of low mood and threaten gender status (Richards, Lankshear et al. 2006). Suppression of emotions can be an alternative strategy to seeking help. In a grounded theory study exploring hidden depression in men (Brownhill, Wilhelm et al. 2005), a finding was that some men only sought help for depression once it had reached a crisis point. The men in this study were recruited based

on if they had felt 'down in the dumps,' rather than a having a diagnosis of depression, however this study does provide a useful understanding of a trajectory of emotional distress that men may experience, with help-seeking being the option once other strategies such as emotional suppression had been exhausted.

The strategies that are most likely to be endorsed as alternatives to help-seeking in men are externalising symptoms (White 2010). In line with this there is evidence that those that strongly adhere to hegemonic masculinity are more likely to display externalising depressive symptoms, this has been shown in both quantitative studies (Magovcevic and Addis 2008, Genuchi and Valdez 2015) and qualitative studies (Brownhill, Wilhelm et al. 2005, Valkonen and Hänninen 2013, Vandello and Bosson 2013). As discussed above, displaying of externalising symptoms has also been linked to a higher risk profile in depression, particularly if those externalising symptoms lead to substance misuse or increased risk-taking behaviours.

Most of the work around men's help-seeking has focused on the man's initial contact with a professional for diagnosis (Seidler, Dawes et al. 2016). While this is a key step, (some treatments can only be accessed through this route) it is not the only time men engage (or do not engage) in help-seeking during the course and management of this potentially long-term condition (Seidler, Dawes et al. 2016). There is a lack of attention, or at least a lack of differentiation, on the different dimensions of help-seeking throughout recovery. In addition, lay help-seeking (non-professional) is an important dimension of help-seeking, yet within the literature, there has been less focus on the phenomena as a whole, such as considering one's social connections and support networks (Johnson, Oliff et al. 2010).

From what is known there could be a gendered aspect to these other dimensions of help-seeking. Due to gendered socialisation men may be less familiar with discussions around their mental health. In a study around suicide, men spoke about how silence around mental health and suicide was normalised (Oliffe, Creighton et al. 2017).

Historically men have been socialised to not talk about their feelings, or mental health (Garside and Klimes-Dougan 2002). Gender, culture and identity can negatively intersect resulting in men 'silencing' mental health (Ward and Mengesha 2013). One effect of this is that men may see depression and emotional distress as less normative than it statistically is. Viewing a phenomenon as non-normative can hinder help-seeking behaviours (Addis and Mahalik 2003, Harding and Fox 2015). As a population men have fewer support networks compared to females. Another result is that men may be less skilled in being able to seek support. Men are less articulate in mental health and emotional vocabulary, which can hinder help-seeking (Emslie, Ridge et al. 2007, Seidler, Dawes et al. 2016).

Men, as a population have fewer social support networks when compared to women (Conrad and White 2010). Social support networks have a positive buffering effect on depression, being positively related to help-seeking for mental health, and increased mental health literacy (Santini, Koyanagi et al. 2015), particularly in men (Lee, Hwang et al.

2020). The social connectedness amongst men is known to be diverse (McKenzie, Collings et al. 2018). Within this diversity a more dominant discourse is that sharing of emotions was not a norm, and to establish such relationships was difficult, often needing to be actively sought (McKenzie, Collings et al. 2018). In addition to help-seeking, the act of receiving help is also not a neutral phenomenon. There can be a cost to receiving help, which should also be considered as an important aspect of the help-seeking phenomena (Bohns, 2010, Lee, 2002, Galdas, Cheater et al. 2005). Particularly as some men can see independence as central to their masculine self-concept (Yousaf, Grunfeld et al. 2015). In a study exploring men with cancer, including some with depression, an important dynamic of accepting help from their support network, was being able to offer it back in some way, otherwise men spoke of feeling uncomfortable in relation to accepting support (Wenger and Oliffe 2014).

Depression recovery

Gendered relations also influence men's depression recovery. Experiencing and being diagnosed with depression can be seen as a threat to some, particularly if the man strongly adheres to hegemonic masculinity (Valkonen and Hänninen 2013 Mahalik, 2006, Emslie, 2006). Studies have shown that men can self-stigmatise in depression. Some feel they should have overcome their depression, eliciting a sense of failure, which links to lower self-esteem and hindered recovery (Latalova, Kamaradova et al. 2014, McKenzie, Oliffe et al. 2022). Men may also have to navigate external stigma.

Findings suggest men, particularly those with no personal experience of any mental health problems, hold more stigmatizing attitudes towards those with depression (Oliffe, Ogrodniczuk et al. 2016, McKenzie, Oliffe et al. 2022). The weight of external stigma can be damaging for recovery (McKenzie, Oliffe et al. 2022).

There are numerous examples of how men have used various tactics to navigate around some health damaging aspects of masculinity, even when they adhere to hegemonic masculinity, and self-stigmatise depression. Men can reframe their masculinity and draw upon aspects such as self-reliance, responsibility, and a desire to protect more valued traits, to positively manage their depression, and enhance treatment (Owen, Wong et al. 2009, Englar-Carlson and Kiselica 2013, Fogarty, Proudfoot et al. 2015). For some men, reconstruction of one's masculinity is part of depression recovery (O'Brien, Hunt et al. 2005, Emslie, Ridge et al. 2007). As mentioned, men are active social agents in this flexible construct. Men, including those who have experienced negative restraints of hegemonic masculinity, can go through a process of reframing their masculinity and be positively influenced by it (Emslie, 2007, Seidler, 2016, Valkonen and Hänninen 2013).

In summary gender is suggested to be important in men's experiences of depression, when men's depression is considered as a generalised phenomenon. Understanding this offers insights into men's depression. That hegemonic masculinity is an important concept, is an assumption that underpins this thesis. It is also understood that men are not a

homogenous group and that multiple characteristics can intersect to influence one's experience of depression and the healthcare system.

In terms of the research paradigm, this study assumes hegemonic masculinity to be a multidimensional and social concept. Yet masculinity is not always conscious, or a salient concept for men. This can cause issues in qualitative research, because men may consider aspects of the concept relevant, but not be versed in expressing it. This has been shown in other qualitative studies, for example, Oliffe et al.'s study around male suicide found many men had internalized failures to live up to an ideal, and struggled to process these; yet this was a co-constructed finding, with only one participant specifically articulating this as part of his narrative (Oliffe, Creighton et al. 2017). This is not necessarily problematic; however it is something to be aware of when considering methods and conducting analysis.

2.5. Treatment for depression; a focus on antidepressants

Treatment for depression can be either pharmacological, psychological, e.g. forms of psychotherapy, or feature both. There is limited evidence to suggest one strategy is more effective than another (Kamenov, Twomey et al. 2017). What seems most predictive of an effective strategy is the patient being prescribed a treatment that they are engaged with (Winter, 2013, Kamenov, Twomey et al. 2017).

In the UK guidance from the **National Institute for Health and Care Excellence (NICE)** influences the antidepressant prescribed, with selective serotonin reuptake inhibitors (SSRIs) being first line, and the most commonly prescribed antidepressants (NICE 2009, Marasine, Sankhi et al. 2021). For most they have an acceptable side-effect profile, however they can have unacceptable side effects. In some men sexual difficulties may be viewed as particularly problematic, and a commonly experienced side-effect (NICE 2009, Read, Cartwright et al. 2014, BNF 2021). Another common side effect is emotional blunting or apathy (Read, Cartwright et al. 2014, Plowden 2019) which Goodwin et al. found is particularly reported in men (Goodwin, Price et al. 2017). For some men who experienced side effects, these were seen as a favourable trade-off vs the negative consequences of not taking the medication (Scholz, Crabb et al. 2017). In terms of adverse health outcomes (unintended pharmacological effects), an umbrella systematic review by Dragioti et al. (Dragioti, Solmi et al. 2019), found highly suggestive, but not convincing, evidence of antidepressant association with adverse health outcomes. The most common being gastrointestinal bleeding and reduced bone density. However, these adverse effects are often able to be monitored and managed within routine healthcare (NICE 2009, Dragioti, Solmi et al. 2019).

There has been historical debate about antidepressants and their effectiveness (Kirsch, Deacon et al. 2008, McAllister-Williams 2008, Khan and Brown 2015). Cipriani, Furukawa et al. have conducted a systematic review which demonstrates clinical effectiveness in the most commonly prescribed antidepressants worldwide (Cipriani, Furukawa et al. 2018).

Their comprehensive study looks at 522 trials, while also assessing their risk of bias, and pooling accordingly (Cipriani, Furukawa et al. 2018). Their pooled findings under-represent men; only 37.7% of the pooled subjects were male. This, however, is unlikely to undermine their conclusion because, based on an overview of the evidence, it is improbable sex significantly impacts current antidepressant efficacy. While some studies have suggested differences in antidepressant efficacy in male and female subjects (Susan G. Kornstein, Alan F. Schatzberg et al. 2000, Fišar, Kališová et al. 2008), most studies have not found clinically significant differences between the sexes (Frederic M. Quitkin, Jonathan W. Stewart et al. 2002, Kokras, Dalla et al. 2011, Kokras and Dalla 2017, LeGates, Kvarita et al. 2019). Therefore, commonly prescribed antidepressants such as SSRIs are effective in treating moderate to severe depression, and were also found to have a protective effect against suicide in adults aged over 19 years (Dragioti, Solmi et al. 2019).

While antidepressants are an effective option for treating moderate to severe depression (Cipriani, Furukawa et al. 2018), there are barriers to their practical application. These include poor adherence (Lingam and Scott 2002, Woodward, Bereznicki et al. 2016, Gauthier, Guérin et al. 2017), ambiguity on treatment duration (Kato, Hori et al. 2021), and stigma (Castaldelli-Maia, Scomparini et al. 2011, Latalova, Kamaradova et al. 2014, Ho, Jacob et al. 2017). Understanding such phenomena has improved patient outcomes in depression (Chong, Aslani et al. 2011, van Geffen, Hermsen et al. 2011, Buus, Johannessen et al. 2012).

Firstly, in terms of poor adherence with antidepressants, this can, but does not always, result in poor treatment outcomes (Geddes, Carney et al. 2003), and could put patients at risk of withdrawal effects, particularly with antidepressants that have short half-lives (Marken and Munro 2000). It is estimated that 30–60% of patients independently stop their antidepressant drug treatment within the first 3 months (Lingam and Scott 2002, Woodward, Bereznicki et al. 2016, Gauthier, Guérin et al. 2017), with most discontinuing within the first month (Olfson, Marcus et al. 2006, Gauthier, Guérin et al. 2017). This has been linked to poor treatment outcomes (Demyttenaere, Enzlin et al. 2001, Geddes, Carney et al. 2003). Interestingly it has been suggested that primary medical adherence, which means the pick-up rate of a prescription, is higher than the adherence rate of antidepressants, at around 85% (Freccero et al., 2016). This could suggest that most patients who are non-adherent do present (or their representatives present) initially at the pharmacy to collect their antidepressants.

Poor antidepressant adherence is shown in both men and women, with a modest yet statistically significant finding that men are less adherent than females in ages under 20 years and over 50 years (Krivoy, Balicer et al. 2015). Serna et al.'s (Serna, Cruz et al. 2010) study looking at duration of antidepressant treatment using prescription database data with a retrospective cohort from 2003-2007 found that men were more likely to stop antidepressants than women, although the study looks at some antidepressants that are not often used in current UK practice such as maprotiline and clomipramine (Serna, Cruz et al. 2010).

It is also important to note that multiple measures of adherence are used throughout the literature which may explain large variances in the extent of adherence which has been reported. Another consideration is that antidepressant continuation may not have been appropriate, for example due to misdiagnosis. Despite this, the overall pattern is that poor adherence can be problematic, contributing to worse treatment outcomes in depression in all genders. This is important not only during initial treatment, but also throughout treatment (Gauthier, Guérin et al. 2017).

Withdrawal effects are another potentially problematic phenomenon with antidepressant use. Withdrawal effects are more likely to occur when antidepressants are stopped suddenly, particularly when high doses have been used or for long durations. A systematic review estimates 56% of those stopping antidepressants get withdrawal symptoms. Typically, they last a few weeks, though their length can be unpredictable and can last months (Fava, Gatti et al. 2015). Complications of withdrawal can include undesirable adverse effects but could also lead to longer duration of antidepressant treatment if withdrawal effects are misdiagnosed as poor functioning without antidepressants, leading to longer duration of antidepressant treatments (Davies and Read 2018). The withdrawal effect can create confusion and uncertainty for patients and the public (Chakraborty, Avasthi et al. 2009, Maund, 2019). As a result, some people believe them to be addictive (Prins, 2008, Schofield, 2011, Verbeek-Heida, 2006, van Geffen, Hermsen et al. 2011, Chakraborty, Avasthi et al. 2009), and this may be particularly true for male patients compared to females (Churchill, Khaira et al. 2000).

Patients' beliefs about their treatment and depression are influential on adherence and treatment outcomes (Lehane, 2007, Buus, 2012). Poor attitudes to antidepressants have been linked to poor adherence and acceptance of antidepressants (Castaldelli-Maia, Scomparini et al. 2011, van Geffen et al., 2011), particularly initial beliefs (Warden et al., 2009). Addressing beliefs has shown improvements in adherence to antidepressants (Hung, 2014; Sansone & Sansone, 2012). Communication about common side effects is a predictor of adherence (Woodward Bereznicki et al., 2016), yet patients that have experienced side effects from antidepressants reported feeling poorly informed about potential side-effects (Garfield, 2004, Prins, Verhaak et al. 2008, Anderson). This could be particularly pertinent for men, who typically have poorer mental health literacy (Milner, Shields et al. 2019).

Antidepressant users can hold complex, potentially negative, views of antidepressants. Particular concerns reported for all genders are around antidepressants being seen as having effects on one's sense of self (Schofield et al., 2011, Maund et al., 2019, Bayliss and Holtum, 2015), being concerned about their 'mind-altering potential' (Anderson et al., 2015), and not being essential therapy (van Geffen et al., 2011). Many patients also hold ambivalent feelings around antidepressants, and weighing these views up is a complex process (van Geffen et al., 2011, Gask et al., 2003, Gibson et al., 2016).

Current literature exploring views of antidepressant users has shown patients question

both the validity of their condition as having a bio-chemical cause (Buus, Johannessen et al. 2012), and the validity of a pharmacological treatment (Read, Cartwright et al. 2015). This results in patients who continue treatment creating a moral framework to legitimise their treatment choice (Ridge, Kokanovic et al. 2015). A meta-ethnography of patients' experience of taking antidepressants found that taking medicines involved both a decision and meaning making process (Malpass, Shaw et al. 2009). For example, participants experience conflict over 'duty to be well' vs 'taking the easy way out'. For both these examples social contextualisation can influence the importance and meaning of the concept to the individual, and this can be a constant re-evaluation process (Malpass, Shaw et al. 2009).

There is limited knowledge about view on antidepressants, from the perspective of men experiencing depression. Studies suggest findings are similar to non-gender specific studies, although hegemonic masculinity is influential for some aspects (Emslie et al., 2006, Gibson et al., 2018). This finding would be in line with the discussions above, where the decision to take antidepressants is a socially embedded process. Some men felt taking antidepressants compromised hegemonic masculine traits such as control, autonomy, and self-management (Gibson, 2018, Wood, 2021, Oliffe, Kelly et al. 2010). These traits are especially valued by men (Spendelov, 2015, Johnson et al., 2012).

Gibson, Cartwright and Read's 2018 study is the first to specifically focus on men's views of antidepressant treatment (Gibson, Cartwright et al. 2018). Their theoretical perspective matches this thesis in that they state the social world may be influential in views around antidepressants. Specifically, Gibson et al. took a critical realist view. They accounted for the subjective views of participants, and the chemical effects of antidepressants. Data was collected using open-ended narrative-style interviews, which can help generate data, and is an approach in line with the study's theoretical perspective (Rapley 2001). Gibson et al. recruited only from New Zealand. One participant was of Māori heritage and may have particular social experiences that are unique to the New Zealand culture, and not represented in UK culture. Otherwise, New Zealand culture is considered westernised and has similarities to the UK. The overarching theme was that men hold conflicted and complex views on antidepressants. Some, but not all, felt a stigma of being a man and requiring antidepressants, and this underpinned multiple conflicts, for example taking antidepressants when it changed their sense of agency and control. Importantly men spoke about being able to overcome these difficulties when they were addressed and were able to reframe their view of depression, treatment, and masculinity. These findings, particularly about undermined sense of agency and self, were also found in a later 2021 thematic analysis study (Wood, Griffiths et al. 2021).

The finding of self-stigma and perceived public stigma when taking antidepressants is well established (Castaldelli-Maia, Scomarini et al. 2011). Antidepressant self-stigma is linked with perceived emotional weakness, and failure to deal with problems (Castaldelli-Maia, Scomarini et al. 2011). When depression is stigmatised, antidepressant use can compound this by being a visual representation of needing something to treat the disease.

(Knudsen, Hansen, Traulsen, & Eskildsen, 2002). While this is not sex specific it has been suggested depressed men are particularly vulnerable to stigma, and negative effects of it (Vogel, Heimerdinger-Edwards, Hammer, & Hubbard, 2011).

In summary mixed gender studies show that those taking antidepressants can have a spectrum of views around taking antidepressants. However, there is a link between negative views of antidepressants with poor adherence and poor treatment outcomes. Men may particularly hold conflicted views of taking antidepressants, seeing taking antidepressants as challenging to certain aspects of hegemonic masculinity. Being poorly informed about antidepressants is problematic. Those that felt informed about antidepressants were more likely to continue them, compared to those that had unaddressed information needs or concerns (van Geffen et al., 2011).

2.6. Community pharmacists and their role in supporting men prescribed antidepressants; a problem focused perspective

Community pharmacists have potential to support men being treated for depression, particularly those taking antidepressants. They will routinely interact with these patients, and have expertise to address issues relating to medicines, as well as extensive training on patient focused care, which could be important in addressing both the medical, and the social views relating to antidepressant therapy (Rubio-Valera, Chen et al. 2014, Chong, 2013). Community pharmacies are well placed, accessible, and can be accessed without appointments. Optimally utilising community pharmacists could also alleviate pressures elsewhere in the healthcare system (RPS 2018, Thomson, 2019). Yet men underutilise community pharmacists (Granville, 2009, Boardman, 2005) and there is little knowledge about what men taking antidepressants see as the role of the pharmacist in their treatment journey, or how pharmacists can better support them. To the best of the PhD authors' knowledge, a publication from this research [see (Brydges, Rennick-Egglestone et al. 2020)] was the first research study to focus on men's views of antidepressants for their treatment of depression, and the community pharmacist's role within their treatment journey.

From non-gender specific knowledge, it is known that antidepressant consultations by community pharmacists predominantly focused upon bio-chemical counselling, as opposed to psychosocial discussions (Chong, Aslani et al. 2014), with community pharmacists viewing their key contributions as providing information, ensuring medicines safety, and side effect management (Guillaumie, Moisan et al. 2015). Patients also view the community pharmacist's role as supplying the medicine, and providing information about medicines and side effect management (Guillaumie, Moisan et al. 2017, Guillaumie, Ndayizigiye et al. 2018).

Community pharmacists typically spend more time counselling patients who are newly prescribed antidepressants compared to those collecting antidepressant repeat

prescriptions, and do not tend to proactively counsel these refill patients (Geffen, Kruijtbosch et al. 2009, Chong, Aslani et al. 2013, Guillaumie, Ndayizigiye et al. 2018). Yet antidepressant users report desiring the pharmacist to provide proactive counselling throughout their treatment (Murphy, Martin-Misener et al. 2016) and to pre-empt their information needs (Guillaumie, Ndayizigiye et al. 2018). These patients want to capitalise on community pharmacists' knowledge but can struggle to know what to ask (Murphy, Martin-Misener et al. 2016). A suggestion from patients taking antidepressants in a Canadian study was that the community pharmacist should initiate regular discussions so that important topics could be discussed naturally (Guillaumie, Ndayizigiye et al. 2018).

Community pharmacists have good mental health literacy as perceived by themselves, patients, and in empirical studies (Guillaumie, Moisan et al. 2017, Rimal, Lin et al. 2022). Community pharmacists endorse positive attitudes towards those with depression. For example they reject negative biased statements about mental illness (Phokeo, Sproule et al. 2004, Rimal, Lin et al. 2022). Yet despite a good mental health literacy, community pharmacists can still have insufficient knowledge about depression and particularly recovery (Morral and Morral 2017) and can have low confidence in how to support recovery orientated care, and what the expectations and needs of these patients may be (Morral and Morral 2017, Rimal, Lin et al. 2022).

Overall westernised and UK mental healthcare service provisions have been criticised for not focusing on recovery orientated care (Slade, Amering et al. 2014, Ng, Bourke et al. 2016), and for the dominance of clinical recovery (the focus being on clinical outcomes) over personal recovery (recovery meaningful to the individual) (Slade, Amering et al. 2008, Maruthappu, Sood et al. 2014, England 2017). While community pharmacists have not been specifically discussed, the discussions above suggest community pharmacy care is not an exception and could benefit from better alignment with recovery-oriented care. Improvements here may be particularly important as reticence about raising concerns has been reported by antidepressant users when they perceive the pharmacist as being uncomfortable (van Geffen, Kruijtbosch et al. 2009).

Further barriers reported by pharmacists include lack of time (Scheerder, De Coster et al. 2008, Liekens, Smits et al. 2012, Watkins, McKee et al. 2017), privacy when discussing sensitive issues (Vinay Phokeo, Beth Sproule et al. 2004, Liekens, Vandael et al. 2014, Mey, Fowler et al. 2014, Guillaumie, Moisan et al. 2017), lack of training, or confidence when counselling those with depression (Vinay Phokeo, Beth Sproule et al. 2004, Scheerder, De Coster et al. 2008, Knox, Hattingh et al. 2016), limited access to patients' records (Crump, Boo et al. 2011, Liekens, Smits et al. 2012) and lack of collaboration with other mental healthcare providers (Guillaumie, Moisan et al. 2017).

2.7. Overall conclusion

Depression can be a debilitating long term condition, and the treatment for depression using antidepressants can be problematic for some men for a variety of pharmacological issues, psycho-social issues, and also the interplay of these issues. Utilising community pharmacists to support these patients can potentially benefit the patients and the NHS. There is, however, a need to understand further how this might be done, and in ways that are acceptable and support person centred recovery.

Chapter 3: Methodology and methods used in developing a complex intervention

3.1. The research paradigm.

The research paradigm is the perspective that the researcher takes on what influences should be studied, and how they should be studied (Lather 1986). This follows through into the methods selection, and helps provide clarity on the suitability of methodology and methods to answering the specific question and aims of the study (Denzin and Lincoln 2011).

It is important in a thesis to be transparent about one's research paradigm. This is because the chosen paradigm will have an impact throughout the research, and how the findings are interpreted (Bunniss and Kelly 2010, Denzin and Lincoln 2011). It requires the researcher to consider and articulate what assumptions have been made, which can enable greater critical thought and awareness (Bunniss and Kelly 2010, Williams, Boylan et al. 2019). Providing this clarity can also help facilitate other researchers, enabling them to build upon knowledge contributions while still understanding any theoretical underpinnings, and assumptions in cited work (Ryan 2018, Park, Konge et al. 2020).

A research paradigm is based on the studies' ontology and the epistemology perspectives. Ontology is about the nature of reality. Epistemology is about how one can examine reality, or know about a reality. An ontological stance can potentially influence one's epistemological thought, particularly when a researcher has made a conscious, critical, decision about what approach fits their research question (Bryman 2007).

There are various types of ontology. These can be categorised into two major beliefs, positivism and constructivism. Positivism is the belief that there is a single reality, which can be measured and known (Bernard and Bernard 2013, Park, Konge et al. 2020).

Considerations of concepts such as the truth, and reproducibility become important (Park, Konge et al. 2020). In contrast, constructivism is the belief that reality is multiple, and socially constructed (Guba and Lincoln 1994). Concepts such as context and interpretation become important (Guba and Lincoln 1994, Carson, Gilmore et al. 2001).

Epistemology, like ontology, has several stances, yet there are overall two major stances. The first is that knowledge can be measured, and this is compatible to a positivism belief and that there being one reality (Park, Konge et al. 2020). The second is that knowledge should be interpreted to understand the underlying meaning, and this is linked to the constructivism belief that reality is multiple and constructed (Bernard and Bernard 2013).

In this study a constructivist research paradigm is taken. This is because the thesis is

concerned with the development of a complex intervention, and there is a belief that the experience and views of participants and service users should be considered and need interpreting. There is an underlying assumption in this thesis that the contexts that this intervention operates within are multiple, complex and socially constructed.

Community pharmacy activities have multiple levels of influence from the individual practitioner to the healthcare system. These activities and interactions are socially constructed or socially influenced, from the policies and routines in the practice, to a community pharmacies' physical architecture.

In terms of methodology, or the research approach, the methodology used is a RtD approach underpinned by qualitative methods. RtD, although well established in computer sciences, is a relatively unknown approach in healthcare research, and is explained further in section 3.8. Fundamentally RtD, as a methodology, guides the researcher to construct something new and learn about it (Zimmerman, Stolterman et al. 2010). It is focused on future, preferred states (Zimmerman, Forlizzi et al. 2007). Qualitative methodology meanwhile studies the current world, capturing its depth and complexity (Bernard and Bernard 2013).

This research is about developing a complex intervention for use in a community pharmacy. It requires in depth knowledge about a current state, but also to discuss a preferred state, again with depth and detail. There may be multiple versions of these current and preferred states. Therefore, the constructivism belief, that reality is multiple and constructed, fits well with this thesis and its research. RtD, as a methodological approach, aligns with this and guides the researcher to construct something new, and learn about it.

While a RtD approach is used, qualitative methods are also used. Methodology and methods do not need to be synonymous (Bryman, 1984; Howe, 1992), and though qualitative research and RtD are different methodologies they do fundamentally align with a constructivism ontology. It is assumed the knowledge required and generated in this thesis will be complex, in-depth, and require an interpretation, rather than being a measurement of a single, objective truth.

For this reason, qualitative methods are used in this thesis. Qualitative methods are useful when experience, meaning and perspective are important to capture and understand. The associated methods can capture depth, detail context and interpretations. It also allows flexibility to capture, or acknowledge factors, that are outside of the research focus. All these factors will be required for this thesis. For example, the flexibility of qualitative research will be valuable in this study since complex settings are being explored and it is possible factors outside of the initial understanding of the research focus may need to be considered or acknowledged.

Similarly capturing detail and depth will be important to understand participants' perspectives, and the meanings underpinning these perspectives.

In addition to approaches outlined above, guidance from the Medical Research Council (MRC) on complex interventions has a core organising influence on this thesis, and this will be discussed now.

3.2. Medical Research Council Guidance on Complex Interventions.

As stated in the thesis title, this research explores the development of an asynchronous peer-support intervention for men experiencing unipolar depression, for use in community pharmacy. The research is positioned as complex intervention research because the intervention developed will operate within a complex social setting, will have multiple interacting components, and potentially seeks to influence multiple outcomes.

There are various approaches and strategies used in research on complex interventions (O’Cathain, Croot et al. 2019). An authoritative, and widely cited guidance is the MRC guidance on developing and evaluating complex interventions (Craig and Petticrew 2013).

The MRC guidance is the approach that is used to underpin the research approach in this thesis. Using guidance can aid with providing a transparent description of the research approach. The rationale for why the MRC guidance has been chosen is firstly because this guidance advocates a theory and evidence-based approach, combining theory and published evidence. A second reason is that, as a piece of scholarly work, it has been robustly developed, and undergone numerous peer reviews, including three revisions. This was in response to criticisms following its real-world usage (Rodriguez, Smith et al. 2020), and to accumulate the methodological and theoretical developments. Therefore, it represents ‘real-world’ tested guidance. It is also a widely cited and used guidance in successful grant applications (Craig and Petticrew 2013), and positioning work within this approach and using its language could aid publication. It is for these three reasons that its guidance was used to underpin the research approach in this thesis. Three revisions exist of MRC guidance (2000, 2008, 2021). At the point of study design the 2008 guidance was the current version. The guidance used for this thesis predominantly refers to the 2008 guidance, but with a retrospective awareness of the 2021 revision.

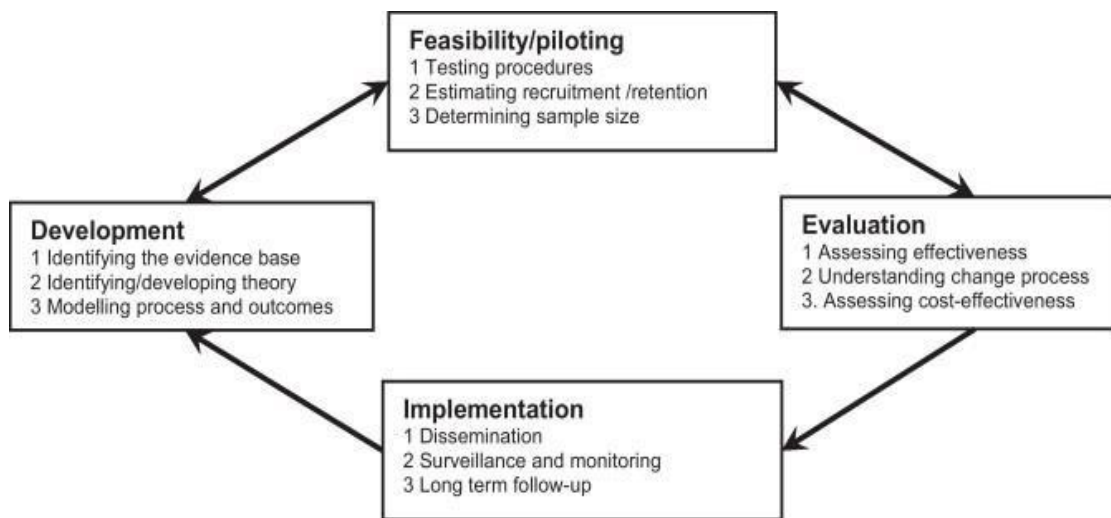
It is worth stating that although the decision to have the MRC guidance as a core underpinning approach in this thesis was made, there is little evidence to suggest that theory and evidence-based interventions result in more useful interventions compared to those developed without theory. A review of systematic reviews found no association between explicit use of theory and intervention effectiveness; with interventions developed using theory no more effective than the non-theory driven interventions (Dalgetty, Miller et al. 2019). It is possible that some non-theory interventions did use theory to develop their interventions, but not been explicit about it. Therefore, it could be that a theory and evidence-based approach will lead to more effective interventions. However, this is not proven. Yet, as already stated, the MRC approach is widely used, including by experts in the field, and the logic of a theory and evidence based approach

aligns with the researcher's own views, therefore the MRC's theory and evidence-based approach will be used in guiding this thesis research approach and methodology.

The MRC guidance defines four research phases. Figure 1 highlights four key elements for researchers developing and evaluating complex interventions and is taken from the MRC guidance 2008 (Craig, Dieppe et al. 2008). In Figure 1 the key steps and considerations are highlighted for each phase.

Figure 1: Key elements for researchers developing and evaluating complex interventions.

Taken from Craig et al. 2008.



These phases are iterative and there is no defined starting point for the research process, with movement between phases not necessarily linear or cyclical, yet work in one phase will influence the next phase (Michie 2014, Craig, Dieppe et al. 2008).

For the development phase, the MRC guidance is clear on the need to start by identifying the evidence base, and to identify or develop relevant theory. They further expand on their guidance in the development phase by getting the researcher to consider core questions. These questions are highlighted in Table 2.

The questions also reiterate advice around using theory and evidence to guide the intervention. Also highlighted is the need to consider later stages (such as implementation and evaluation) in the development, and that development, although a separate phase, is not considered an isolated phase, and that the intervention's context and real world settings need to be considered at development. In updated work the MRC guidance also suggests (but does not prescribe) incorporation of other methods and frameworks that can

facilitate with the development process. Examples are the use of intervention mapping (Bartholomew, Parcel et al. 1998), Steps for Quality Intervention Development (6SQuID) (Wight, Wimbush et al. 2016), and behaviour change wheel. In this thesis the behaviour change wheel was used and this is discussed further.

Table 2: Questions for researchers adapted from MRC guidance on complex intervention development (Craig, Dieppe et al. 2008)

	Questions:
1	Are you clear about what you are trying to do, what outcome you are aiming for, and how you will bring about change?
2	Does your intervention have a coherent theoretical basis?
3	Have you used this theory systematically to develop the intervention?
4	Can you describe the intervention fully so that it can be implemented properly for the purposes of your evaluation and replicated by others?
5	Does the existing evidence [or lack of evidence]—ideally collated in a systematic review—support the development of your intervention so that it is likely to be feasible, effective, or cost effective?
6	Has future implementation in multi-centre research settings and future translation into the real world been considered?

The MRC guidance contains considerations of how the developed intervention should be reported. This is an important consideration. Historically, the quality of descriptions of interventions has been poor, and often not given significant focus in publications (Hoffmann, Glasziou et al. 2014, Croot, O'Cathain et al. 2019). This results in lack of clarity around the intervention (Hoffmann, Glasziou et al. 2014). One useful tool to aid reporting is the Template for Intervention Description and Replication (TIDieR) checklist (O'Cathain, Croot et al. 2019). This 12-item checklist has been developed systematically from a Delphi survey of experts, and a literature review (Hoffmann, Glasziou et al. 2014). A TIDieR checklist has been included in chapter 7 to transparently report how the intervention has

been developed.

Since MRC's 2008 guidance, a 14-item checklist called GUIDED has been developed (Guidance for reporting intervention development studies). GUIDED has been systematically developed using a consensus study (Duncan, O'Cathain et al. 2020). This is a method in line with core guidance on how to develop health research guidelines (Moher, Schulz et al. 2010). The purpose of GUIDED is to provide greater transparency about the intervention development process, and to improve the quality of intervention publications, and GUIDED can be used alongside TIDieR guidance. A complete GUIDED checklist is included in appendix 1 to transparently report how the intervention has been developed.

In summary, the MRC's guidance in complex intervention development has been used to guide the approach of this study. The MRC refers to different phases in complex intervention research. The work in this thesis focused on the development phase.

Medical Research Council Guidance on Complex Intervention; a focus on the development phase.

The research presented in this thesis focused on the development phase of complex intervention research. Developing an intervention has inherent value; it is an evaluative and creative process that enables forward focused research, and in doing so aligns research goals with guidance on how to achieve excellence with impact (Chandler, 2014, Richards and Hallberg 2015). However, innovative concepts can be considered high risk work with low relative value since there is no proof of viability in its innovative state (Walport and Craig 2014). Therefore, it is important to take a careful and phased approach to manage risk and capture value in intervention development.

Dedicating adequate time and focus on the development phase can potentially reduce research waste (Chalmers and Glasziou 2009, Richards and Hallberg 2015). Failure to adequately consider intervention development has resulted in ineffective interventions being advanced to expensive evaluations studies, such as costly randomised controlled trials (Richards and Hallberg 2015).

Although this is not to say that studies concluding intervention ineffectiveness have no use. They can be useful, but only if the intervention had been sufficiently developed so that it may be reasonable to expect a beneficial outcome. For example, if intervention X had been developed based on theory and prior evidence, and successfully pre-piloted, and yet in a randomised controlled trials intervention X is shown to have no effect on its desired outcome, then this is a useful result. There has been publication bias causing limited dissemination of knowledge for interventions showing non-significant or negative results on desired outcomes (Song, Parekh et al. 2010). Yet this data can be important (Richards and Hallberg 2015).

This leads onto a second point for why the development stage is so important. Evaluation

is concerned with not just concluding if an intervention works, but more importantly articulating what are the aspects of the intervention, within its context, that work. Development is key to help understand active components of the intervention, and program theory (Skivington, Matthews et al. 2021). If during the evaluation an intervention shows effectiveness (or ineffectiveness), the next question is to understand how i.e. what parts of the intervention are effective (or not effective) and by what mechanism. This is called the program theory (Skivington, Matthews et al. 2021). To identify the program theory at an evaluation stage is difficult, particularly because, as is the nature of complex interventions, there are potentially numerous interacting components (Skivington, Matthews et al. 2021). Richards and Hallberg (Richards and Hallberg 2015), who have published work on research methods for complex interventions, use a 'black box' analogy to represent this problem. To address this 'black box,' work at the development stage should explore and articulate the active component of the intervention and highlight theoretically how the intervention could have an impact, which will aid later evaluation, and ensure those interventions that do get to large scale evaluation studies can produce useful knowledge.

Another important aspect to address at the development stage is acceptability to service users and other stakeholders. Even if an intervention is predicted to be effective, it would be a waste to evaluate the intervention if it has low acceptability (Richards and Hallberg 2015, Sekhon, Cartwright et al. 2017). Similarly, the development stage can also address experimental issues such as recruitment strategy, and if intervention can be delivered as intended, which in turn limits the risk of expensive evaluations such as RCTs having to be cancelled because of issues with recruitment, or poor adherence to protocol, or poor acceptability to its service users (Chalmers and Glasziou 2009, Richards and Hallberg 2015). Therefore, it is important to allow adequate time to investigate such issues. This is particularly relevant to acceptability, which is a multi-constructed concept (Sekhon, Cartwright et al. 2017). Acceptability, and how it is measured in this thesis will be discussed in further detail later in this chapter.

Finally, an additional reason for why this thesis is focusing on the development stage is that this is an area where little attention has typically been given in research studies. While this is increasing, there are still limited studies and limited knowledge on how to best develop a complex intervention (O'Cathain, Croot et al. 2019). By conducting this work and reviewing the findings this thesis can help increase the body of work discussing developing a complex intervention.

Therefore, the scope of this research was on the development and modelling phase. This stage was considered a connected stage to other aspects (e.g. implementation phases) as complex intervention research is a connected, iterative process, rather than isolated steps.

Craig et al define the development phase to be the period when the 'intervention must be developed to the point where it can reasonably be expected to have a worthwhile effect' (Craig, Dieppe et al. 2008). Yet as O'Cathain et al. point out, this is problematic because the

development phase is often an iterative process that may overlap with subsequent phases (O’Cathain et al., 2019). This has been called the ‘grey area’ (Croot, O’Cathain et al. 2019). It can be difficult to determine a start and end point for the process.

In terms of research methods and methodology the MRC guidance, which as discussed is highly regarded and highly cited, gives minimal detail on the development stage, other than recommending a theory and evidence-based approach, suggesting key questions to be answered (see Table 2), and acknowledging flexibility is required for iteration.

Findings from a systematic review identified 22 other approaches (23 in total) to development of a complex intervention (O’Cathain, Croot et al. 2019), and the authors comment that there are likely to be more approaches. It could be that incorporation of another development approach with the MRC guidance could give further direction for this thesis. Unfortunately, there has been little discussion to date around the strength and weaknesses of the other approaches, and little understanding of what circumstances may lead to one approach being superior to another for intervention development, and why (Duncan, O’Cathain et al. 2020).

Table 3: Core domains actions in developing healthcare interventions.

Core domain	Action	Suggested methods / further details
1. Conception	Describing problem identification	Literature search.
2. Planning	a) Identify development research team and who has editorial rights	
	b) Understand the problems and cause of problem	Literature search. In-depth understanding of target population and context. Explore theory and published research.
	c) Understand the experiences, perspectives, and psycho-social context of the potential target population	Synthesis of qualitative research or conduct primary qualitative research.
	d) Make a decision about specific problem and the context	
	e) Identify possible ways of change to address problem	
3. Designing	a) Generate ideas about solutions, and components and features of an intervention	Work with stakeholders creatively. Iterative prototypes, divergent thinking and moving to convergent thinking.
	b) Make decisions about the content, format, and delivery of the intervention	
4. Creating	Make prototypes or mock-ups of the intervention as relevant	Early cheap prototype. Think aloud method, usability testing, interviews or focus groups
5. Refining	a) Test on samples for feasibility and acceptability	Qualitative research with those receiving and delivering the intervention. Think aloud interviews with

		target population.
	b) Optimise the intervention for efficacy prior to RCT	Can intervention be delivered as intended, will recruitment strategy work etc.
6.Documenting	Document and describe the intervention so others can use it	Use Manuals, TIDieR framework (Hoffmann, Glasziou et al. 2014)
7. Planning for future evaluation	Develop the objectives of the outcome and process evaluations.	Agreement with key stakeholders how to define and measure success

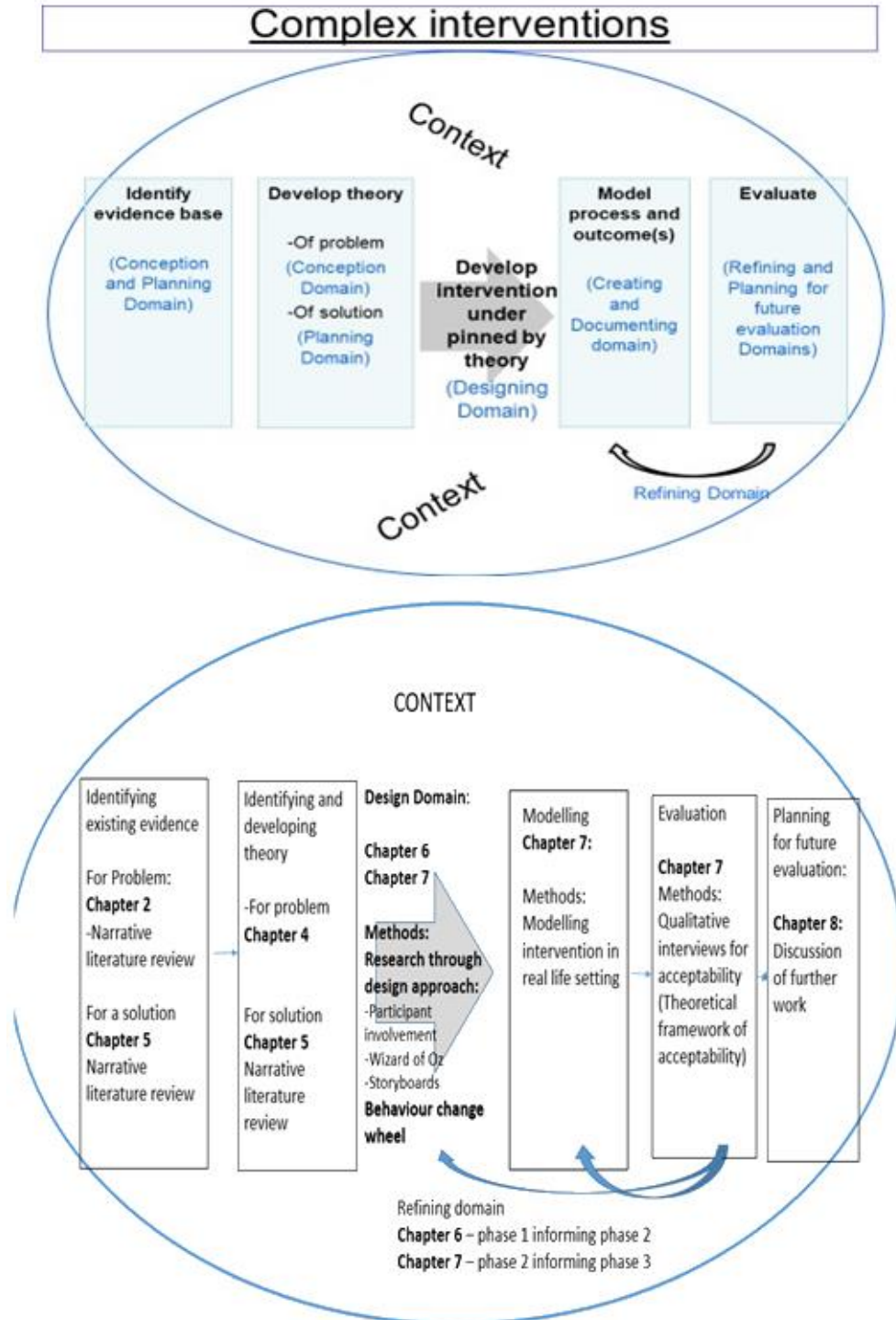
Yet despite this, when considering all the 23 approaches at a higher level, there are shared core actions, and these actions can be further categorised into seven domains (O’Cathain, Croot et al. 2019). These domains can be used as an overall structure for the research approach. These domains are highlighted in Table 3. This is a simplified adaption from work in the INDEX study (O’Cathain, Croot et al. 2019). Actions that the thesis author viewed were not required for intervention development have been removed to create a simplified table.

Table 3 and the MRC guidance on developing a complex intervention have been used to create Figure 2, which is a schematic of the thesis (see Figure 2).

This Figure has been used to structure the research approach and help the reader map how the research work links to the development of an intervention. The key steps outlined by the MRC (identifying the literature, identifying and developing theory and modelling processes modelling, evaluation and refinements) have been mapped out. The design domain has been highlighted in bold and not boxed. This is to mark that it is not an identified stage in the MRC guidance, yet this thesis believes that this is an important stage in the development of a complex intervention.

Variations of Figure 2 will appear at the start of each chapter to re-orientate the reader as to what contributions the relevant chapter makes in the development of a complex intervention, and how this fits in within the MRC guidance. Particularly this is intended to increase clarity as the work discussed is sometimes iterative, interlinked, and is making a methodical contribution by integrating MRC guidance with a research through design approach and the behavioural change wheel.

Figure 2: Schematic used to map overall thesis structure



3.3. Orientation to core research chapters in thesis

The core primary research studies are in chapter 4, 6, and 7. Table 4, highlights the research activities, and where this is discussed within the thesis. The patient public involvement (PPI) session was not recorded or analysed, but used to guide study design.

Table 4: Data collection phases in the design, modelling, and evaluation domains

Title of research activity area:	Participants	Method	Recruitment notes:	Thesis chapter
PPI	6	Interview/discussions (non-recorded)	3 males with history of depression, 1 as part of research team throughout. 2 pharmacists, 1 healthy male	N/A
Interview piloting	4	Interview pilot	2 men also in PPI session	N/A
Primary data collection for background knowledge	14 male participants	Interview	Recruited via poster or pharmacist recruitment	4
Design stage study	3 male participants 1 community pharmacist	Role play, low fidelity modelling	Poster recruitment	6
Pilot study - Pre intervention	14 male (peer) participants	Storyboard with interviews	Recruited via poster or by pharmacist	7
Pilot study – Post intervention	11 male (peer) participants, 3 pharmacists	complex intervention piloted, with follow- up qualitative interviews	11 males recruited from the pre-pilot study. One pharmacist was also both a male peer and pharmacist	7
Number of individual participants in total (excluding PPI/interview piloting)		20 (16 men experiencing depression taking antidepressants, 1 not taking antidepressants, 3 pharmacists)		

3.4. Qualitative Methods for Chapter 4 and Chapter 7 (Primary Research studies)

The two qualitative research studies in this thesis are presented in chapter 4 and 7. Chapter 4's research study was conducted to better understand the needs and perspectives of men experiencing depression, and the role of the community pharmacist within their care. Prior to intervention development some empirical work is often required to develop theory and evidence, and to understand the needs of the population (Craig, Dieppe et al. 2008). This is particularly required when there is limited evidence and theory to underpin the intervention of interest. In this thesis, where the intention is to develop a complex intervention for men experiencing unipolar depression, for use in community pharmacy, there is a knowledge gap (see chapter 2 and 5) and therefore further empirical work was required.

Chapter 7 meanwhile is focused on exploring service users' views on the intervention acceptability (pre and post pilot). It is also about generating an understanding on what the program theory and active components of the intervention may be, and if further reiterations are required.

Chapter 4 and 7 research questions required depth and detail, which is a strength of qualitative methods. Understanding the needs, views, and experiences, particularly from those treating depression, can involve complexities, confusions, and subtleties. Qualitative research, with its engagement with participants and epistemological underpinnings would be better suited to manage these issues in comparison to more positivistic enquiries (Bryman 1984, Bryman 2007). Qualitative methods are also flexible which has advantages in studies where new information may emerge; research frameworks and directions can be quickly revised as new information emerges (Kvale and Brinkmann 2009, Anderson 2010). With quantitative methodology and methods, changing the research framework to capture new information can be problematic and slow (Bayley 2002, Anderson 2010). As these topics are relatively under-researched, and the research exploratory, it is likely new information may come up, therefore the flexibility of qualitative research is valuable. Another benefit of qualitative research's flexibility is that it allows adaptation to a participant's needs, and facilitates a research relationship (Kvale and Brinkmann 2009). This is important in this study because sensitive topics, such as participant's depression or mental health will be discussed.

Qualitative research, when conducted properly, is a rigorous approach. Yet it is important to consider what makes qualitative research rigorous and use this to demonstrate research integrity (Cypress 2017). This is particularly important because qualitative research has been criticised for not being rigorous (Cypress 2017). It can be harder to assess and demonstrate rigour in qualitative research compared to quantitative research (Anderson 2010, Morse 2015). Aspects that constitute rigour in qualitative research such as trustworthiness (credibility, dependability, conformity, transferability) and quality can be multifaceted, subjective (O'Brien, Harris et al. 2014, Morse 2015) and sources of doubt for researchers (Pereira 2012). Standards for Reporting Qualitative Research (SRQR) exist (O'Brien, Harris et al. 2014). The use of standards such as the

SRQR has often been advocated by publishing journals and peer reviewers (Peditto 2018, BMJ Open).

These standards have been used to improve rigour in this study and position the research study in line with standards desired in publishable research. The SRQR standards are used because they consider qualitative research broadly. There are different approaches to frame qualitative research (e.g. phenomenological, action research etc.) and due to epistemological and methodological differences within these approaches there are different quality-related criteria, standards, and guidance (Chiovitti and Piran 2003, von Elm, Altman et al. 2007). The SRQR, however, considers overall criteria that can increase rigour in qualitative research. This makes the SRQR appropriate for this research study, where no framed approach to qualitative research is followed.

Appendix 2 shows the 21 criteria for reporting qualitative research, and where they have been addressed in the thesis. It is important to state it is not assumed that designing and reporting this study in line with these standards automatically equates to a rigorous qualitative study. It is also important to uphold deliberate and conscious reasoning throughout and provide a coherent account of all processes (Amin, Nørgaard et al. 2020). Therefore, in addition to aligning the study with the SRQR, the conscious process of reasoning throughout also forms part of the research methodology.

Member checking is a technique used in qualitative research that can improve the credibility and trustworthiness of qualitative data (Lincoln and Guba 1985, Kornbluh 2015, Amin, Nørgaard et al. 2020). In member checking data or results are returned to participants to check for accuracy and resonance with their experiences. This process can improve credibility by providing another check that the data and/or initial analysis represents what the participants were saying. Yet while this can improve the credibility of results, it can also introduce epistemological and methodological challenges (Birt, Scott et al. 2016, Motulsky 2021). Unintended coercion could occur if a participant felt inclined to agree with researcher views. If disagreement occurs there is the issue of how to manage this (Caretta and Pérez 2019). As this thesis holds a constructivism ontology; believing reality as interpreted and constructed, rather than seeking to identify a singular truth, this may be a challenge.

In this thesis, member checking was done in two stages for the qualitative interviews. For the work presented in chapter 4, and for the pre-pilot interviews presented in chapter 7, face-to-face member checking interview occurred with participants. This took place about 2 weeks after initial interviews, and after the interviewer had done some initial analysis of interviews. The focus on the member check interview was on verification of researcher's initial interpretations, and opportunity for further expansion or adding to data. This member checking method potentially decreases participant distress when compared to other member checking methods such as returning transcripts to participants for checks (Birt, Scott et al. 2016).

Checking data at different stages can enhance overall study validity (Cho and Trent 2006). A second step involving member checking of synthesized analysed data was part of the method;

however, no participants responded to this request, potentially due to this request being issued over a year after participants' initial interviews (see chapter 8 for further discussion).

3.5. Methodological considerations for Semi-structured Interviews

In both chapter 4 and 7 interviews were conducted. The methods sections in these chapters give further specifics on the method. This section focuses on the methodological considerations of semi-structured interviews.

Interviews were semi-structured. A semi-structured interview allowed freedom to focus on themes as they occurred, but gave more structure than an unstructured interview, which can be time consuming and demanding on participants (DiCicco-Bloom and Crabtree 2006). A semi-structured interview can improve reliability by allowing greater flexibility during data collection, and expansion of discussions (Brod, Tesler et al. 2009).

It is important to understand that interviews are not neutral interactions. Research interviews are social practices with the purpose of knowledge generation (Brinkmann 2016). Knowledge produced can be influenced by the setting within which it is created and influenced by the interactions within the interview. There is a need to articulate these dynamics as they could influence data.

Firstly, there is a research relationship between the researcher and the participant. This study has the potential for the researcher to be seen by participants as an 'outsider'. In this study a female who has not had depression was conducting the semi-structured interviews. The insider/outsider concept had potential to influence the interview and knowledge produced, for example men may feel they need to explain themselves more to an 'outsider'. Alternatively participants may feel less able to speak about sensitive discussions to an 'outsider'. This does not unduly and negatively influence the study but did require the researcher to have an awareness of the concept prior, during, and after interviews (Berger 2015, Mercer, 2007). To manage this the researcher familiarised herself with core literature and theory around men's depression prior to the interview. A member of the research team was a male with experience of depression and his views were sought throughout the project. This enabled a greater awareness of potential 'insider' concepts (Dwyer and Buckle 2009, Mercer, 2007). During the interviews, a technique used to gather further depth or clarification was to respond in a meaning orientated way by reformulating the implicit message, and to encourage further discussion, (Kvale and Brinkmann 2009).

Another issue is that the researcher is a pharmacist. A topic of focus in the interviews will be experiences in community pharmacy. Participants may give different answers, for example they may desire to give more socially acceptable answers. There is a concept called social desirability bias (Krumpal 2013, Bergen and Labonté 2020). This is a tendency to present reality to align with what is perceived to be socially acceptable, for example participants may present a more favourable account of community pharmacy if they knew they were talking to a pharmacist, compared to a researcher. The researcher introduced herself as a researcher where possible.

A power imbalance can occur between researcher and interviewee in any interview since it is the researcher who asks the questions and guides the interview topics (Kvale and Brinkmann 2009). Therefore, to limit this power imbalance time was spent during interview to develop rapport and encouraging participants to speak freely.

Developing rapport is important in interviews. It facilitates gathering deeper personal knowledge (Herbert Rubin 2005). Demonstrating respect for participants and creating trust are core aspects of developing rapport (Kvale and Brinkmann 2009). Care was taken to develop positive trusting relations and demonstrate sensitivity and integrity. Prior to interview participants were given assurance about ethical principles, such as anonymity and confidentiality. This can facilitate rapport, and the interview data collection (Gill, Stewart et al. 2008, Britten, 2006).

Interviews occurred in private physically comfortable rooms, with water available always. Reduced distractions and comfortable environments can aid interview data collection (Gill, Stewart et al. 2008). These rooms were located within the participants' local pharmacy, or in a university room in a School of Pharmacy. This was an accessible location for all participants but may not be a neutral location. The interviewer was sensitive to participants needs throughout, and participants were informed they could request breaks or reschedule if required.

As the interviews in chapter 4 and 7 are semi-structured, a brief interview schedule was developed (appendix 3-4). For chapter 4, topics were chosen to address identified gaps in the literature. Key topics were around men's views of antidepressants, experiences of the community pharmacy, insights into unmet care needs and potential improvements. For chapter 7, questions were around core components of the intervention, and acceptability of intervention. Participants were deliberately not asked about the causes of their depression as the reasons for their depression was not considered important in answering the research questions in this thesis.

The interview schedules were piloted prior to use. This involved internal testing with two researchers experienced in qualitative methods, and field-testing with three males, two of whom had experience of taking antidepressants to treat depression.

Based on the piloting some changes were made. The word 'intervention' was replaced with 'service'. Although intervention is a terminology used within healthcare research disciplines, based on infield testing the term could link with negative meanings, with one male pilot interviewee saying; *'I didn't like the word intervention at all, if I had blood pressure it would have just shot up right now.'*

Another change made was that a question was added to ensure a shared understanding between participants and interviewer on the definition of 'community pharmacist'. The interview questions for chapter 4 were also shortened based on the piloting. This was done to limit researcher and participant fatigue. This may be a particularly important consideration due to the sensitive nature of discussions, and that those with mental illnesses can be more vulnerable to psychological and emotional exhaustion both in general, and in response to research (Dickson-Swift, James et al. 2007).

Deliberately having a standardised opening question that was a closed factual question was piloted and implemented. (For chapter 4, 'How long have you been taking your current antidepressants' and for chapter 7 'How approx. long did that last consultation take?'). This was done to create an easy opening into the interview for participants, compared to a challenging open question (e.g. 'What are the main challenges with taking antidepressants?').

3.6. Data Analysis Methods and Theory introduction (Chapter 4 and 7)

This section discusses the methods for data analysis and introduces frameworks used in the data analysis. Chapter 4 uses thematic analysis. Chapter 7 uses thematic analysis, and content analysis. In chapter 7 the framework of acceptability is used in the analysis of results. This section gives an overview of these methods. Specific details relating to the data are discussed in the relevant research chapters (chapter 4 and 7).

Thematic analysis (chapter 4 and 7)

For chapter 4 and 7 thematic analysis was chosen to allow for the meaningful identification and analysis of themes, and to interpret the meanings and significance underpinning the themes. A particular benefit for this study was the flexibility that thematic analysis allows for capturing major themes, and for capturing deviant cases, which are cases that do not align with the overall themes. As this was an exploratory study, this flexibility was important. The thematic analysis conducted in this thesis follows the method outlined by Braun and Clarke (Braun and Clarke 2006). The core seven-steps were: transcription, familiarization, coding, generating themes, reviewing themes and writing up. This section briefly gives an overview of these steps.

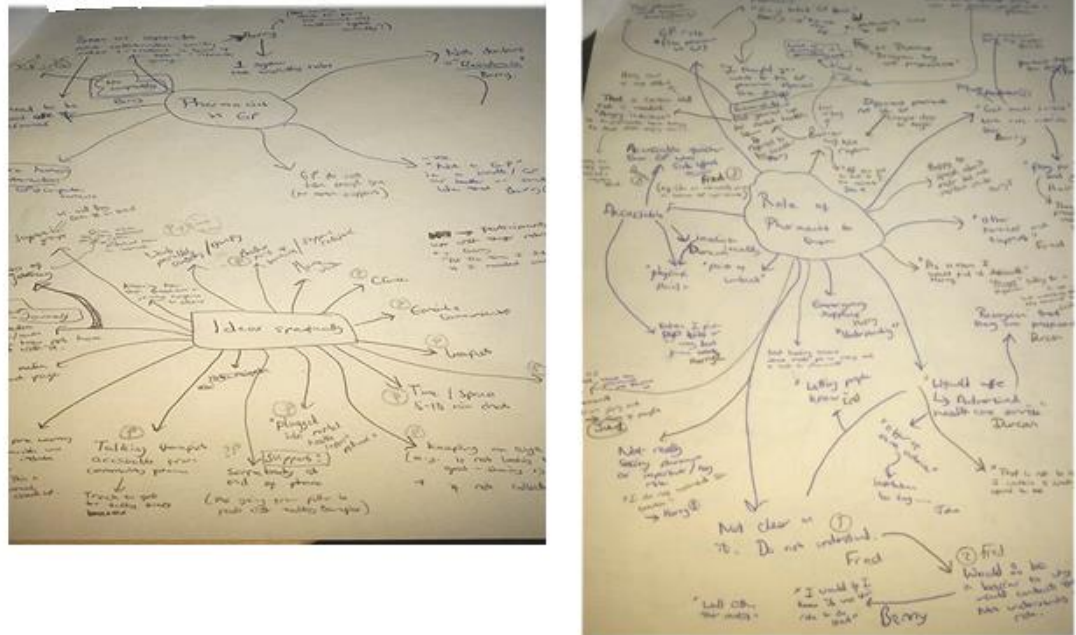
Firstly, the interview data was transcribed. Transcription practices can be a continuum between naturalism, in which everything is transcribed in detail, or denaturalism, in which all idiosyncratic elements of speech such as nonverbal utterances or false starts are removed (Oliver, Serovich et al. 2005). A naturalistic transcription is useful for when the mechanics of the conversation, or words used have meaning for the analysis (Potter and Shaw 2018). A denaturalised transcription would be more useful when the meaning behind the words has the most importance, rather than the exact way the words were said (Cameron 2001). Explaining which transcription approach was used can improve trustworthiness by increasing transparency (Oliver, Serovich et al. 2005). In chapter 4 and 7, it was the meaning which was the most important aspect to capture from the interviews, therefore a more denaturalised approach was taken. False starts, and incoherent additions within sentences were not transcribed.

The next step was familiarisation. In both chapter 4 and 7 it was the author of this thesis who did the transcribing and interviews, and this aided her familiarisation. The researcher carefully read and re-read the data prior to coding, and iteratively throughout the data analysis, including re-listening to original audio when relevant. As Braun and Clarke (2013) highlight, this was done with "analytical sensibility," (Braun and Clarke 2013), where reading occurred while simultaneously considering the research and its paradigm.

The next step was coding. Coding is breaking up the transcript and ascribing units of meaning to them. This is a categorisation process, and care was taken for it to be considered a separate stage to interpretation. Any interpretative thoughts at this stage were acknowledged but recorded within brackets. Coding can be inductive, where codes are derived from the data, or deductive, where predetermined codes are mapped to the text (Fereday and Muir-Cochrane 2006). Thematic coding also supports the hybrid approach, integrating both (Fereday and Muir-Cochrane 2006). The hybrid approach was used in this thesis.

The fourth step was generating themes. In both chapter 4 and 7 a technique described by Ziebland and McPherson called the one sheet of paper technique was used (Ziebland and McPherson 2006). This is shown in Figure 3. Key codes were represented in a physical diagram, and connections were identified by drawing links. This facilitated theme generation and understanding of links. The resulting subordinate themes were then organised into themes. Themes were judged on if they were meaningful to the topic, and if they created a coherent purposeful account. This was not always a linear process, and themes were not always determined by most prevalent codes, which is acceptable and in line with thematic analysis (Braun and Clarke 2006).

Figure 3: Photograph of the 'one sheet of paper' being used in data analysis



The next step was reviewing the themes. Themes were reviewed based on analytical judgments on if they were meaningful to chapter 4 and 7's aims and created a coherent purposeful account. This was not always a linear process. Coding and themes were cross checked by two other researchers. Overall, the research analysis team comprised of a community pharmacist (the thesis author), a social pharmacy professor, and a male researcher with personal experience of depression. The purpose of this stage was to find the best fit for the themes and underlying codes and discuss interpretations. The decision to not have all codes cross checked by another researcher was based on the argument that the greatest value for cross checking themes comes from the process of exploring alternative interpretations. An agreement on how codes are termed is not necessarily important. Rather it is the associated thoroughness required to explore competing explanations for the data that most contributes to increasing rigour (Armstrong, Gosling et al. 1997). Focusing the cross-checking process in this way has been recommended because it reduces costs and time compared to independent cross coding of the whole data set.

The final step is producing the report, where decisions are made on which quotes best support the themes.

Content analysis (chapter 7)

In chapter 7 content analysis was used. The purpose of using content analysis was to present a more manageable understanding of the content from the complex intervention designed in chapter 6 and piloted in chapter 7 (a peer support service). Content analysis enabled the researcher to identify and interpret meaning in qualitative data by identifying the presence of certain concepts. Firstly, key variables were defined to structure the content analysis. These variables included both manifest variables (easily identifiable content), such as length of peer responses, and latent content (requiring an interpretation), such as supportive content from peers. A content analysis was then implemented by systematically going through the qualitative text line by line. For manifest content, this was taken at face value, but for the latent content the researcher first immersed themselves in the data before coding, and assigning the theme, which is a recommended approach for latent coding (Kleinheksel, Rockich- Winston et al. 2020). A summary of the content, and a tally of how many media responses featured the relevant theme were presented and discussed as part of the content analysis.

Case example – a focused analysis (chapter 7)

In chapter 7 an analysis on a focused case example was conducted. The thesis author had observed an interesting phenomenon (introducing bias through cognitive distortion, and how this may impact a peer scheme) and she wanted to consider material in greater depth while keeping context. The data was analysed using interpretative phenomenological analysis. Initially the data was read line by line, then exploratory comments were made linked to relevant lines of texts. These comments were then further considered, and clustered with descriptive labels leading to the formulating an overall theme, or concise phrase (see Table 51-52). Some exploratory comments were not developed into themes if they did not link to the phenomenon of interest (i.e. introducing bias via cognitive distortion). The overall themes, and consideration of the case study characteristics were triangulated with data from the semi-structured qualitative interviews.

Theoretical Framework of acceptability (TFA) and using acceptability as a research outcome (Chapter 7)

The acceptability of an intervention to its service users is a key consideration when developing a complex intervention. Acceptability is a necessary requisite for service effectiveness, and implementation (Skivington, Matthews et al. 2021). Therefore, it is important to consider in the development stages of a complex intervention. However, definitions of acceptability have been problematic, and have led to ambiguity of the concept and subsequent analysis. One problem is that acceptability is a multi-faceted construct that is influenced by both cognitive and emotional responses. A recent publication by Sekhon et al. (Sekhon, Cartwright et al. 2017) has developed a theoretical framework of acceptability. It looks at acceptability as having seven constructs. The work was developed following a systematic review of literature, and an inductive and deductive processes with experts in the field. This approach can enhance theory development (Thompson 1956, Hox 1997). The theoretical framework of acceptability has been used in work developing complex interventions in community pharmacy settings (Chew-Graham, Kitchen et al. 2022). This theoretical framework will be used in chapter 7 for data analysis. The core constructs of acceptability in the framework are highlighted in Table 5.

Table 5: Key constructs of acceptability based on the framework of acceptability

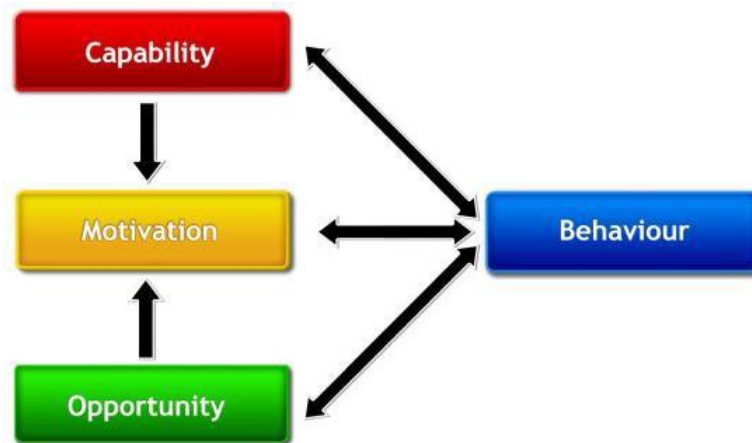
Constructs (alphabetical order)	Definitions of constructs
Affective Attitude	How an individual feels about the intervention
Burden	The perceived amount of effort that is required to participate in the intervention
Ethicality	The extent to which the intervention has good fit with an individual's value system
Intervention Coherence	The extent to which the participant understands the intervention, how it addresses their condition and how it works
Opportunity Costs	The extent to which benefits, profits or values that must be given up to engage in the intervention
Perceived Effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention

3.7. Methodology for intervention design (Chapter 6)

The first part of this subsection discusses the behaviour change wheel. The behaviour change wheel can help facilitate intervention development by getting intervention designers to consider a range of behaviour options and choosing those that are most promising based on theory and evidence (Michie, van Stralen et al. 2011). The behaviour change wheel was used to inform the design of this intervention by setting the design parameters for the final part of chapter 6.

The behaviour change wheel was developed from 19 frameworks of behaviour change. It has at its core a behaviour model called the COM-B model. The COM-B model is illustrated in Figure 4: The COM-B system, a framework for understanding behaviour. This model illustrates interactions of capability (C), opportunity (O), and motivation (M) produce behaviours (B).

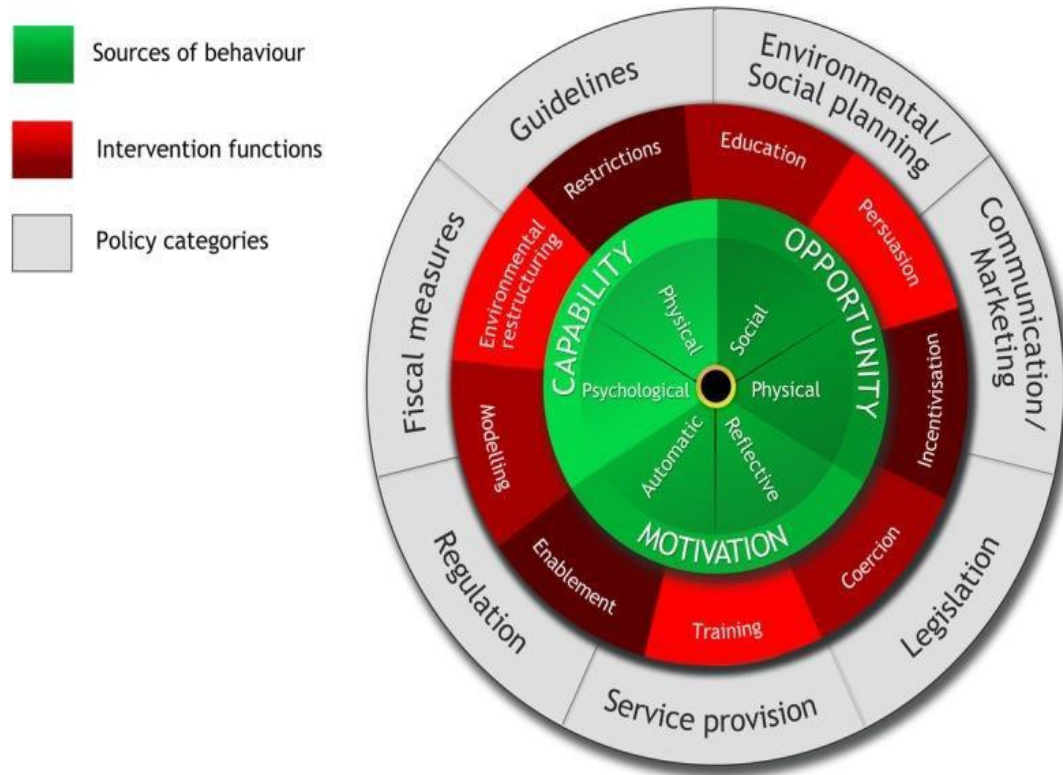
Figure 4: The COM-B system, a framework for understanding behaviour



Capability is classified as the individual's psychological and physical capacity to engage. For example, someone having the necessary knowledge and skills to do a behaviour would come under capacity. Motivation can be reflective motivation but also automatic motivation such as habitual processes and emotional responding. Opportunity is defined factors that lie outside the individual that make the behaviour possible or prompt it. These can be physical or social.

The behaviour change wheel links the COM-B behaviour theory to intervention functions, and policy categories. The behaviour change wheel is illustrated in Figure 5. The behaviour change wheel encourages designers to consider that behaviours do not occur in isolation, they are part of a system.

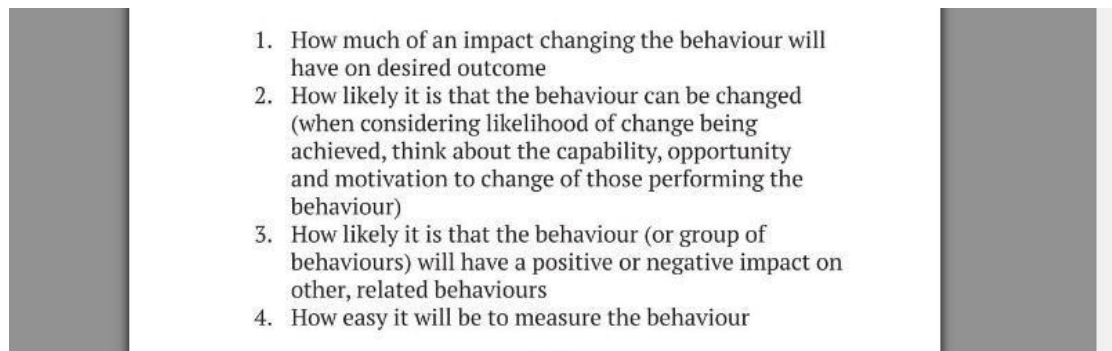
Figure 5: The Behaviour Change Wheel



The first step in the section of this thesis was to define the problem to be in behaviour terms. Following on from this the target behaviour to be addressed from the intervention was selected. To do this a long list of candidate target behaviours was generated. These behaviours were then prioritised based on criteria 1-4 (see Figure 6), and the most promising behaviours specified as the target behaviours. Then these target behaviours were further detailed e.g. who needs to do it, and when etc.

The next step was to identify what needs to change. To do this the COM-B section of the behaviour change wheel was used, with each aspect considered on how it may influence the target behaviour(s). Part of the behaviour change wheel method involves considering behaviours as within a system. To cause an increase in a behaviour does not only involve the promotion of specified behaviour, but also the consideration of potential inhibiting behaviours or goals which compete with the desired behaviour(s).

Figure 6: Criteria for prioritizing behaviours that could be targeted in an intervention

- 
1. How much of an impact changing the behaviour will have on desired outcome
 2. How likely it is that the behaviour can be changed (when considering likelihood of change being achieved, think about the capability, opportunity and motivation to change of those performing the behaviour)
 3. How likely it is that the behaviour (or group of behaviours) will have a positive or negative impact on other, related behaviours
 4. How easy it will be to measure the behaviour

Consideration was also given to alternative behaviours and goals that may be competing with the target behaviour at this stage.

Once it was identified which parts the COM-B framework were important to enable the behaviour change, work from Michie was used to map the COM-B frameworks to intervention functions, and therefore which function options could underpin the complex intervention design. This is shown in Table 6. Where a few intervention function options had been identified, the APEASE (affordability, practicality, effectiveness, acceptability, safety, equity) criteria was used to aid judgment on which intervention functions could underpin the intervention.

Table 6: Link between COM-B components and potential intervention functions taken from (Michie, van Stralen et al. 2011)

Aspect influencing behaviour	Potential Intervention functions
Capability – Psychological	Education, Environmental restructuring, Enablement, Modelling, Training
Capability – Physical	Training
Motivation – Reflective	Coercion, Education, Enablement, Modelling, Incentivisation, Persuasion
Motivation – Automatic	Coercion, Enablement, Environmental restructuring, Modelling, Incentivisation, Persuasion, Training
Opportunity – Social	Enablement, Environmental restructuring, Modelling, Training, Restriction,
Opportunity – Physical	Enablement, Environmental restructuring, Modelling, Restriction,

A step advocated by Michie et al. is to now consider what policy would support the behaviour change. This step was not taken in this thesis. This was because the focus of this thesis was on service provision, and other policy options would be outside of the scope of this study e.g. legislation or fiscal measures.

Following identification of intervention functions, the final stage was to identify potential content, based on established behaviour change techniques. Michie et al. have identified a long list of behaviour change techniques that can be considered for an intervention function (see Michie 2014). From this list behaviour change techniques were chosen, and these were used to define design parameters that would be worked with in the RtD stage.

3.8. Introduction to Research through Design

RtD is a research approach that is concerned with a design process. RtD formalises the design process as a research contribution (Zimmerman, Stolterman et al. 2010, Gaver 2012). In particular, RtD is a way of articulating knowledge gained through the process of designing an artefact (Gaver 2012). An artefact may be a physical prototype or a product that illustrates future visions or ideas, such as a process or protocol. RtD has a forward focused nature, looking at future preferred states, rather than research on 'what is' or 'what was'.

RtD has a long-established use in the field of Human-Computer Interaction (HCI), and is having an emerging use in other disciplines, such as healthcare, for example its use to generate knowledge about stroke recovery (Balaam, Egglestone et al. 2011). The use of design to generate knowledge may facilitate opportunities to learn about vulnerable groups, particularly allowing these groups to share their experiences in relation to design, while allowing them to withhold personal experiences if desired (Rennick- Egglestone, Knowles et al. 2016, Lindberg 2019).

Although RtD is a relatively underdeveloped approach outside of HCI, it holistically integrates knowledge and theories from across many disciplines (Zimmerman, Stolterman et al. 2010) suggesting its appropriateness for use in multidisciplinary research. It is used in this thesis to help guide the development and design aspect in developing a complex intervention. This is a novel use of this approach as it has not been used either in pharmacy disciplines, or in work relating to complex intervention development. Therefore, part of this work will evaluate the appropriateness of RtD as a design approach, and how well it integrates with MRC guidance on developing a complex intervention. This reflective discussion is presented in chapter 8.

RtD suits particular research problems. These are problems that, due to their complexity and multilevel connections, are intractable, and cannot be solved. The types of problems that are particularly amenable to investigation through RtD have been conceptualised and termed as wicked problems (Rittel and Webber 1973). Table 7 highlights ten key points that define Wicked Problems, as presented by Rittel and Webber et al. in 1973.

Table 7: Ten characteristic definitions of Wicked Problems. Adapted from Rittel and Webber et al. (Rittel and Webber 1973)

Wicked Problem conceptual characteristics:	
1	There is no definitive formulation of a wicked problem. Different approaches to the problem see it differently.
2	Wicked problems have no stopping rule.
3	Solutions to wicked problems are not true-or-false, but better or worse.
4	There is no immediate and no ultimate test of a solution to a wicked problem.
5	Every solution to a wicked problem is a “one-shot operation”; because there is no opportunity to learn by trial and error, every attempt counts significantly.
6	Wicked problems do not have an enumerable (or an exhaustively describable) set of potential solutions. (There is no comprehensive list of possible solutions.)
7	Every wicked problem is essentially unique
8	Every wicked problem can be considered to be a symptom of another problem.
9	The existence of a discrepancy representing a wicked problem can be explained in numerous ways. The choice of explanation determines the nature of the problem’s resolution.
10	The planner has no ‘right to be wrong’, i.e. there is no public tolerance of Initiatives or experiments that fail.

The definitions of these wicked problems originate from work based around building and town planning. Some terminology from Rittel and Webber may not be directly transferable to health and pharmacy research or disciplines (e.g. see point 10 and the terms planner and public tolerance). Yet as concepts, the ten points of a wicked problem are applicable to healthcare research, and the term ‘wicked problem’ has been used to describe healthcare problems (Schiefloe 2021), and healthcare interventions (Balaam, Egglestone et al. 2011).

The research question in this thesis seeks to answer how community pharmacy can improve support for men using antidepressants to treat depression, through a complex intervention

(including recovery-orientated outcomes). This is a wicked problem. There is no definitive solution, rather what is being sought in this thesis is to offer an improvement to a current situation. Therefore, RtD is appropriate for this research question, and through the process of design, research and knowledge will be produced.

The formalisation of the design stage as a legitimate research contribution produces different types of knowledge. The most obvious type of knowledge produced from RtD is the knowledge related to the designed artefact. This can be termed design knowledge. Choices and decisions made in designing the artefact, and the output is considered a research output in its own right.

Social and theoretical knowledge can also be produced in RtD. Through the process of designing an artefact social knowledge can be gained about the social environment, the problem, the context in which the artefact operates, and the practice of people interacting with the designs (Frauenberger, Good et al. 2015). RtD helps in eliciting insights that are difficult to communicate verbally (Sanders, 2012). Furthermore, because RtD is forward focused, it enables researchers to discover unanticipated future effects in relation to a specific problem space, context of use, and set of target users, which can also aid social knowledge.

A disadvantage of RtD is that there are no prescribed methods for RtD. This is problematic. Researchers should choose methods that are validated and will produce an output that meets the stated objectives. Without established methods it is more challenging to uphold high rigour standards.

A common method output in RtD is annotated portfolios. This is the documentation of decisions throughout the design process. It may also include examples of practice or design that illustrate more conceptual themes that might be important to the design (Gaver 2012, Kelliher and Byrne 2015).

Another established method used in RtD within the HCI discipline is 'Wizard of Oz'. This is about easy low-cost ways to test. An experimenter (the "wizard") simulates the behaviour of a computer room. For example, a test subject may think they are interacting within a computer program as their input is causing a response. However, it is the experimenter manipulating the system. As a concept this could also be applied to design outside of HCI. It is about creating low-cost prototypes that can be quickly adapted to understand how participants may act, or desire to act with a system.

Another way around the methods issue is to look to validated methods that still apply to the philosophy of RtD. Two such methods are 'Think-aloud' or the related 'Retrospective Thinking Aloud' (Boren and Ramey, 2000) which involves the participants voicing their internal thoughts as they do an activity or partake in a design, often utilising watching a video of the task for the retrospective think-aloud. This approach is suggested to reveal more issues than just assessing participants' reported perceptions (Anderson et al., 2012). Therefore, it will be a useful method to select.

3.9. Research through Design as a design approach in this thesis

This section discusses the methods used in the design inquiry section of this thesis. Prior to considering the design, design parameters were set. This was done based on work from the behaviour change wheel (chapter 6), and from knowledge about the theory and evidence base (chapter 2, 4, and 5).

Early design ideas were discussed as part of PPI, and within the research team. One of the members of the research team was a male with experience of depression, and this experience was used to help guide the intervention and consider design directions.

As part of the design stage male participants who had experience of stress were recruited to model out a potential protocol for a complex intervention, and to facilitate the design of this intervention.

'Wizard of Oz' techniques were used so that core functions of an iterative design could be experienced without the need to create workable prototypes or partake in any computer programming. This meant that any changes to design, or protocol could be quickly adapted and then re-trialled by participants within the design and modelling sessions, and feedback could be collected on designs within the session.

The retrospective think-aloud method was used, where participants watched back their interactions with various protocol designs. Their comments created part of an annotated portfolio, where design decisions could be tracked, and resulted in decisions made on the procedures and activities that would form part of the design for the complex intervention. This work is presented in chapter 6.

3.10. Ethical approval and considerations

Research ethics was obtained for the research presented in chapter 6 (School of Pharmacy ethics), 4 and 7 (NHS/ Health Research Authority via The Integrated Research Application System (IRAS)). Each chapter discusses the ethical considerations specific to each specific study. There are some overall ethical considerations that apply throughout all the studies, and these are discussed below.

This research captures sensitive data and information such as one's depression and medical treatments. It is important participants are briefed about this before participating in the study. In all research studies (chapter 4,6 and 7) potential participants were given a patient information sheet (PIS). These are included in appendix 5-7 for the respective studies. The PIS described to the potential participants what they may expect the study to involve. It also included a section asking potential participants to consider if such discussions may pose any risk to them, and asking them to consider their own personal boundaries on information sharing.

When devising interview schedules thought was taken to consider if questions were necessary for

the research question and study aims. For example when interviewing those with experience of depression questions were deliberately not asked around causes of depression, as this was not relevant for the study, and could be considered unethical to ask without a purpose. If participants volunteered such information then this could be discussed, and participants were reminded prior to interview that they did not need to discuss anything they did not want to.

Interviews can be demanding on participants. As highlighted in the methods, proactive considerations were made in the study design, as well as the researcher being sensitive and reactive to participants needs throughout the study, particularly so for any patients experiencing depression.

All participants were offered a debriefing after interview to discuss anything raised by the interview. There were also mental health signposting sheets available and an opportunity to receive a summary of findings following data analysis.

All information was treated with confidence throughout all study stages (recruitment, interview, data analysis and dissemination). All the research team endeavoured to protect the rights of the study's participants to privacy, and adhered to the Data Protection Act, 1998. To ensure confidentiality data management procedures were in place. Identifiable or confidential information was either stored as password protected documents if digital, or kept in a locked safe. Only personal data that was required for the management of the study was collected, and this was securely destroyed after 3 years (unless agreed otherwise). Pseudonyms were used while data was collected.

Participants were asked not to refer to any names of real people (i.e. doctors names etc.), and any real names were edited out of transcriptions. When a shared office was used headphones were worn for transcriptions, and phone calls were made in private rooms. For publications and dissemination only anonymous quotes were used.

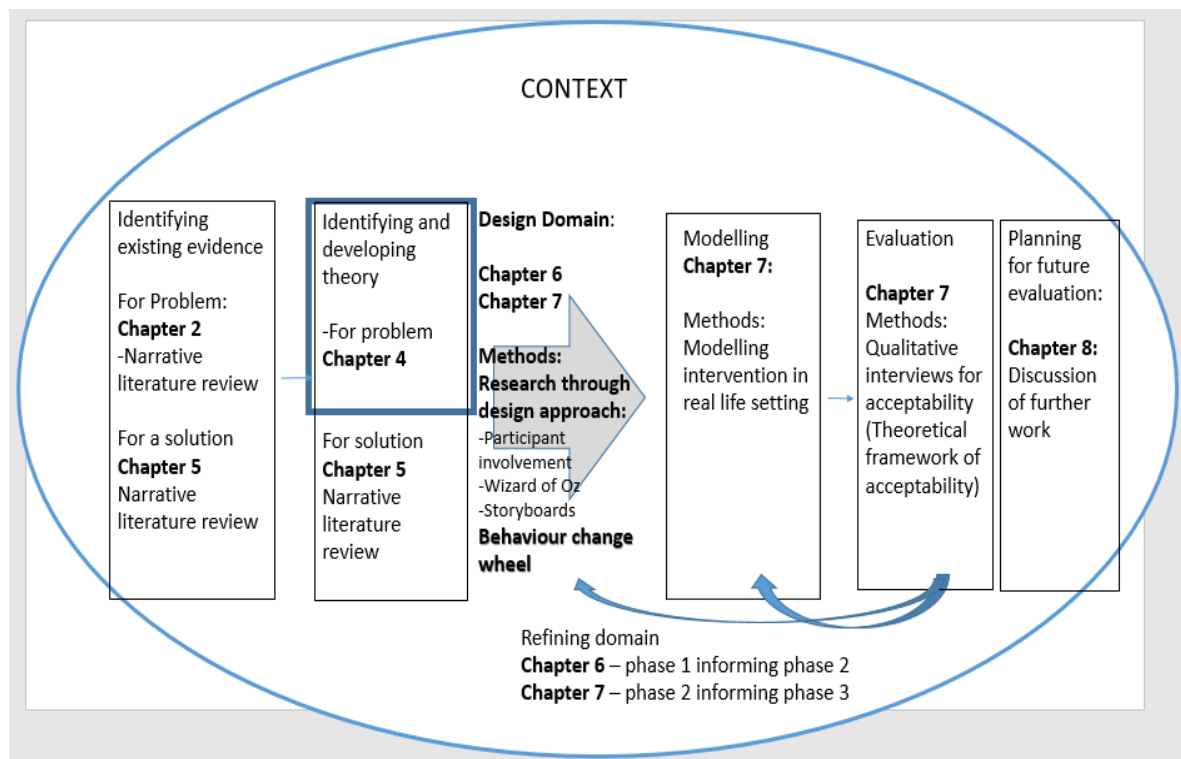
An exception to the confidentiality agreement was that the research teams were allowed to breach the confidentiality of a participant if they felt there was a concern, and would need to seek further professional support e.g. participant expressed suicidal intent, or if the well-being of another (dependent) led to safeguarding concerns. Participants signed and agreed to this exception in the PIS prior to participation.

Laptop computers, tablets and other mobile devices were only used for confidential information when research was conducted outside of the University of Nottingham. Any mobile devices were password protected, and any data recorded or stored was encrypted and the data uploaded onto a secure server or desktop as soon as possible, and then sensitive data was removed from portable devices using secure data destruction methods.

Chapter 4: A thematic analysis of qualitative interviews to explore men’s views of antidepressants for the treatment of their depression, and the role of community pharmacy in their treatment journey.

4.1. Introduction and aims

Figure 7: Introduction to chapter 4; highlighting the purpose, and situating it within the thesis schematic.



This chapter seeks to better understand the perspectives and experiences of men who are taking antidepressants in relation to their treatment, and the role of the pharmacist in their treatment. This is an under researched topic, and there is no coherently articulated theory for this area. This is problematic when seeking to use theory and evidence to construct an intervention as recommended by the MRC guidance. There is a need for further empirical work, and theory development prior to intervention development. Figure 7 highlights this, showing that chapter 4 is

about identifying and developing theory.

Further knowledge about the perspectives of men in this area can also be used for healthcare practitioners, to understand experiences from this populations perspective, and potentially contribute to better care and understanding.

The aims of chapter 4 are to:

- 1) Explore men's views around antidepressant treatment, including the influences of hegemonic masculinity.
- 2) Consider these men's perceptions of the community pharmacists' role in their antidepressant treatment.
- 3) Explore support and information needs for the men of interest, and generate ideas on directions for future interventions.
- 4) Consider what these findings from Aim 1-3 mean for community pharmacy practice, and opportunities for healthcare interventions.

4.2. Ethics and Methods

Ethics approval

UK Research Ethics Committee and University of Nottingham granted ethical approval [Ref: 17/EM/0264]. All participants signed a consent form and were offered a £10 voucher for participation. Pseudonyms were used. Participants agreed their confidentiality could be breached to access a professional (e.g. GP) if the research team had safeguarding concerns. See also chapter 3 where overall ethical considerations are discussed.

Method

This qualitative study has been designed and reported in line with SRQR guidelines (appendix 2).

Initial Engagement and Piloting.

An initial patient-public engagement session took place, where the researcher (thesis author) spoke to four men about the study. Three of these men had been prescribed antidepressants (one currently taking) and the fourth identified as suffering from stress. This session helped with exploring the aims and potential methods of the study.

Recruitment was also discussed, and these discussions influenced the decision to use multiple

recruitment methods, and convenience sampling (discussed further in recruitment section).

Two of these men, and an additional male without depression then also took part in a field-testing of the interview schedule.

A brief interview schedule was developed to address identified gaps in the literature. Key topics were around men's views of antidepressants, experiences of community pharmacy, insights into unmet care needs and potential improvements. The interview schedule was piloted prior to use. This involved internal testing with two researchers experienced in qualitative methods, and field-testing with three males, two of whom had past experience of taking antidepressants to treat depression. Based on the piloting some changes were made. Firstly, a standardised opening question was used to establish an understanding on participant's antidepressant history, and to ease participants into the interview. Secondly, the word 'intervention' was replaced with 'service' as 'intervention' was a word that carried connotations of a paternalistic style of healthcare relationship. 'Service' however was felt by all to be a more neutral term. A second change made to the interview schedule was to add a question to ensure a shared understanding between participants and interviewer on the definition of 'community pharmacist'.

Participants Eligibility

The inclusion and exclusion criteria are highlighted in Table 8. Males under 18 years were excluded since this age range has unique antidepressant prescribing guidance due to different pharmacokinetics and treatment risk (BNF 2021). Those over 65 years were excluded since depression in the elderly can be influenced by factors related to ageing (Büchtemann, Luppá et al. 2012), and this was not the focus of this study. It also meant that the age range represented a working population, which could have benefits for future work, relating to costings of the intervention design. Participants with diagnosed schizophrenia, psychosis or dementia were excluded.

Recruitment

Fourteen participants were recruited in total. Convenience sampling was used for recruitment. Recruitment (and interviews) occurred from August 2017–November 2018. This was before the COVID-19 epidemic and the implications of this are discussed further in chapter 8.

Table 8: Inclusion and Exclusion Criteria for study.

Inclusion criteria	Exclusion criteria
Male*	Female
Aged 18-65 years	
Prescribed an antidepressant to treat unipolar depression ⁺	Patients with bipolar depression, dementia and/or psychosis.
Fluent in English (written and oral)	
Agree to protocol and sign consent form.	Have a mental or physical illness or disability that means their participation in the research project is not appropriate ⁺⁺
⁺ Those born as male sex and currently identify as being male. ⁺⁺ Those prescribed antidepressant to treat anxiety or obsessive compulsive disorder with associated depression are still eligible	⁺⁺ Decision on what 'appropriate' means is made between the research team and the potential participant, although the research team will make the final decision

Recruitment occurred via poster recruitment either at a UK University (two participants), or at five participating UK community pharmacies (three participants), or by the community pharmacists in these branches identifying and approaching eligible participants who presented in the pharmacy (nine participants). Pharmacists were able to identify eligible participants by the use of the pharmacy medication record. This is a legal record of all medications that the pharmacy has supplied for a particular patient. The pharmacy medication record does not state what participants are prescribed medication for, therefore the pharmacist needed to clarify with potential participants what they are taking their medication for when not clear (i.e. some antidepressants can be prescribed for other conditions). Following the identification of eligible participants, the pharmacist explained the study to the participant who could leave their contact details if they were interested in taking part. These recruitment discussions occurred in private areas, such as the community pharmacy consultation rooms. For all participants recruited a subsequent discussion was held with a researcher prior to participation to confirm they met inclusion criteria and they understood the study. Written informed consent was obtained on the day of the interview.

Recruitment occurred until data saturation. In qualitative research there are no calculations to

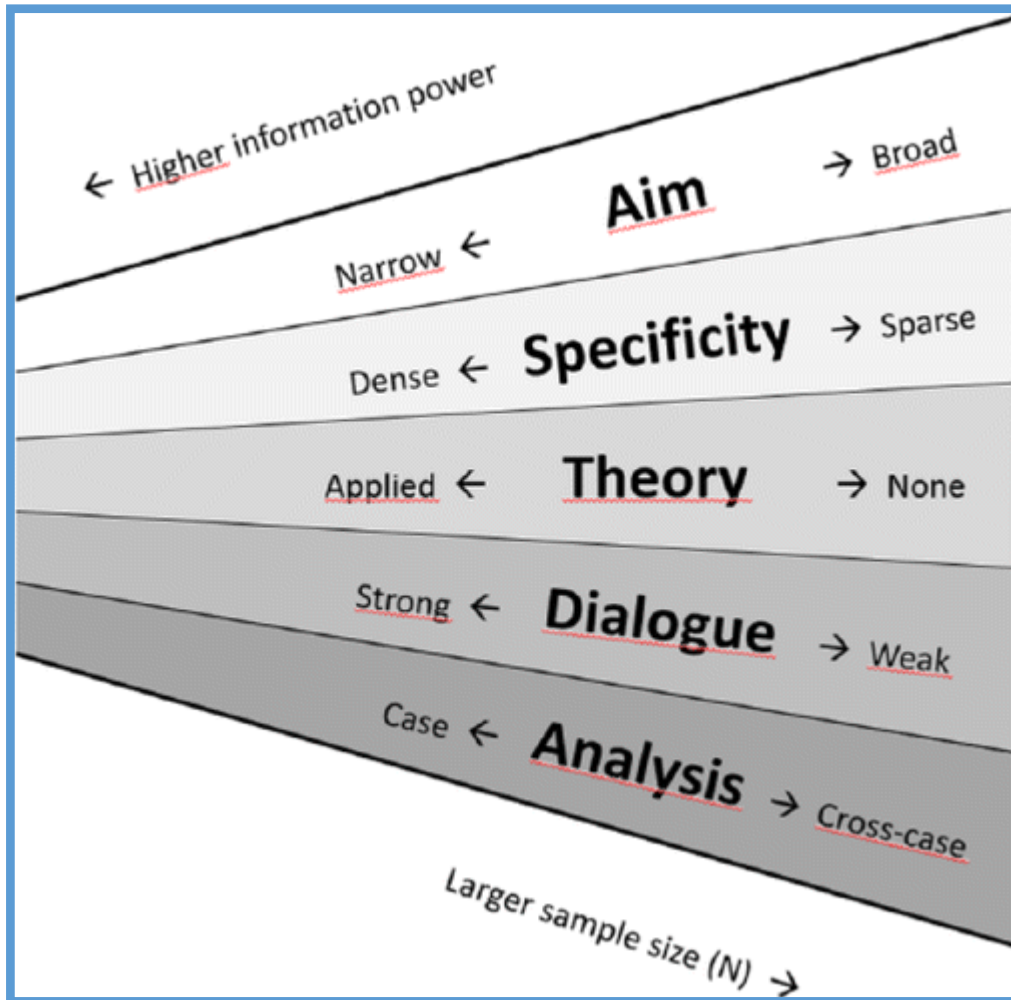
calculate sample size, as would be the case in quantitative research. This is because qualitative research does not require participants to be a representative sample of the norm. Instead data saturation is an important concept. This is when no new themes are coming from the data. It is hard to prospectively plan or state when data saturation will occur and is best determined iteratively. In this study recruitment and data analysis occurred consecutively, and data saturation was determined when the last two interviews produced no new themes.

Information power (see Malterud et al. 2016) was also considered to 'sense check' if data saturation was likely to have occurred. The key components of this concept are highlighted in Figure 8.

Fourteen participants were recruited in total before data saturation, and this was sense checked prior to stopping recruitment. A relatively small number of participants could reach data saturation because the study has a fairly narrow aim, and participants hold specific knowledge and experiences relevant for this aim. This also follows through to the specificity of this study being relatively dense, due to the participants' experiences.

There is some applied theory (unlike other qualitative approaches such as grounded theory, where there is no applied theory and typically do require high number of participants for data saturation). In terms of the strength of dialogue, as in-depth semi structured interviews were being used, resulting in-depth dialogue, the dialogue was strong.

Figure 8 : Information power and the components. Taken from (Malterud, Siersma et al. 2016)



Finally the study is interested in thematic analysis of narratives from selected participants, rather than a cross-case analysis. Therefore overall it is likely each interview will hold high information power, and fewer participants would be needed for data saturation. Fourteen participants seemed reasonable for data saturation to have occurred and passed the 'sense-check'.

Some potential participants who were approached did not take part in the study. Seven participants were approached but did not take part in the study (making twenty-one men approached in total). Two of these participants declined to take part at the initial discussion stage with the pharmacist. This was either due to lack of time, or lack of interest in the study. Three participants showed initial interest, and supplied contact details (all emails), but could not be further contacted. A policy was set that if a participant could not be contacted, then an additional attempt should be made, but then after this the potential participant should not be further

contacted. This was to get a balance between managing recruitment (e.g. participant may have forgotten to reply, or not have had time) and not overburdening the potential participant (e.g. participant may deliberately not reply as does not want to take part, or may interpret multiple emails negatively). Two participants agreed to an interview date, but did not end up taking part in the study. In one case the participant withdrew on the interview day stating it was not something they felt they could do due to their depression. For the other participant, the researcher had to cancel the appointment with them due to researcher's illness and another suitable time could not be found. It is not known how many eligible participants saw the poster and did not take part.

Participants that were recruited from the pharmacies were invited to take part in a linked study (discussed in chapter 7). They were aware of both studies at the time of recruitment. They did not have to take part in both studies, although all those that were contacted showed interest in partaking in both phases.

Data collection

The method for data collection was individual semi-structured audio recorded interviews. Interviews ranged from 39 to 71 min. The mean duration was 56 min. All interviews were conducted by the same female researcher (SB) who was a qualified pharmacist. This researcher had received extensive training on interviewing prior to conducting the interviews. The participants were briefed that the interviewer was a pharmacist, however she was introduced to participants as a 'researcher'.

All interviews occurred in a private and quiet room with only the researcher and the interviewee present. All interviews were conducted when other people were present in the building (in other rooms) to avoid lone working. Participants were advised they could request a break or stop the interview at any time. Two participants stopped the interview. One was due to time constraints, and one was due to interview fatigue (this participant had only been taking antidepressants for a week). Both participants suggested and partook in a follow up interview within that week to complete the interview.

Interview analysis

Interviews were transcribed and analysed using thematic analysis (e.g. see Braun and Clarke 2006). As discussed in chapter 3, a hybrid approach was taken to coding. Predominantly data was coded inductively, however 'hegemonic masculinity' and 'Stigma' were coded deductively. This approach complemented the research aims. It allowed an exploratory, data led approach. This was particularly useful for aim 2 where little research had been done previously. Yet as discussed in chapter 2, stigma and hegemonic masculinity are known socially constructed concepts that may be influential in this population and context. The use of deductive coding also allowed this to be integrated into the data analysis. Eight (out of fourteen) participants completed the member checking.

4.3. Results and Thematic analysis; generating themes and presenting participant characteristics.

Fourteen males aged 26-61 years were recruited. Table 9 highlights participant demographics. Nine out of fourteen participants had used antidepressants for more than one year, five for less than one year, and of those five, three had prior episodes of depression treated with antidepressants. The men had a mix of employment and relationship status, yet were predominantly aged 40-60 years and Caucasian.

From the coding, a candidate set of super-ordinate categories and sub-themes were created. These were reviewed and further refined by the research team and resulted in five defined themes. The themes were 'Antidepressant's attributions to benefits' , 'Views of pharmacist's role influences engagement', 'Reflection of support and information needs', 'Hegemonic masculinity and taking antidepressant' and 'Influence of cognitive state' .

These are further discussed in the next section, beginning with Figure 9 highlighting how themes relate to each other. There is a hierarchy of themes in terms of their utility in use for the future intervention with the most useful highlighted in bold, and the hierarchy further illustrated in Figure 10.

Table 9: Characteristics of Participants. KEY: AD = Antidepressant.

Participant ID	Age (years)	Length of AD treatment for current episode.	Used ADs before?	Prior episodes treated with ADs?	Ethnicity	Employment status	Relationship status.	Sexuality
P1	59	8 months	No*	No *	White	Unemployed	Divorced/Single	Heterosexual
P2	58	20 years	Yes	No+	White	Unemployed	Divorced/Single	Heterosexual
P3	46	2.5 years	Yes	Yes	White	Unemployed	Divorced/unknown	Heterosexual
P4	61	11 months	Yes	Yes	White	Retired	Married	Heterosexual
P5	41	6-7 years	Yes	Yes	White	Unemployed	Divorced/unknown	Heterosexual
P6	40	11 months	Yes	Yes	White	?- Paternity leave	Married	Heterosexual
P7	41	10-15 years	Yes	No+	White	Employed	Unknown	Homosexual
P8	43	8-9 years	No	N/A	White	Employed	Married	Heterosexual
P9	59	6-7 years	No	N/A	White	Employed	Married	Heterosexual
P10	59	4-5 years	Yes	No+	White	Employed	Married	Heterosexual
P11	51	1-2 weeks	No	N/A	White	Unemployed	Single	Heterosexual
P12	60	4-5 months	Yes	Yes	White	Employed	Married	Heterosexual
P13	40	1.5 years	Yes	Yes	White	Self- employed	Married	Heterosexual
P14	26	2 years	No	N/A	White-ethnic	Employed	Married	Heterosexual

4.4. Thematic analysis of results discussed; five defined themes.

Figure 9: Hub and Spoke model showing how themes connect, and a hierarchy theme (demonstrated by bold font).

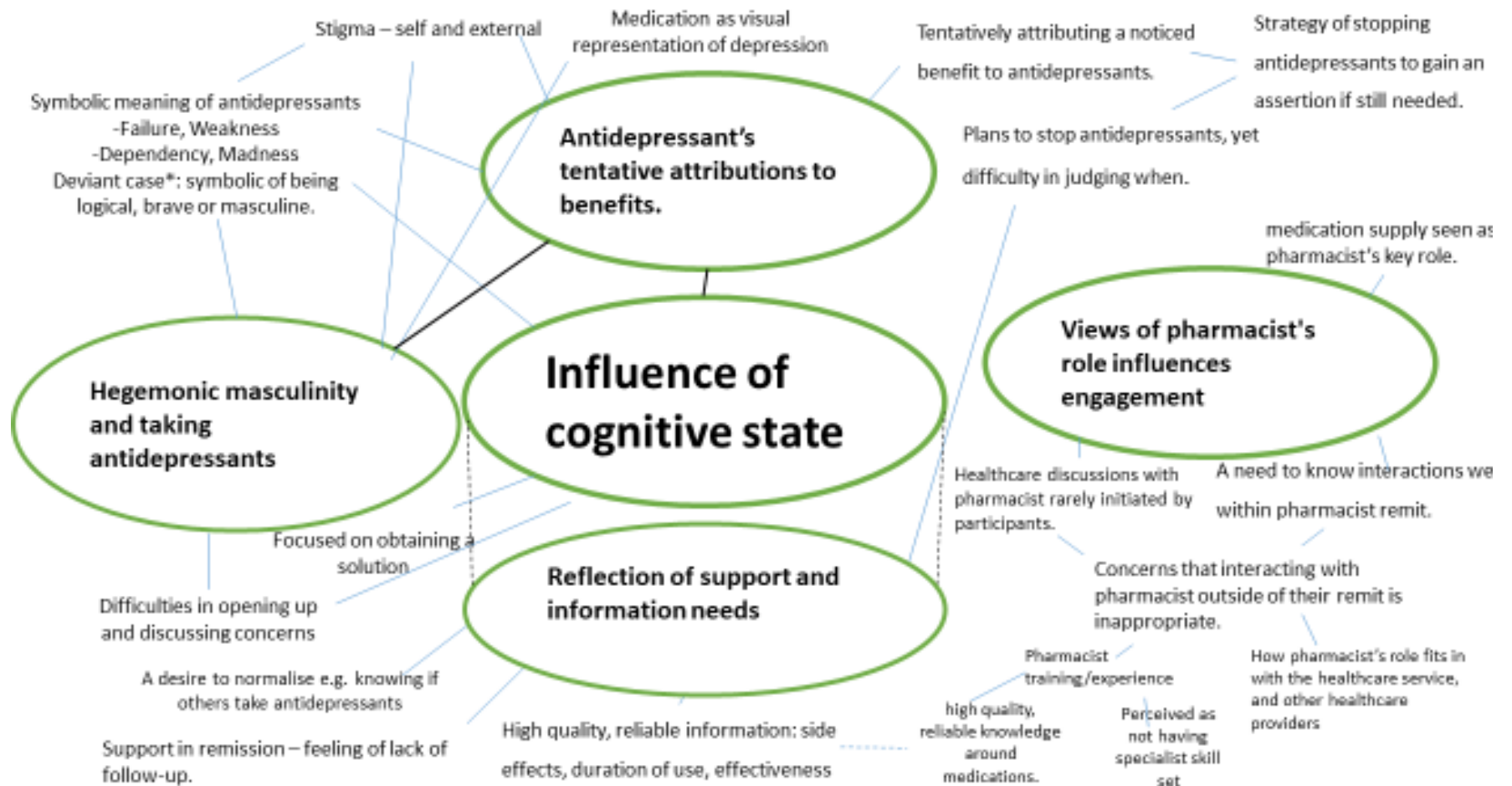
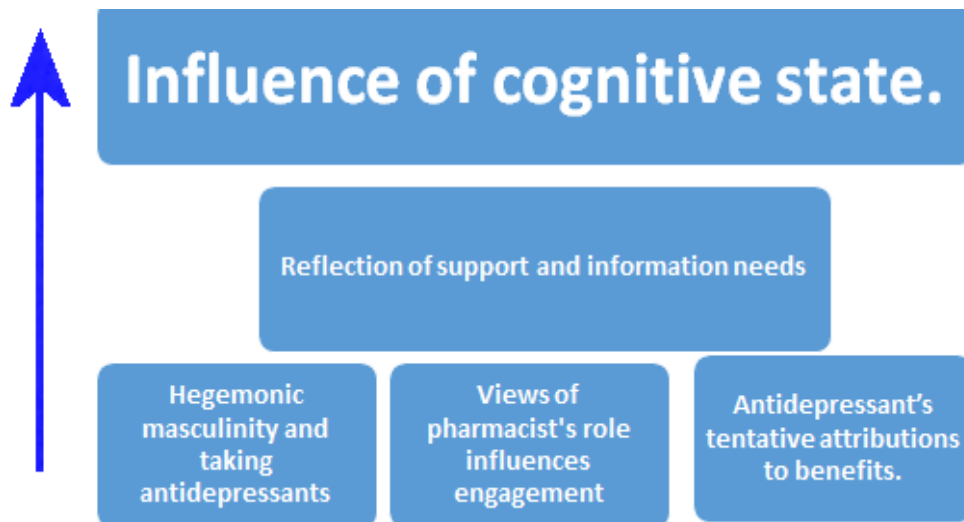


Figure 9 shows the themes and subthemes that emerged from the qualitative work, and how they relate to each other. Both Figure 9 and 10 demonstrate a hierarchy of the themes in terms of the importance to the knowledge emerging, the strength of that knowledge and the utility of the intervention being developed. The influence of cognitive state was the most influential theme in terms of justifying the need for an intervention, and how without an intervention potentially men may not engage in seeking support or help, despite them having information and support needs. This is elaborated on further in the results and discussion below.

Figure 10: Hierarchy of themes in terms of importance.

Hierarchy of themes in terms of importance to the knowledge emerging (i.e. the strength of that knowledge and the utility of the intervention being developed.) The direction of the arrow illustrates the hierarchy.



Antidepressants: attributions to benefits.

All of the men in this study identified an improvement in their functioning when taking their current antidepressants.

P7: "Those really dark, horrible, awful thoughts. I have considerably less when taking the medication"

These improvements enabled them to function in desired roles such as being a father, a partner, or breadwinner.

P10: "The benefits was trying to dampen down the anxiety so I could process properly with my son."

Yet there was uncertainty about what extent these benefits were attributable to antidepressants. Some held tentative views upon antidepressant benefits to protect themselves, not having belief in their biochemical effect.

P2: " It might all go back to the fact that I've never given it enough credit for what the medication has done for me really, but I'm sort of scared, all this, you know, you get it in the news. 'Citalopram does not work anymore' [P2 makes a gasping sound]."

For others, a lack of objective proof on what effect the medication was having caused them to have doubts on medications benefits. They held these doubts throughout the treatment.

P1: "I would like to think, and I'm sure it is, that the tablets must've been kicking in that gave me the motivation to go out and go running, but I don't know you see that's it. I don't know if it was."

Most men tolerated this uncertainty. It however became problematic when they were considering stopping. Some men stopped antidepressants to ascertain if they could function without them.

Researcher: “ What was your reasoning for weaning yourself off?”

P10: “Because I thought that... I'm not a great fan of taking medication that is not necessary and the only way to know if it is not necessary...”

Many men had unsuccessful withdrawal attempts. They spoke of suddenly feeling “flat” or “awful” and feeling they must restart antidepressants. They were then unsure how to explain their unsuccessful withdrawals, potentially attributing it to placebo effects.

These experiences made men more cautious about stopping antidepressants, yet they still reported desiring to do so at some point.

P8: “I never know if I can wean myself off or whether I should stay on the level I am on, but to me I have tried to reduce the amount before and I felt shaky and nervous, whether that is placebo effect or not I do not know.”

Some men sought a discussion with a healthcare professional to ascertain if the dose and/or the continuation of antidepressants was appropriate. If they had not had such a review, this led to feelings such as being “lost in the system”, “drifting along” or being on their own.

Views of community pharmacists' role influences engagement.

Medication supply was seen by most participants as community pharmacists' key role in their depression treatment. Most accounts highlighted community pharmacists' dispensing role, and occasions when community pharmacists had taken action to ensure participants had medicines, e.g. an emergency supply. There were some accounts of community pharmacists counselling and supporting participants, which in turn increased participant's confidence in their treatment.

P11: “(the pharmacist) said you will probably see some improvements after a few weeks [...] If somebody encourages me, they say this will help you; people who know what they are talking about like the pharmacist and the doctor, I do listen to people.”

Yet mainly interactions with community pharmacists were sparse and most participants had not sought-out advice from community pharmacists.

P10: “They are just basically a dispenser and it is usually the assistant that hands it out. The pharmacist you tend never to talk to.”

Researcher: “Ah-huh.”

P10: “I have never sought to talk to the pharmacist about it.”

These participants did not express dissatisfaction with community pharmacists input in their treatment journey. Yet two participants, both who had a vocational association with the profession, felt more support could have been offered from community pharmacists.

P14: “ It just would have felt nice that someone would have concerned themselves with me [...] It seemed like a very closed interaction.”

Some reflected how not understanding the potential role of the community pharmacists stopped them from discussing concerns because they were not aware of the option.

This was confounded by how they were feeling in their depressed state, being inclined to keep things in, particularly when they had not previously established a clinical relationship

with the community pharmacists.

P6: “ It would be really difficult to convince me to have a chat with the pharmacist. Partly because I did not understand their role, partly because of the mind-set at that point in time. I guess I have always had a good relationship with my GP and I did not with my pharmacist back then.”

The physical environment and staff resources were also barriers to sensitive discussions.

P13: “There is a till and you talk to someone and everyone’s there [...] you can't really say anything discreetly [...] also I would want to know that they have the time. If I can see that there is ten people in the queue I am not going to feel like I can have a 10 minute conversation with them.”

If community pharmacists proactively suggested interactions it was felt this could facilitate engagement, yet participants would need to know community pharmacists had appropriate expertise, resources, and that interacting with the community pharmacists was in line with collaborative care. One participant (P2) linked interacting with community pharmacists as “going behind the GP’s back” believing instead their role in the NHS model of care system was to supply medication. Alternatively another participant (P4) referenced how the pharmacy was being advertised as a healthcare resource to utilise, and used that as a justification for engagement. It was also noted in the interviews how often participants made comparisons to the GP when asked questions around the community pharmacists.

Reflection of support and information needs.

Participants spoke about needs to normalise taking antidepressants and contextualising information such as wanting to know if their dose was high or low, and therefore what this said about their condition. They also wanted support to critically interpret information from the patient information leaflet and the internet, and to understand any adverse drug reactions that would be likely based on their dose.

P8: “An awareness of the side effects would've been more useful. I was not aware how clouded my mind would become when I was on a high dosage, that might've been a bit more useful.”

Participants felt the accessibility of the community pharmacists, and their knowledge and skill set, meant they could help them with these medication support and information needs. Participants also reflected upon struggles with coming off antidepressants, and mismatched expectations of treatment duration, some initially viewing it as a 'quick fix'.

P2: “How long do I have to be on them? That's the one that's the biggest one, I haven't even mentioned that, that's the big one. I am still on them. Researcher: Am I right that you did not think to ask that when you first started?”

P2: “No, I was just like give me something that will make it better, something that will quick fix please, and it's 12 years later 'yes quick fix', nope.”

P2s quotes show how some men were not aware of some of their information needs, or assumptions at the start of the treatment, and it was only through reflecting on their lived experiences were they able to share insights that may have benefited them at the start of their treatment.

During the interview participants were asked about service ideas or support pharmacies could offer. Most struggled to suggest developed ideas. Predominantly, ideas focused around improving healthcare access such as hosting talking therapies or peer support groups at the pharmacy, and this was linked to how easily extra steps to engagement became barriers.

P14: “ I was signposted to a counselling service or a therapy service, and I had to phone them, book an appointment, whereas if a doctor or a pharmacist has the opportunity to just do that for me then it would have joined it up better. [...] it's very easy to find an excuse not to engage.”

There was a desire for community pharmacists to be another point of contact, being able

to triage men who are struggling, and this was linked to reflections that asking for help could be difficult. Some mentioned gender sensitive training or services, as there was an awareness that men could perceive threats to masculinity due to depression. However, equally men did not want to be patronised or stereotyped.

Hegemonic masculinity and taking antidepressants.

Antidepressants causing benefits was, for some, an assertion that they had not solved their depression themselves. For them it symbolised a weakness, failure, madness, or dependence upon something.

P14: "You feel a bit mad, you know you have been given these drugs you are told you are mad."

Researcher: "Ah-huh."

P14: "Well the doctor hasn't said that. "

Researcher: "No, no."

P14: "But it is symbolic of that."

And

P13: " You feel you need something just to get by. I think it feels like a failure."

These feelings could be problematic with one's masculinity.

P10: "Maybe it is a male thing about the perceived strength... I do not need this because I am a male."

Yet for others taking antidepressants could be seen as a logical approach, symbolic of taking ownership to solve problems. One participant symbolised his masculinity by positioning men not taking prescribed antidepressants as not being masculine.

P3: " I was going to say 'a big...big girls blouse' well yes stop being a big girls blouse, and basically pull your finger out and take it."

Influences of masculinity could cause challenges in healthcare interactions. When P9 is asked about his views about being approached by the community pharmacists to discuss medication he perceives a potential threat to his masculinity.

P9: "I don't know. I honestly could not say because is there a maybe a little bit of stigma attached 'oh this bloke has got antidepressants'."

Some men were not used to opening up about their feelings. This caused barriers to discussions around depression treatment and concerns.

Researcher: "Linked to your concerns [about taking antidepressants], where those concerns you felt that you could ask as a question?"

P6: "To the pharmacist? Researcher: To anyone. Yeah no."

Researcher: "Ah-huh."

P6: "Definitely."

Researcher: "Can you describe why that was?"

P6: "I suspect it was partly a gender thing, although I do not want to generalise too much. I did feel quite isolated as a man and that men do not really talk about it."

Influence of cognitive state.

At the point of first being prescribed antidepressants, the men spoke of being focused on obtaining a solution to their depression. Underlying this focus was a desperation; a feeling they had no choice but to seek treatment. The men explained that their impaired cognitive state hindered approaches such as gathering information, deliberation, or exploring concerns relating to antidepressants.

Researcher: "You have not used them before, was there any concerns about taking them?"

P5: "I did not even think about it. Researcher: Did not think about it. Ah-huh."

P5: "Because I did not... I did not feel normal at all."

Exploring concerns could also be seen as counterintuitive to obtaining a solution.

P2: "I think I was of a state where I was like just give me something. I am not going to start quibbling."

One participant presented an analogy to illustrate difficulties in mind-set when one has impaired mental health. He suggests that, when depressed, one may not make rational, engaged choices; yet when in a healthier mind one may have more purposeful engagement with treatment once that treatment has shown to facilitate recovery.

P3: "Well when you are depressed it is a bit like being dehydrated, the last thing you want to do is drink water when you are dehydrated, but then when you start drinking the water you get the taste for it and then you force it down, eventually start to get thirsty and you want to drink water and then obviously become rehydrated again, it is kind of similar."

Participants spoke of frustration when their initial strategy to take the antidepressants did not result in quick recovery. This led to feelings of being alone, frustration with the prescriber, the manufacturers of the medicine, and disbelief in the treatment strategy. Few felt able to express these concerns, instead presenting a front.

P12: "The thing with antidepressants is they're not quick enough...Every time they said to me 'are you going to kill yourself?' So I thought I'll say no but it's a bit of a cop-out because you go around the corner and you think, God I feel awful today. I really feel horrible today, and I'll wait till everybody's gone to work and then I'll do what I do."

4.5. Discussion

Discussion for aim 1 and 2

This study is the first study to give salient voice to men's reflections on how their condition impaired gathering of information, and a decision making process. This is particularly highlighted in the theme 'influence of cognitive state'. At the point of antidepressant initiation, a primary drive for the men was to obtain a solution to their depression. This was their focus. They were not giving cognitive space to explore concerns or beliefs when first prescribed antidepressants. They were not seeking to deliberate and gather information. In some cases such an approach was likened to being a barrier to obtaining antidepressants, and obtaining a solution.

It is known depression can hinder decision making ability, particularly by impairing deliberation and appreciation of information (Hindmarch, Hotopf et al. 2013). Despair as a phenomenon has been connected to impaired engagement and information gathering in patients with mental illness (Rennick-Egglestone, Knowles et al. 2016). Those with depression have also shown to have impaired functioning on effortful attention related tasks (Hammar and Årdal 2009, Hasselbalch, Knorr et al. 2011).

While these findings are not gender specific, the theme of 'influence of cognitive state upon healthcare interactions' may be particularly pertinent for men. Many men suffering from depression present to healthcare professionals at the point of desperation and despair (Brownhill, Wilhelm et al. 2005). This pattern has been linked to hegemonic masculinity, where men advocate stoicism or solving depression themselves first, and delay help-seeking until a point of despair (Rochlen, Paterniti et al. 2010, Seidler, Dawes et al. 2016). This theme also found participants spoke about how they were inclined to keep concerns in check, and were not used to discussing their mental health. Previous studies have found that men may be less articulate than women when depressed (Emslie, Ridge et al. 2007, Ridge, Emslie et al. 2011, Ramirez and Badger 2014). This is echoed in the theme 'Hegemonic masculinity and taking antidepressants', where some participants felt, due to their gender, that they were not used to opening up and talking about issues.

Yet, when bringing in the findings from 'information and support needs' it can be shown that men did have unmet support needs. Additionally men, when taking antidepressants, may hold negative or factually incorrect views around antidepressants, and these men were not seeking to verify their beliefs or discuss concerns, but when retrospectively discussing these they reflected that this was problematic.

Key initial support and information needs were predominantly around normalising the condition and contextualising their treatment. Men wanted to know what their prescribed dose meant in relation to their condition and how it compared to others.

Some men in this study showed self-stigmatising beliefs in relation to the diagnosis of

depression, or taking the medication, or both. Other studies also shown men can self-stigmatise for taking antidepressants (Chakraborty, Avasthi et al. 2009, Latalova, Kamaradova et al. 2014) and may undergo a meaning making process, involving cognitive realignment on what it means to take antidepressants. It may be that men need supporting in this process.

As well as support and information when starting antidepressants, men also highlighted a need for staggered support over time. In particular men wanted active monitoring of their treatment plan, for example discussing if the dose, and/or continuation of therapy was required. There was a view of being “lost in the system” once stabilised on the medication. Men struggled to know when to stop their antidepressants, a finding also shown in mixed-sex studies (Maund, Dewar-Haggart et al. 2019). This finding is linked to uncertainty on the extent antidepressants were causing noticed benefits, and initial unrealistic views of treatment duration. These initial unrealistic views could go unchallenged as men, due to their cognitive state, were not seeking to verify beliefs.

There were support and information needs highlighted around withdrawal. Those who had had unsuccessful withdrawal did not know how to explain their experiences, and many proposed a placebo effect. Evidence from a 2019 systematic review suggests withdrawal effects are underestimated in clinical guidelines, and more than half of people who attempt to come off antidepressants experience withdrawal effects, and for nearly half of those the reaction will be severe (Davies and Read 2019). Unsuccessful withdrawal attempts made men more cautious about stopping antidepressants in the future, even if they still desired to do so. This also links into the theme of ‘Antidepressant's attributions to benefits’, where most men felt they could not objectively determine if the antidepressants (as pharmacological agents) were causing a noticed beneficial effect on their mood. For some men, this difficulty in evaluating the antidepressants pharmacological effects, and the lack of active monitoring by healthcare professionals led to self-initiated antidepressant withdrawal to ascertain if they still needed the medication. Therefore, information and support at various time points to address issues such as antidepressants duration and withdrawal would be important.

Men spoke about barriers to community pharmacy interactions. Some barriers found in this study have already been shown in other literature, such as the physical set up of a pharmacy causing privacy concerns (Murphy, Martin-Misener et al. 2016) which was linked to stigma, and concern of antidepressants signifying meaning to others.

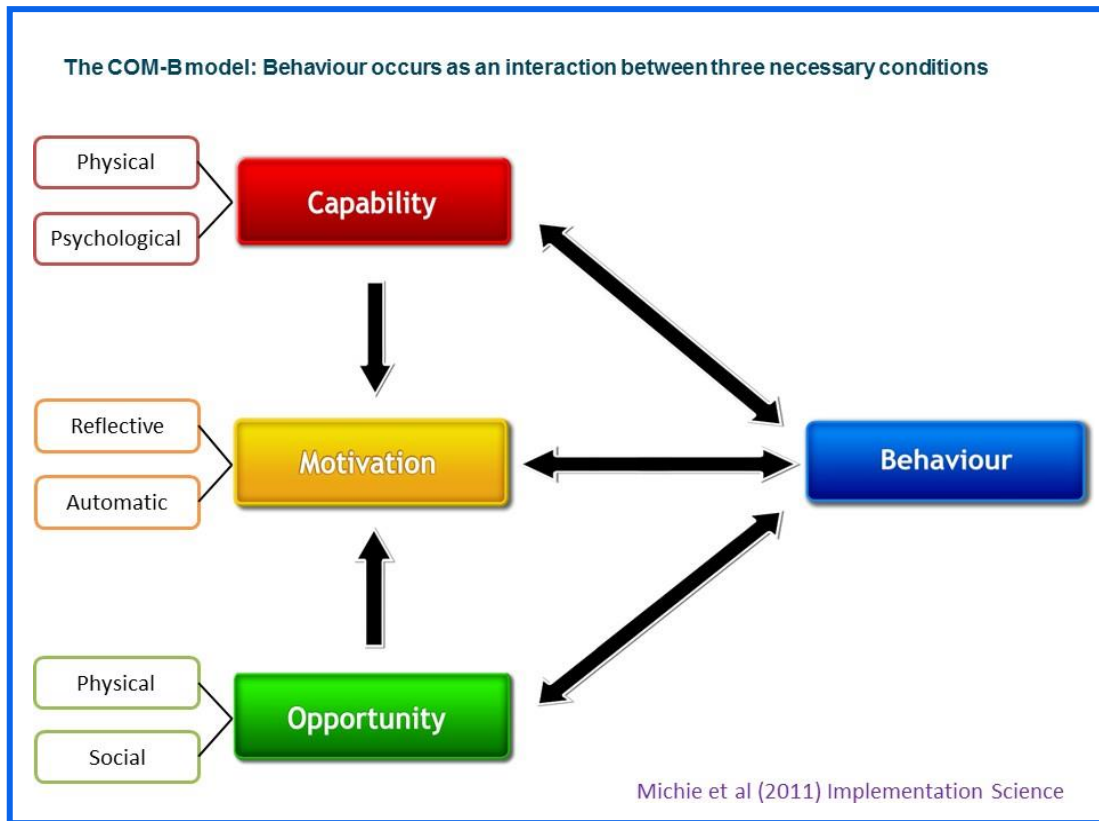
An interesting finding was the need for participants to know as a requisite for engagement, that they were interacting within the community pharmacists' scope of practice and competency, and as part of the wider NHS strategy of care. This makes the finding that participants saw the role of the community pharmacists predominantly as a supplier of medicines all the more pertinent, creating a barrier for unsolicited engagement. Particularly concerning was that participants could liken turning to community pharmacists for advice as “going behind the GP's back”.

Applying the COM-B model to findings (aim 2 and 3)

The discussions and results above have helped generate an increased level of understanding in men's views of their depression treatment, and the community pharmacist's role in their journey, as well as information needs. This has been put in the context of what is already known in the field. For this next section it will be useful to map these findings to the COM-B model. This will help with the chapter's aims, particularly aim 2 and aim 3. For aim 2 applying a behaviour theory to findings may lead to a more explicit articulation of the findings. For aim 3 the use of the COM-B model is particularly helpful. This is because for aim 3, the purpose of this chapter is to help with the development of a complex intervention. As discussed, using theory to underpin an intervention may result in better intervention design. The COM-B theory is the underlying theory used in the behaviour change wheel. This will feature in chapter 6 to identify potential intervention functions for a complex intervention design. Therefore the use of the COM-B model helps align findings with theory, and in doing so can then be used to further develop an intervention, in line with MRC guidance.

The COM-B model is re-highlighted below and demonstrates how capability, motivation, and opportunity can influence a behaviour. In this case, behaviour would relate to discussing information needs and medical concerns with the community pharmacists. Men who are taking antidepressants do have unmet information and support needs, and as argued in chapter 2, community pharmacists have a skill set that could be utilised to support here. As this domain of the thesis is seeking to develop theory of the problem, the specific behaviour would be problem focused. Therefore the 'problem' behaviour is men, who are treating depression with antidepressants, not discussing concerns, beliefs or information needs with the pharmacist. (For simplicity this will be referred to as the 'behaviour').

Figure 11: COM-B model Taken from (Michie, van Stralen et al. 2011)



It is important to clarify that this thesis is not saying men not talking to their pharmacist about treatment concerns is a problem, but what is being argued is that this could potentially result in a problem and changing this behaviour may potentially result in a more positive outcome for men in this population.

In terms of capability, as discussed in the theme 'influence of cognitive state upon healthcare interactions', psychological capability is important. Men may not seek to engage with the community pharmacists and ask questions around their medication because in their state of depression they are not thinking to do this. This is further compounded by the finding that men tend to delay help-seeking till crisis point. Men are also less articulate in their depression compared to women.

Both physical and social opportunity influenced the behaviour. In terms of physical opportunity, a lack of privacy, and perceiving the pharmacist to be busy were barriers. In terms of social opportunity, the community pharmacist was viewed as a supplier of medication, rather than someone to discuss concerns with. Therefore men did not have that social drive to trigger discussions with the community pharmacists. Some felt the onus was on the pharmacist to initiate discussions. Discussions with the community pharmacists could even be viewed as detrimental to their relationship with the GP as highlighted by the

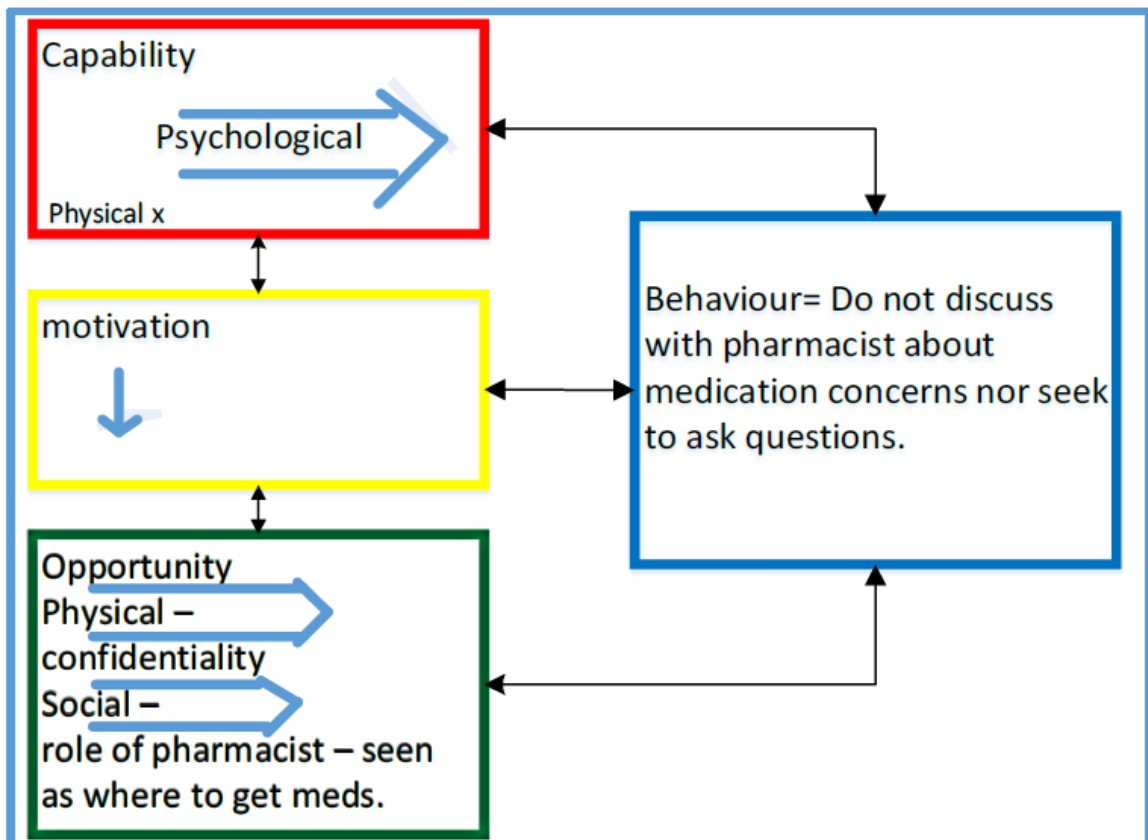
'going behind the GP's back' comment.

These conditions then link into motivation. The participants did not express high motivation to discuss concerns or information needs with the community pharmacists during this study. As shown in the theme reflection of support and information needs, men often had unmet information needs, but were not aware of some information needs, or had not reflected on their information needs at the start of their treatment.

Therefore it is likely motivation is low to begin with, and then will be further reduced by capability and opportunity. Figure 12 highlights a COM-B model adapted to demonstrate the findings from Chapter 4 taken from a problem focused perspective. Implications for the development of a complex intervention (aim 3) is that psychological behaviour theory has helped to identify the factors that influence a target behaviour.

This is from looking at the behaviour from a problem focused perspective. The work in Chapter 5 will look at the evidence base from a solution focused perspective. Then the use of the behaviour change wheel in Chapter 6 can help develop feasible intervention strategies, which can then be iteratively modelled.

Figure 12: COM-B model linked to Chapter 4 study



Discussing the implications for community pharmacy practice (aim 3).

There is seemingly a disconnect between what participants in this study view as the community pharmacists role within their care, and what the profession visualises their role to be. The pharmacy profession advocates for a greater role for community pharmacists in mental health (RPS England 2018). Yet the findings of this study showed most participants viewed community pharmacists' role to be around safely dispensing their medication, and accounts of the community pharmacists involvement in their care were sparse; a finding also found in studies looking at both genders (Anderson,

Kirkpatrick et al. 2015, Nederlof, Cath et al. 2017). Participants did not express dissatisfaction with this, except two participants who had a vocational association with the profession.

This study shows some men may be unlikely to proactively engage with the community pharmacist in discussions around depression and treatments. Men did not view this approach as part of their recovery strategy. As illustrated in the Figure 12 COM-B model there are multiple factors that led to this behaviour.

Instead pharmacy could consider ways to facilitate engagement, such as proactively offering services. Men could be educated that discussions around antidepressants and wider holistic care is within community pharmacists' scope of practice and expertise.

Community pharmacists should encourage patients to explore their concerns and beliefs. This is particularly important since patient beliefs around antidepressants influence adherence (Hung 2014). Community pharmacists may need to help participants normalise their condition and treatment. This may include giving information on dose ranges, and how their dose relates to these ranges. Community pharmacists should ensure patients are aware of potential side effects of antidepressants when newly starting, or when having a dose change. Literature shows minimal evidence of negative impact of such discussions (Jose and AlHajri 2018). Community pharmacists could reiterate that antidepressants should not be considered as a "quick fix", and ask monitoring questions throughout treatment, as some men feel "lost in the system" when stabilised on the medication. In particular this study found a need for staggered support over time, and that is where the accessibility of community pharmacists could be particularly useful, a finding supported by other literature (Hattingh, Scahill et al. 2016, Santina, Lauzier et al. 2018). Some participants had unsuccessful attempts at stopping antidepressants and attributed this to placebo effects. An awareness that patients can hold such views could help pharmacy practice. Particularly as it is possible such experiences could be linked to withdrawal symptoms, which can vary in severity and duration between patients (Fava, Gatti et al. 2015). Patients should be educated on withdrawal and managed appropriately.

Pharmacy as a profession should seek ways to implement closer collaborative care with other mental health providers. In the UK community pharmacy access to a patient's clinical records is restricted. They can access a patient's NHS Summary Care Record, yet the accessible information is clinically limited (Hindi, Jacobs et al. 2019), and collaborative working models between community pharmacists remains minimal (Hindi, Jacobs et al. 2019), a finding also found in other countries (Dey, de Vries et al. 2011, El- Awaisi, Joseph et al. 2018). Researchers have recommended that community pharmacy interventions incorporate strategies to link with prescribers (Anderson, Kirkpatrick et al. 2015, Scahill, Fowler et al. 2015). This current study strengthens this recommendation, but also further expands on it; both the collaborative system, and patients understanding of it, needs improving. Relevant healthcare professionals should help patients understand collaborative care behaviour, and improve patients' perception of a community pharmacists' role within a collaborative care model.

While this study did not assess adherence it is worth noting all the men were currently taking their antidepressants and either felt antidepressants improved their mood, or perceived a need to be on antidepressants. Literature has shown that perceived need for antidepressants can increase adherence, although only if this outweighs concern on the medication (Aikens, Nease et al. 2005). Overall, it is important for community pharmacists to explore patients' views on antidepressant need, highlight the potential benefits of the medication, while also exploring any concerns as highlighted above.

These findings come from male participants, but not all findings are gender specific. It seems that antidepressants could challenge masculinity, yet not all men will experience this. Care should be taken not to patronise or stereotype men as this could be detrimental (Wilkins and Kemple 2010). Community pharmacists should also be aware that men when depressed may put on a front, as a strategy to keep concerns in check, and this could be a barrier to communication.

Translation of these recommendations into routine practice will need careful planning and support from leaders of the profession as some barriers such as time (Knox, Hattingh et al. 2016, Guillaumie, Moisan et al. 2017), lack of pharmacists confidence in talking to those with depression (Rickles, Dube et al. 2010, Knox, Fejzic et al. 2014, Liekens, Vandael et al. 2014, Knox, Hattingh et al. 2016) and lack of collaboration with physicians (Knox, Hattingh et al. 2016, Guillaumie, Moisan et al. 2017) need addressing at both an individual and organizational level (Scahill, Fowler et al. 2015).

4.6. Strengths and limitations

There were various strengths and limitations of this study.

A strength of this study was that it was an novel contribution to knowledge. This work was published and to the best of the authors knowledge this was the first paper to be published looking at men's views of antidepressant treatment for depression, and the role

of the community pharmacist in this treatment journey.

The use of qualitative methodology and methods used were appropriate to the aims and increased the credibility of this study. It allowed a deeper exploration of the views of men on a sensitive subject, also supported incorporation of relevant theory in data analysis. The use of both data saturation and information power to determine if the number of participants was appropriate was a strength. For data, the detailed description and link with appropriate quotes helped increase the confirmability of findings, which is a core part of trustworthy qualitative research (Amin 2020, Denzil 2011).

Another strength with this study was the use of a patient and public engagement session, and pre-piloting of the interview. It resulted in critical changes of some of the terminology; particularly the use of the term community pharmacist. Upon reflection the thesis author may have initially had a contextual bias, as she was a part time community pharmacist and had assumed this term to be more common place than it was to the lay public. Establishing a shared understanding on what a community pharmacist was at the beginning of the interview was potentially a particularly important step, as otherwise the results could have been compromised if it was not clear to participants what a community pharmacist was.

Reflexivity was embedded throughout the study. In particular the fact that the researcher was a pharmacist was considered throughout. This issue is discussed in more detail in chapter 8, as it is a factor that would have influenced all the research studies in this thesis.

There were some limitations to this study. Firstly there was an overrepresentation of males of white ethnicity. This is not representative of the UK population. Qualitative research does not necessarily have to be statistically representative or transferable to the population, but it may be that themes pertinent to other ethnicities were missed, and the research question was focusing on men as a population, not the experiences of men of white ethnicity.

Convenience sampling was a method chosen. This was both a limitation and a strength. Convenience sampling was chosen because it was predicted that men treating depression could be hard to recruit, and convenience sampling can help minimise such issues (Etikan, Musa et al. 2016). The prediction that men treating depression would be hard to recruit was an assumption based on previous mix sex studies with patients treating depression. In most studies females were overrepresented (Emslie, Ridge et al. 2007). This assumption was also reiterated during a patient-public engagement session. The men suggested that recruitment could be challenging as men may not want to talk about depression. Additionally, this research study was conducted as part time research and there were time and financial limitations. Convenience sampling tends to be quicker and cheaper (Etikan, Musa et al. 2016). Convenience sampling allowed a suitable number of eligible men to be recruited so that data saturation was reached within the time scales and resources of the study. The limitations of convenience sampling are that it may lead to over representation of certain characteristics, and therefore results may not be as

generalizable. The issue discussed above about ethnicity might have been able to be addressed if purposeful sampling was chosen. Some other variables that could be

influential to one's mental state were recorded. These were age, ethnicity, sexuality, duration of depression treatment, previous depression history, employment, and relationship status. With the exception of ethnicity and age there seemed to be a mix of these characteristics.

There was also a range of experiences in terms of antidepressant duration and history. This was both a strength and a limitation. As a strength it could have meant different experiences were offered, and only through participants reflections were some of the themes able to be articulated. A weakness however is that there is a higher risk of recall bias. Recall bias is where participants may recall events differently due to time. With depression it is suggested there may be a recall bias particularly for recalling negative events and emotions (LeMoult and Gotlib 2019, Colombo, Suso-Ribera et al. 2020).

Possibly for the themes in this study the impact of this would be unlikely to have compromised the findings, although result should still be taken with caution.

Some participants were approached about the study but did not participate. It may be that themes could be missing from those who did not participate. Not all participants partook in member checking. The reason given in all cases was lack of time. Having all members partake in member checking could have strengthen the study, however the majority did partake, and this was a strength.

4.7. Conclusion

This study has helped build the evidence base on men's views of antidepressant treatment, including the influences of hegemonic masculinity. It depends on how these men view the role of the community pharmacist in their treatment. Some men, particularly those that adhere to hegemonic masculinity may not seek out consultations with community pharmacists around their condition or treatment. It is known hegemonic masculinity can delay men seeking treatment until a point of desperation. In this state, they are not giving cognitive space to explore their information needs nor their underlying views around antidepressants. Most men had not sought advice from the community pharmacist. Medication supply was seen as the principal role of the community pharmacist in their care.

The results and discussions have also been analysed using the COM-B model to develop theory and provide groundwork for developing a theory-based intervention.

Additionally considerations of what these findings mean for community pharmacy practice have been discussed.

It would be beneficial for community pharmacists to create opportunities for men to

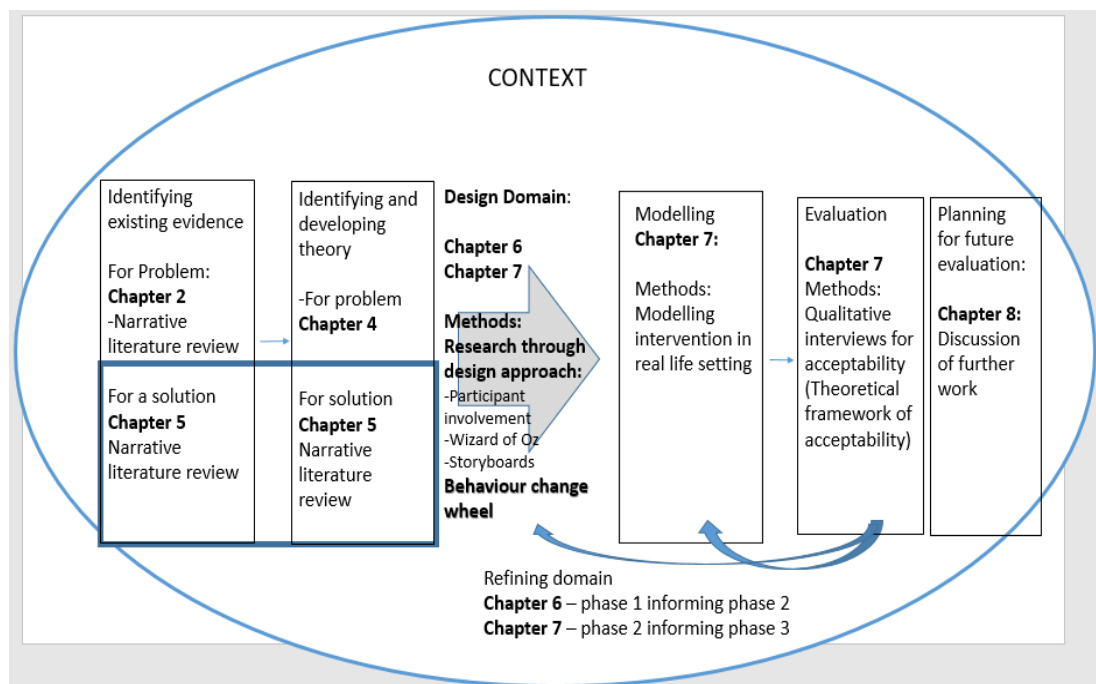
engage in conversations around their antidepressants, and wider support needs. If men view such interactions as within community pharmacists' scope of practice and expertise, part of a collaborative healthcare system, and not threatening to their masculinity, then these engagements are more likely to be acceptable to men. Such interactions can be beneficial at first prescription but also throughout treatment, and at discontinuation.

Chapter 2 and 4 have taken a problem focused perspective to further understand the situation from a problem. The work in chapter 5 looks at what has worked, and in what context, to provide a solution focused theory to aid the development of a complex intervention intended to facilitate care given to men that are taking antidepressants from community pharmacy.

Chapter 5: Develop theory, and explore evidence base for a solution.

5.1. Identify evidence base

Figure 13: Schematic showing an overview of chapter 5 and how it situates within the thesis



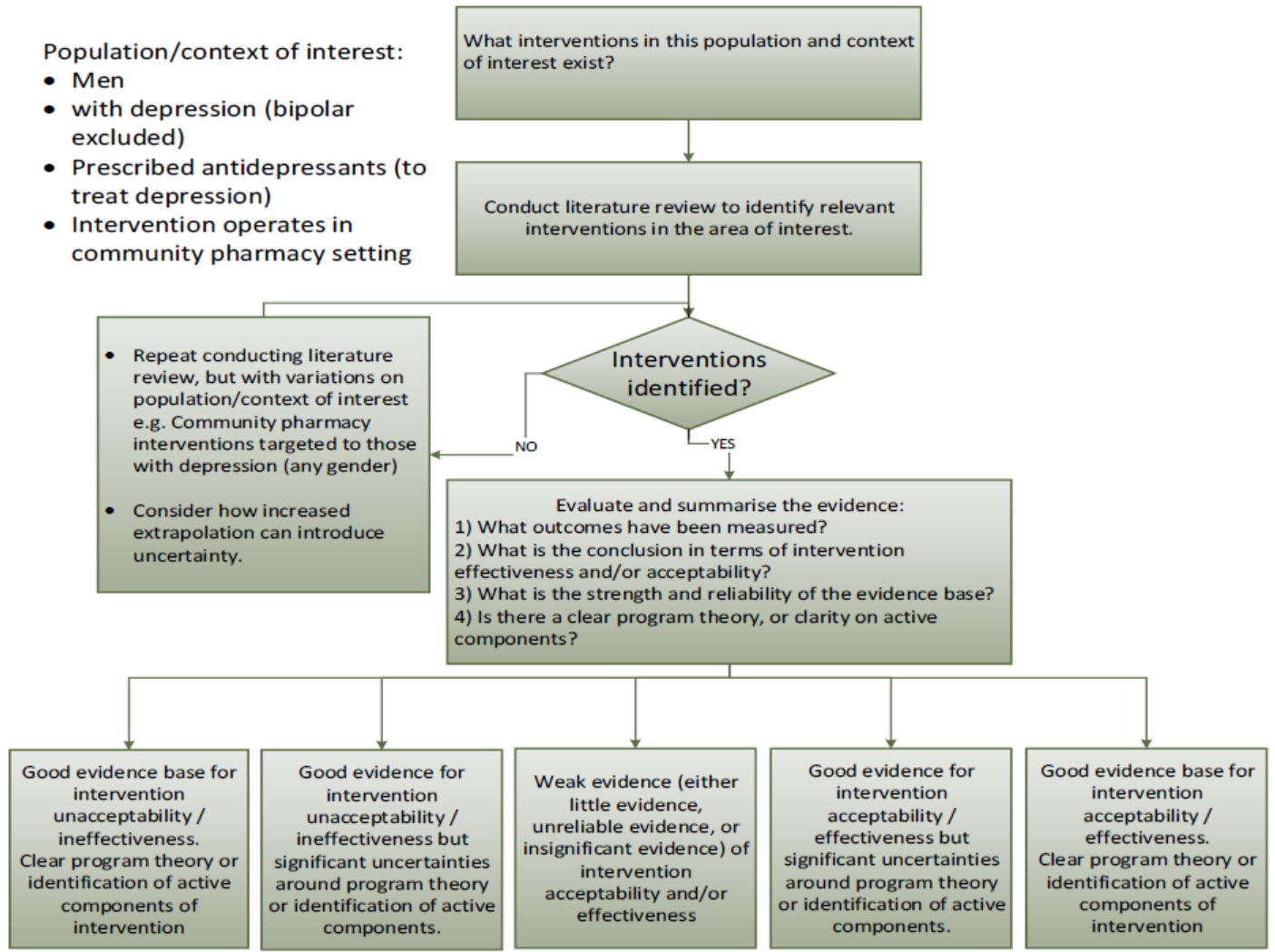
The purpose of chapter 5 is to identify relevant interventions already existing, including those that might be at development stages, and to explore their program theory. As highlighted in Figure 13 it is about identifying the existing evidence and developing theory but now by taking a solution focused perspective rather than focusing on understanding the problems (which has been addressed in chapter 2 and 4). As shown in Figure 13, the findings from chapter 5 influence the design of the intervention (addressed in chapter 6 and 7). This will support the theory-based approach for the development of the complex intervention development used in this thesis. What outcomes previous studies have measured will also be documented as this is useful in helping understand what outcomes might be useful to measure in future work (discussed in chapter 8) A typology of relevant interventions will be produced, and the evidence base discussed.

Aims for chapter 5:

- 1) Identify relevant interventions in the area of interest, and for these interventions explore active components and program theory.
- 2) Identify the relevant outcomes, and measurements evaluated in the interventions of interest.
- 3) Evaluate the evidence base for interventions of interest and for outcomes of interest.
- 4) Evaluate and identify what active components of interventions and/or program theory is/are most likely to have a beneficial effect and be acceptable.
- 5) Identify core uncertainties and what implications these have.

A schematic of the approach and logic that underpins chapter 5 is shown in Figure 14. The decision was made to conduct a narrative literature review rather than a systematic review. The reasons for this decision are discussed.

Figure 14: Schematic identifying and organising interventions for a theory driven approach in intervention development.



Decision to not conduct a systematic review as part of the literature search

Conducting a systematic review was initially considered because a systematic review can provide a high quality summary of what interventions have been done before in the area, and if they are effective.

Understanding what evidence and knowledge exists is an important step when developing a complex intervention. This knowledge will inform decision making, and activities to focus on within the development stage for complex interventions. For example if a systematic review found that effective interventions exist then the development stage activities would focus more around intervention identification and refining (Croot, O'Cathain et al. 2019). Alternatively, if few interventions exist, or there is poor evidence of effect, then innovation, conception and design become important aspects of the development stage (Rousseau, Turner et al. 2019).

An initial search found no relevant articles. This initial search was methodical and comprehensive, but not a systematic review, and details are highlighted in section 5.2. Since the initial search identified no relevant articles for the population of interest, it is unlikely conducting a systematic review would be an appropriate direction. This is a pragmatic decision based on systematic reviews being labour and resource intensive. A systematic review, in addition to the initial database search, would involve various additional search methods such as searching conference abstracts, institutional repositories, trial registers, and contacting experts. Ideally the work would involve at least two independent researchers, and a pre-defined and published protocol.

At this stage, where an initial comprehensive search of the literature has not identified any relevant studies, it is unlikely a systematic review would add value in relation to its resource costs. For example, a systematic review could identify additional studies, but for these studies to significantly add value and influence this development stage these studies would ideally have a well developed program theory with a strong evidence base. It's likely (but not certain) that studies with a strong evidence base and comprehensive program theory would have been identified in the initial methodical search strategy. Alternatively, a completed systematic review may confirm that no interventions developed for this population of interest exist. While this is valuable knowledge, it does not meaningfully address the research aims for this chapter.

Systematic reviews, due to their focused nature, may not always facilitate finding studies that help explore the 'why' and 'how' intervention work, and in what context. As this development phase is taking a theory-based research perspective one of the core questions to be answered from this search strategy is to understand what outcomes have been measured in intervention evaluation, and the program theory i.e. why interventions are effective and acceptable (or ineffective). A broader search strategy would likely be more beneficial in these circumstances. For this reason, a purposeful narrative literature

review was undertaken. While this was not a systematic review it was still rigorous and methodical and the search strategy is documented below.

5.2. Initial Literature search

Four databases were searched. These were OVID Medline, Embase, PsycINFO and Web of Science. These were chosen as they are all trusted databases and in combination they provide a comprehensive cover of biomedical and leading psychiatric journals. A concept map was produced to consider the key concepts relevant for the search strategy, and what other words could be used to represent these concepts. This is highlighted in Table 10, and each concept was given a search number to help organise the input into databases. Only publications written in English were searched.

An important consideration is when to stop searching the literature. There is currently little guidance on when to stop (Cooper, Booth et al. 2018). Time-limitations unique to the project and subject would be relevant. This project is conducted part-time. For this reason, there are two key timeframes in the search strategy. The first is the main search conducted in 2017, and looks at literature from 2000- 2017. The core design and development stages are based on this literature search. A second literature review was conducted in 2021 (2018-2021) to identify any relevant publications, and where relevant and possible this has been incorporated. Using Boolean logic all core concepts were combined using the 'AND' function. The search results are highlighted in Figure 15.

Table 10: Key concepts in search strategy

Search number:	Concept:	Terms searched (Either as MeSH headings or as key words in title and abstract of article)
1	Depression	Depression OR Depress* OR Mood disorder OR Depressive disorder OR Dysthymi* OR Low Mood OR mental disorders
2	Antidepressant treatment	Antidepressive agents OR Antidepressants OR SSRIs OR serotonin reuptake inhibitors
3	Men	Men OR male* OR masculin* OR gender OR sex difference*
4	Community Pharmacy	Pharmaceutical services OR community pharmac* OR Pharmacist
5	Interventions	Intervention OR Service OR Pilot OR Feasibility OR Project OR development
N/A	Limits/Advanced search:	Human, English language. Literature search 1: 2000-2017. Literature search 2: 2017- 2021.
<p>Exclusions: Papers focused exclusively on people aged under 18 years, or over 65 years, as these age ranges were outside of the inclusion criteria set in chapter 4.</p>		

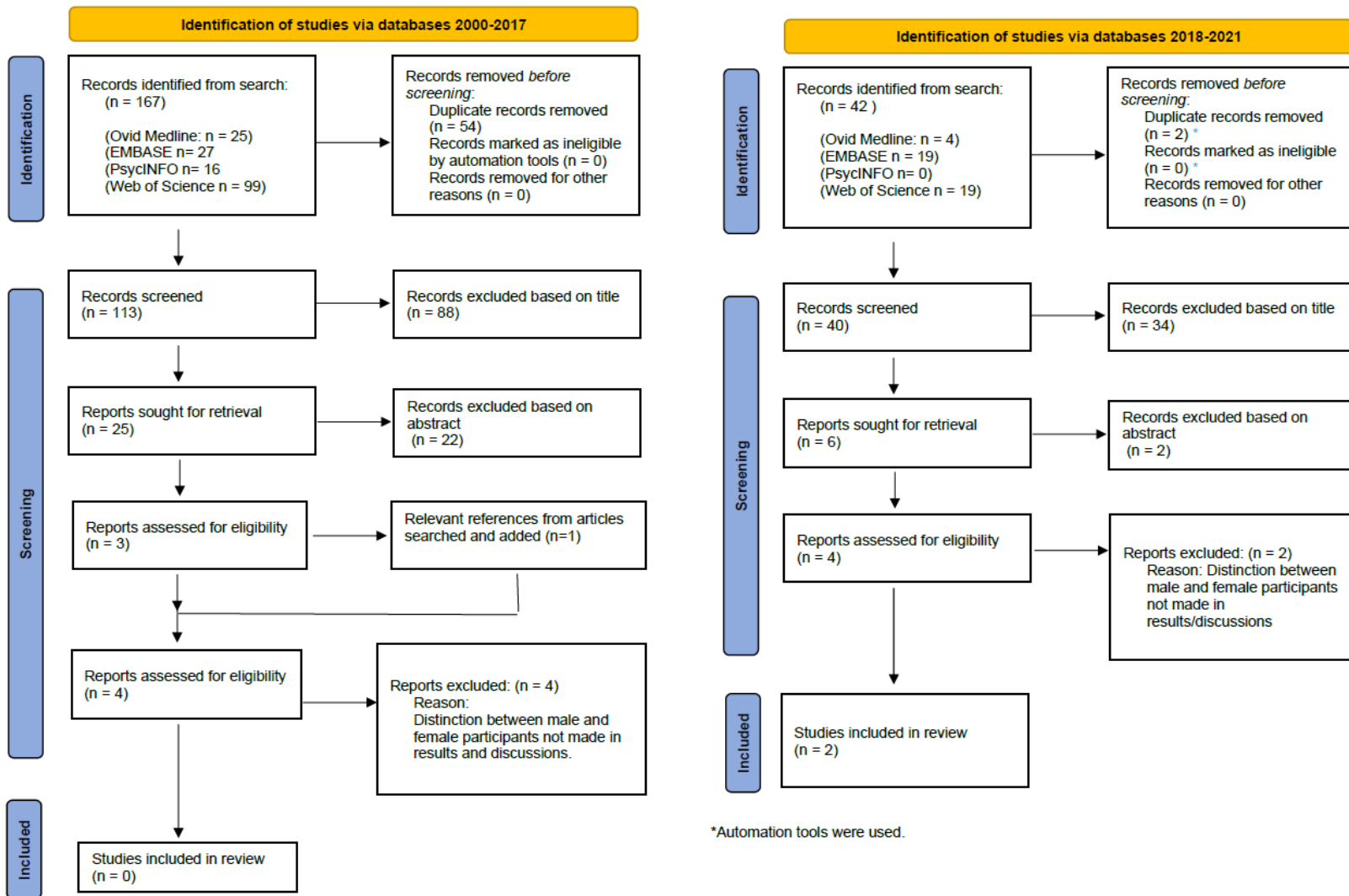


Figure 15: Flow diagram (based on PRISMA flow diagram) showing identification of studies 2000-2017, and 2017-2021

5.3. Literature review: Community Pharmacy Interventions targeted at Men treating Depression with Antidepressants.

As demonstrated in Figure 15, no studies in the original 2000-2017 search met the search criteria. There were some studies on community pharmacy interventions that targeted any gender of patients treating depression, and included a breakdown of male-to-female participants. These studies did not address gender further and therefore, no meaningful conclusion could be drawn about males. As a result, these studies were excluded.

From the second literature search 2018-2021, two studies met all criteria (an intervention study in a community pharmacy setting for men treating depression with antidepressants). These were two linked North American studies; one focusing on pharmacists (Murphy and Gardner 2019), the other male service users (Murphy and Gardner 2019) exploring the acceptability of a training, and signposting website called 'Headstrong'. The content focused on mental illness and addictions in men. 'Headstrong' contains some information sources and apps (some requiring payment) that pharmacists could signpost men to. The program has been developed using a theory-based approach; the developers used the behaviour change wheel. However, as the 'Headstrong' intervention stands, it is not particularly innovative for a UK setting. In the UK, signposting is already a part of community pharmacist essential services (PSNC 2022). Also, while the study specifies what intervention functions have been targeted (education and training; persuasion; modelling; environmental restructuring; and enablement), it does not provide detail on whether the community pharmacy context influenced design decisions for the intervention. Nor does it detail if the intervention was designed for the population e.g. did existing published theory inform the intervention development process. Such details and knowledge would have resulted in these papers being more useful to this thesis, because it could have helped highlight if any components from the Headstrong intervention should or could be adapted into the intervention developed in chapter 6-7. There is however not enough clarity or detail on these design components to gather transferable knowledge relevant for this thesis, and this chapters aims.

What is useful to this thesis is the methods and analytical frameworks in the two studies. Both used qualitative interviews and accessed acceptability. One study published the views of pharmacist participants, the other published the views of the male service users. Acceptability should be considered when designing healthcare interventions and can give valuable knowledge about an intervention (Sekhon, Cartwright et al. 2017, Richards, 2015, Skivington). The studies' use the Theoretical Framework of Acceptability developed by Sekhon et al. (Sekhon, Cartwright et al. 2017) to structure their deductive coding. To date this is the only paper that has used this framework in a community pharmacy setting and with men with reduced mental wellbeing. The framework facilitated the authors in evaluating, and presenting their data, while capturing issues relating to context.

In terms of overall findings of the study, it seems the intervention was acceptable. However, a limitation of this study is the small sample size. In the service user study, only 5 males were interviewed, and it did not appear that data saturation was reached.

From the pharmacist study there were some findings that offered useful insight for this thesis. Overall, the intervention was acceptable, yet a minority (two pharmacists) viewed the focus on men as a negative. It created conflict, with one stating it hindered inclusivity in practice. The study authors do not explore this theme further, however this is a useful insight. It is possible other pharmacists may hold these views. One way to address this could in the training package to highlight that men, as a population navigate depression and healthcare pathways differently to women (as a population) and that experts in the field recommend that gender-sensitive interventions can best target men. It could also be important to give pharmacists an opportunity to consider and voice their views on delivering a service to men only prior to involvement in such an intervention.

In 2022 a feasibility intervention study was published that focused on an intervention termed CHEMIST (The Community Pharmacies Mood Intervention Study) (Chew- Graham, Kitchen et al. 2022). CHEMIST explored community pharmacists giving brief psychological support to patients with long term conditions. The reasoning for targeting this group for brief psychological support is that statistically depression is 2-3 times more prevalent in those with long term conditions compared with the general population (Naylor, Das et al. 2016), as discussed in chapter 2. In this study behavioural activation, a brief psycho-social intervention focusing on goal setting and collaborative care was delivered via six sessions in the community pharmacy setting. Depression symptoms were measured using the Patient Health Questionnaire-9 (PHQ-9), and acceptability was measured using the theoretical framework of acceptability. The publication of the CHEMIST study was done after most of the development work in this thesis, therefore its influence on study and intervention design was limited. However, it did help with the consideration of certain aspects, and further supported the use of some strategies such as the use of the theoretical framework of acceptability. A linked RCT study on this intervention is currently being run.

5.4. Typology of relevant interventions

As discussed previously there is limited knowledge on useful program theory and effective interventions designed for men with depression and delivered in a community pharmacy context. In such a situation a pragmatic way forward is to consider what intervention, evidence and knowledge is available from another context, or for a slightly different population. It may be a key source of intervention development could come from an intervention that has been developed elsewhere.

In the initial search strategy, five core concepts were considered important (highlighted in 10). Searches of some of these concepts in variation could identify further studies or

theory. For example, searching community pharmacy interventions targeting support to those of any gender who are experiencing depression, or searching interventions targeted to men with depression etc.

Therefore, four additional searches were run focusing on:

- Interventions that exist within a community pharmacy setting targeting those with depression, taking antidepressants and seeking to improve clinical and/or recovery outcomes (chapter 5.5).
- Interventions that exist that are targeted to interventions for men experiencing depression, or low mood (chapter 5.6).
- Interventions that exist that are targeted to interventions for those of any gender experiencing depression (chapter 5.7).
- Knowledge base around targeting and designing healthcare intervention for men (chapter 5.8).

The methodology for each of these searches was the same as described in section 5.2 the difference being the concepts searched, and that the searches were iteratively conducted by considering conceptual richness (i.e. do the identified papers help with intervention development and/or program theory development). The relevant search strategy for each section is highlighted in Table 11, which is an adaptation of Table 10. Evidence from subject matter experts and policy papers were included in addition to empirical work when identified from the relevant searches.

Table 11: Search concepts in chapter 5.5-5.8.

The search concepts that were combined using the ‘AND’ function for the 4 subsequent searches in **chapter 5.5** (community pharmacy and depression), **5.6** (Interventions for men experiencing depression/ low mood), **5.7** (Interventions for any gender experiencing depression) and **5.8** (interventions targeting men).

Search number:	Concept:	Terms searched (Either as MeSH headings or as key words in title and abstract of article)	The combined search strategies Section of thesis:			
			5.5	5.6	5.7	5.8
1	Depression	Depression OR Depress* OR Mood disorder OR Depressive disorder OR Dysthymi* OR Low Mood OR mental disorders	✓	✓	✓	✓
2	Antidepressant treatment	Antidepressive agents OR Antidepressants OR SSRIs OR serotonin reuptake inhibitors	✓			
3	Men	Men OR male* OR masculin* OR gender OR sex difference*		✓		✓
4	Community Pharmacy	Pharmaceutical services OR community pharmac* OR Pharmacist	✓			
5	Interventions	Intervention OR Service OR Pilot OR Feasibility OR Project OR development	✓	✓	✓	✓
N/A	Limits/Advanced search:	Human, English language.	✓	✓	✓	✓
		Literature search: 2000-2017.	✓	✓	✓	✓
		Literature search: 2000-2017.				

The purpose of such searches would be to identify evidence and knowledge that will contribute to an evidence base used to develop an intervention (using a theory-driven approach). The findings from the searches were therefore evaluated based on three criteria, firstly does the intervention show beneficial clinical and/or recovery outcomes, and secondly is there a good evidence to support this result. The third aspect is to evaluate is if comprehensive program theory exists (or clear identification of the active components) so that it can be understood how and why the intervention works and in what context.

This is because if an intervention exists that shows significant improvements in clinical and recovery outcomes, and has a strong evidence base to support this result, then to be useful to this thesis the next step is to understand how and why, and if this program theory could work in a different population and setting (e.g. an intervention in a community pharmacy setting targeting men). If relevant program theory does not exist then it limits the usefulness of the knowledge for the purposes of intervention development. Therefore for each search the relevant findings have been grouped in to typologies based on core characteristics of the interventions. Then the knowledge has been prioritized based on how useful it is, with the intention of using the most useful knowledge to help underpin the intervention design.

In addition an aim of this chapter is to identify what outputs have been measured, as this understanding will help guide in intervention development. It will help aid decisions on potential intervention aims, how feasible such aims might be, and how they are evaluated. For this reason, details on outcomes will also be documented in the typology tables.

5.5. Community pharmacy and depression interventions.

Table 12 displays a typology of core interventions and links the outcomes and evidence base.

Table 12: Typology of core interventions for depression interventions in community pharmacy setting

Overarching Intervention category: Additional Support via Community Pharmacist Consultations		
Sub category:	Outcomes and Evidence.	Examples
Patient education	Patient satisfaction and patient reported adherence. No significant effects on adherence in findings from a systematic review (Readdean, Heuer et al. 2018) .	(Bultman and Svarstad 2002)
Patient education/ patient education with enhanced take-away tools e.g. video, pamphlet	Self reported adherence, Attitude to antidepressants (using drug attitude index) Non-significant improvements (Crockett, Taylor et al. 2006, Readdean, Heuer et al. 2018).	(Crockett, Taylor et al. 2006)
Enhanced/more frequent monitoring (drug reactions, symptoms)	Self reported adherence, Attitude to antidepressants (using drug attitude index). Non-significant findings (Crockett, Taylor et al. 2006). Clinical symptoms using PHQ-9: non-significant improvements (Rubio-Valera et al. 2013) Quality of life. measured with health-related quality of life (HRQOL) scale – significant improvements.(Rubio-Valera, March Pujol et al. 2013)	(Crockett, Taylor et al. 2006), (Rubio-Valera, March Pujol et al. 2013)
Enhanced education and monitoring	Clinical depression symptoms (using PHQ-9) – no significant changes (Rickles, Svarstad et al. 2005, Cohen, Taveira et al. 2020) Adherence: Rickles et al. (Rickles, Svarstad et al. 2005) was non significant, significant improvements in Cohen et al. (Cohen, Taveira et al. 2020) Patient quality of life (HRQOL scale). - non significant improvements (Capoccia, Boudreau et al. 2004).	e.g. Cohen et al. (diabetes and depression comorbid patients)(Cohen, Taveira et al. 2020) (Rickles, Svarstad et al. 2005) (Capoccia, Boudreau et al. 2004)

Coaching or motivational interviewing and/or goal setting	Adherence (electrical pill container and pharmacy medication records) - non significant improvements (Brook, van Hout et al. 2005) Depression symptoms (using Hopkins Symptom Checklist) – no effect.	(Brook, van Hout et al. 2005)
	Significant improvements health-related quality of life, perceptions of illness, medication beliefs, treatment satisfaction. Improvements in medication adherence (McMillan, Kelly et al. 2018).	(McMillan, Kelly et al. 2018)
Behavioural activation (CBT based - principle of encouraging depressed people to reconnect with environmental positive reinforcement)	RCT trial run at current – primary outcome to measure depression symptoms using PHQ-9 in sub clinical-depressive patients. Results to be published	(Littlewood, Ali et al. 2019)
Improved links between community pharmacist and other healthcare providers or wider support	Service acceptability, program theory. Little evidence at current.	Bloom Project(Murphy, Gardner et al. 2019, Murphy, Jacobs et al. 2021)
mindfulness meditation	Clinical depression outcomes using PHQ-9 improved outcomes but limited evidence.	e.g. Perepelkin 2019(Perepelkin, Antunes et al. 2019)

Overarching Intervention category: Screening and pre-diagnosis community pharmacist interventions		
Sub category:	Outcomes and Evidence.	Examples
Diagnostic screening in community pharmacy setting	PHQ-9 screening tool most frequently used. Acceptable use in community pharmacy setting, and leads to increased referral. However concern that adequate care systems not established (i.e. referral not leading to follow up care) (Herbert Rubin 2005). Little evidence showing impact on clinical outcomes (Miller, Newby et al. 2020)	O'Reilly (O'Reilly, Wong et al. 2015) Ballou et al. (Ballou, 2019)
Outreach screening and counselling by community pharmacists	Community pharmacists able to provide outreach screening and counselling; Quality of life and depression symptomology using screening questionnaire by the Centre for Epidemiologic Studies-Depression Scale	W. Phimarn, et al. Thailand university setting.(Phimarn, Kaewphila et al. 2015)
Enhanced pharmacist or pharmacy team training		
Outcomes and Evidence.		Examples
Better outcomes from training packages that were: accessible, flexible, targeted knowledge and skill gaps, Education had positive impact on attitudes, knowledge, confidence, and skills		Liekens et al. (Liekens, Vandael et al. 2014)

Systematic reviews show interventions which include additional support via community pharmacist consultations do significantly improve antidepressant adherence when findings are pooled. (Rubio-Valera et al. 2011; Al-Jumah and Qureshi 2012; Bunchuailua et al. 2021). When considering the pharmacy intervention as types, no characteristic of intervention could show a statistically significant impact on adherence and particularly depression symptomology (Rubio-Valera et al. 2011; Karp et al. 2021; Readdean, Heuer, and Scott Parrott 2018; Brown et al. 2019; Bunchuailua et al. 2021).

In most studies improvements in depression symptomology occurred in both the intervention and control group. The symptom improvements were largest in the pharmacist intervention but the difference between the control was not significant. There could be various reasons for this result. Firstly, the differences between intervention and control groups may not be different enough. For example, in some studies the same pharmacists delivered both intervention and control groups. In Cohen et al. (Cohen et al. 2020) a pharmacist commented that their care in the intervention and control group were similar. Similarly in Crockett et al. (Crockett, Taylor et al. 2006) some control pharmacists believed they delivered a control service that paralleled the intervention service, although this was only a small minority (four out of sixty). Usual pharmacist care is complex, hard to define, and not systematically documented (Motulsky et al. 2021). It is possible a pharmacist in a control group may have delivered enhanced care; particularly this may happen if a patient in the intervention control group sought extra support from a community pharmacist.

A second possible reason for non-significant findings in relation to improving depression symptoms is that the measurements and follow up times could have been too short. All follow-up times were completed within 6 months. According to NICE guidelines, 6 months would be the minimum duration for antidepressant treatment (assuming there were no reasons to withdraw prior e.g. side effects etc.) (NICE 2009). A longer follow up time could possibly have given a more robust conclusion on whether pharmacist interventions did or did not improve clinical outcomes.

A third reason is that there may have been other independent variables which were not accounted for or were difficult to control. In most studies comprehensive treatment histories were not taken or compared for. For example, it was not always clear if different doses of antidepressants were being compared, and what non-pharmacological treatments, if any, were being used. There was also little consideration for other aspects that might influence recovery and influence psychosocial functioning. It is plausible that such variations between participants could affect results (Kamenov, Twomey et al. 2017).

Most of the studies included in this review were of moderate quality, with a low-moderate risk of bias. Table 13 graphically shows the risk of bias from the studies and assesses methodological quality. Table 13 is adapted from the Cochrane Collaboration tool for assessing risk of bias for the RCT where appropriate, and work from Readdean et al., and Karp et al. (Readdean, Heuer et al. 2018, Karp, Kinckman et al 2021). The conclusion

from Table 13 is that overall the findings seem reliable, but there were many areas where it was difficult to judge.

Most studies provided clarity on their recruitment strategies and how they reduced selection bias and took steps to get representative samples. This however was not the case for all. In one study (Perepelkin et al. 2019) the population of interest were those with anxiety and/or depression, however the recruitment mechanism (self-enrolment) resulted in participants being involved in the study who did not have clinical anxiety and/or depression. Some participants in this study had also taken part in the intervention (a mindfulness meditation in community pharmacy) prior to the study. This confounds the results and limits confidence that can be placed on the findings. Similarly in the Israeli study by Klang et al. (Klang, Ben-Amnon et al. 2015) the design for recruitment did not account for selection bias (non-randomised), and there were no details on if the sample characteristics were representative. In the study by Klang et al. only participants that were prescribed escitalopram were eligible. Although authors justified their reason for this (in Israel 78% of patients are prescribed escitalopram first line) this does limit the generalisability and usefulness of this study for a UK population.

Table 13: Quality appraisal of studies

Study	Recruitment biases (e.g. Allocation concealment in RCTs, selection bias reduced)	Performance bias (e.g. blinding of participants/and providers to intervention received in RCTs)	Detection bias if RCT e.g. Blinding of outcome assessment etc	Complete outcome data?	Subject follow up suitable? (e.g. completed, and long enough?)	Reporting bias / Selective reporting	Compliance to protocol	Overall risk of bias
Bultman et al.	?	N/A	N/A	?	+	+	N/A	?/Moderate
Brook et al. 2005	+	?	?	+	+	-	+	?/Low
Capoccia et al. 2004	+	?	+	-	?	+	+	?/Low
Crockett et al., 2006	?	+	-	+	-	+	-	Moderate
Klang et al., 2015	-	-	-	+	+	+	-	High
Rickles et al., 2005	+	?	?	+	+	+	+	?/Low
Rubio-Valera et al. 2013	+	?	+	?	+	+	-	?/Low
Cohen 2019	+	+	?	+	?	+	?	?/Low
Perepelkin 2019	-	+	N/A	+	-	+	+	Moderate
Phimarn 2015	-	+	-	+	+	+	+	Moderate

Excluded: Littlewood et al. as results and publication pending.

Key

+

= low risk of bias

?

= unclear risk of bias

-

= high risk of bias

RCT = Random Control Trial

As shown in Table 13 incomplete data was an issue and could result in bias studies. For example, in Rubio-Valera et al. 2013, (Rubio-Valera, March Pujol et al. 2013) it was not clear if during their study the participants were blinded to being in the intervention or not. If this blinding did occur, it was not stated how. In many cases it was not possible to judge risk of bias due to missing or incomplete data (see Table 13). This created difficulties in assessing evidence quality and making judgments on risk of bias.

Some studies covering work by Brook et al. were published as multiple papers. This could be justified as the papers had different outcomes of focus e.g. adherence (Brook van Hout et al. 2005) vs cost effectiveness of intervention (Bosmans, Brook et al. 2007), however multiple papers exploring the same intervention risks distorting the body of evidence for what community pharmacy interventions exist targeting depression. For example, in the systematic review by Al-Jumah (Al-Jumah and Qureshi 2012) both these studies were included as separate entries despite them covering the same intervention and population.

Another issue is that there was large heterogeneity between different studies both within studies of similar intervention characteristics, and between different intervention characteristics. This makes it more difficult to understand if particular intervention types or characteristics have been effective, compared to other characteristics (Brown et al. 2019).

Similarly, different methods were sometimes used to measure the same outcomes. For example in terms of outcomes measures of depression symptomology; the Patient Health Questionnaire was used most frequently, but others also used the Hopkins Symptom Checklist, the K1029 measure of depression, the Center for Epidemiologic Studies-Depression Scale and the Beck Depression Inventory II. This again makes it more difficult to understand if particular intervention types or characteristics have been effective because the outcomes have been assessed using different measurements.

In terms of outcomes, the most frequent primary outcome measured was adherence to antidepressants. Multiple studies also assessed clinical outcomes of depression, but this was often a secondary outcome. Issues such as preventing relapse, withdrawal, and psychosocial variables such as self-esteem, self-worth, hope or stigma were often not assessed. These concepts however can be important concepts in depression pathology and recovery (Livingston and Boyd 2010; Leamy et al. 2011).

Most of the RCT studies did not specifically explore acceptability, or if they did it was reported as the number of participants not attending follow-up. Acceptability is better thought of as a multi-construct, and qualitative methods can give data that are more meaningful on acceptability, while maintaining context and consideration of setting.

Since the initial search in 2017 three studies have measured acceptability using the theoretical framework of acceptability as discussed previously.

Numerous studies looked into pharmacist interventions that occurred in other health settings e.g. hospitals, outpatient clinics, GP practices. Overall outcome findings from these studies were similar in that it could be shown the pharmacist interventions significantly improved adherence, and improvements were shown in depression symptomology but not significantly. There was not enough evidence to show any core characteristics or key program theory that resulted in successful interventions.

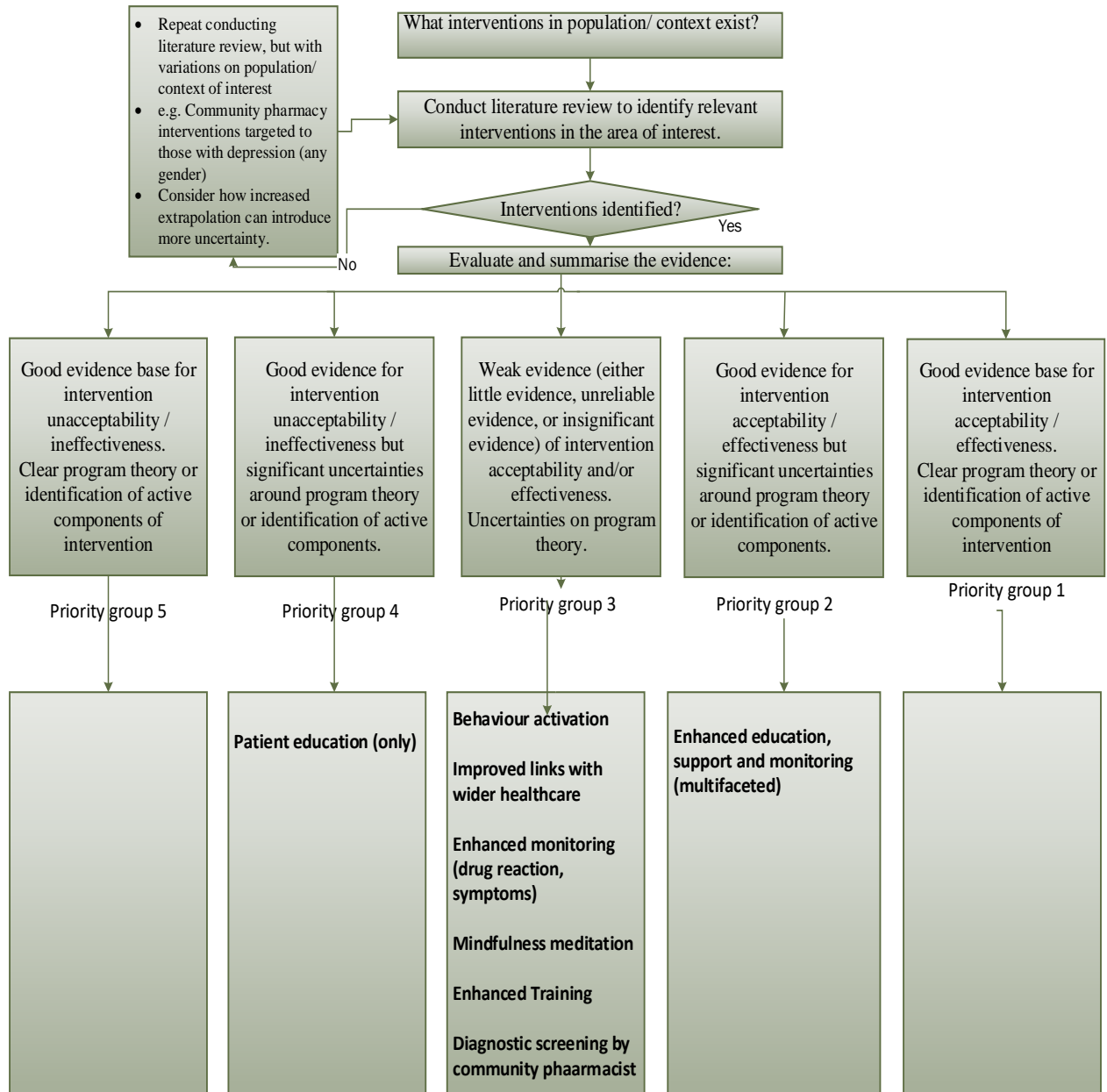
As discussed in chapter 2, a large body of work has been done in Australia exploring the needs of mental health service users in community pharmacy, and the needs of community pharmacists to enable them to assist mental health consumers with their medication requirements. The findings relevant for this chapter are that good patient-community pharmacist relations, patient centred care and progressive patient trust can facilitate pharmacy depression interventions (Mey, Knox et al. 2013, Knox, Fejzic et al. 2014, O'Reilly, Wong et al. 2015, Murphy, Martin-Misener et al. 2016, Kondova, Todorova et al. 2018) and the perception of community pharmacy as a 'safe space' (Mey, Knox et al. 2013, Knox, Hattingh et al. 2016).

As the purpose of this chapter is to identify existing relevant interventions that could potentially help underpin intervention design, work has been done in Figure 16 to judge and organise the usefulness of interventions identified. These are organised as priority groups 1-5 by adapting Figure 14. An intervention in priority group 1 would be of most use in terms of helping provide useful knowledge for a future intervention development. Figure 16 shows no interventions were in priority group 1. There were some interventions in priority groups 2-4 and the active components of these interventions could be considered, yet with caution as either there is limited evidence of beneficial clinical or recovery outcomes and/or insufficient program theory exists to help identify what are the active components of these interventions.

In summary there have been numerous interventions that have sought to improve the care for patients with depression within a community pharmacy setting, or by utilising pharmacists. While these interventions have improved depression symptomology and quality of life they have not resulted in significant improvements. There is stronger evidence that interventions can significantly improve adherence. Unfortunately due to large heterogeneity and limited details around program theory, it is not possible to articulate active components that should feature in the design. Interventions that are multifaceted, and don't focus on solely educational messages, seem more successful.

Therefore, these studies on community pharmacy and depression interventions can provide useful guidance and evidence on what intervention types or characteristics could or could not be likely to succeed. However, there is insufficient evidence, and associated program theory to make any strong statements about what characteristics should be used as core design underpinnings in an intervention development process.

Figure 16: Adaption of Figure 14 to highlight how useful the typologies of interventions identified that target patients experiencing depression in community pharmacy settings can be for this intervention development.



5.6. Depression interventions for men experiencing depression, or targeting men’s mental wellbeing.

Table 14 shows a typology of interventions that are either targeted at men with depression, or target men’s reduced mental wellbeing. In comparison to the work exploring community pharmacy interventions in depression, there are less intervention RCTs, and systematic reviews on this topic. There are however numerous qualitative studies, scoping reviews, commentaries, or expert recommendations that explore the evidence base and incorporate theory, views of patients, experts, and tacit knowledge from those that have been involved in interventions serving men with depression, or designed to improve mental health.

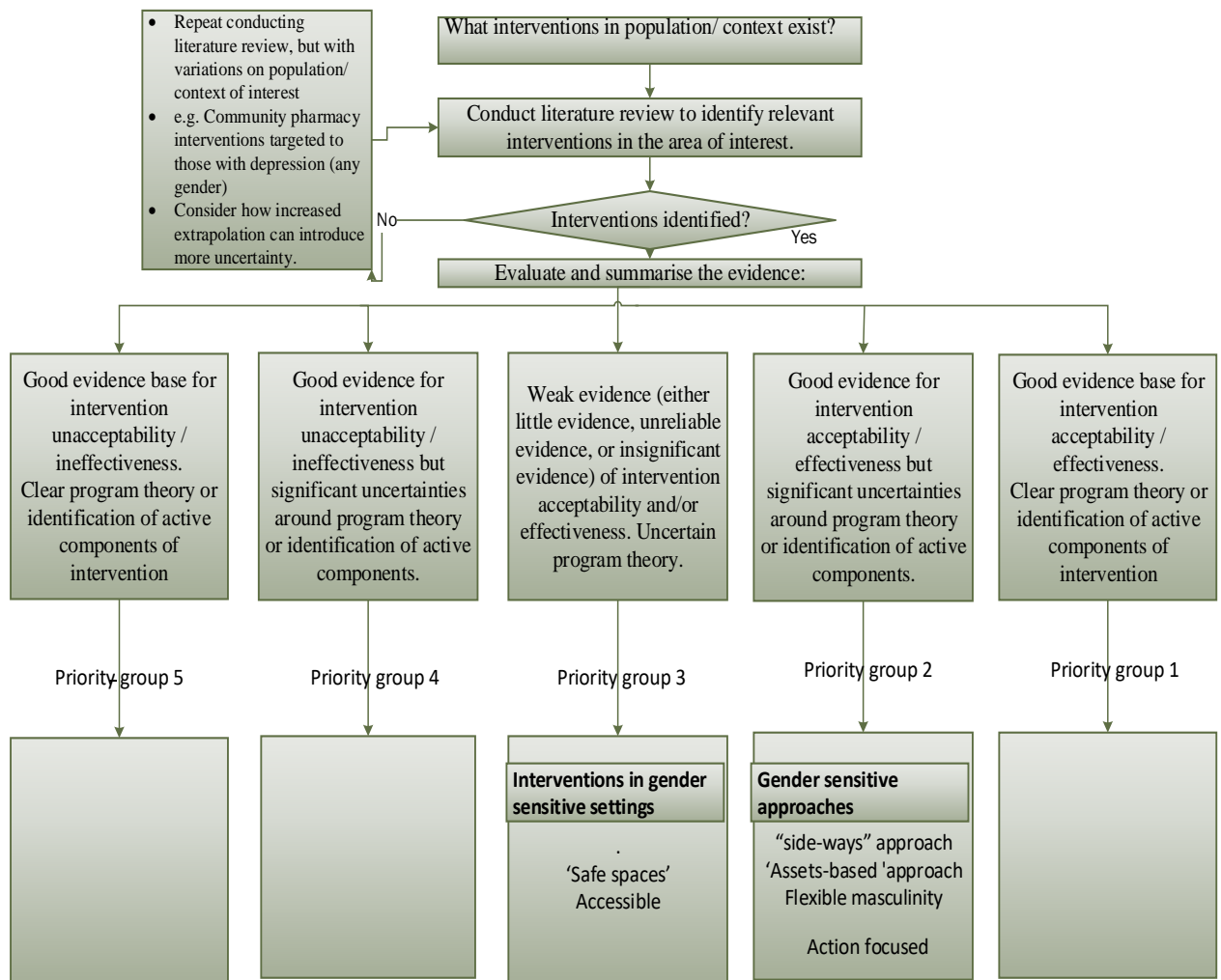
Table 14: Typology of interventions targeting men with depression or their mental wellbeing

Overarching Intervention category: Gender sensitive approaches		
Sub category:	Further details:	References:
“side-ways” approach negotiating gender	Reframing interventions so not ‘emotional focused’ and creating opportunities to engage that are not threatening to masculinity	Robertson, Bagnall et al. 2015 Robertson, Gough et al. 2018 Gosling, Parry et al. 2021
	Providing a ‘hook’ e.g. football / rugby clubs	Friedrich and Mason 2017 Seaton, Bottorff et al. 2017 Robertson, White et al. 2015
Challenging or Raising awareness of influence of Masculinity	The Men's Stress Workshop: a small study sample -6 participants. No clinically significant decrease of depression scores. Service acceptable to participants.	The Men's Stress Workshop (Primack, Addis et al. 2010)
‘Assets-based’ approach / Flexible masculinity	Drawing positive aspects of masculinity Juxtaposed to men being blamed for delayed help-seeking, not feeling believed or cared for by service providers, or experience service provider bias.	Fogarty, Proudfoot et al. 2015, Emslie, Ridge et al. 2006, Proudfoot, Fogarty et al. 2015, Casseti, Powell et al. 2020, Englar-Carlson and Kiselica 2013, Seidler, Rice et al. 2018
Action focused / Fostering ownership	Normalising talking about mental health amongst men. Peer –peer action focused talks	(Seidler, Rice et al. 2018) (Kielan, Stradomska et al.

	improved engagement in resilience building peer support service	2020)
Gender sensitive language / terminology	For example use of term stress rather than depression. Use of therapeutic metaphors have been shown to be helpful with men having difficulty articulating emotions in therapy.	Robertson, White et al. 2015, Robertson, Gough et al. 2018, Pirkis, Schlichthorst et al. 2019, Genuchi, Hopper et al. 2017
Overarching Intervention category: Setting and delivery considerations		
Sub category:	Further details:	References:
safe spaces	Focus on acceptance, not threatening to males. Not 'feminised' spaces. Some evidence male only settings/groups preferred, but evidence is conflicting	Cassetti, Powell et al. 2020 Conrad, 2010, Robertson, 2018)
Delivered in a setting easy to access	Setting must be physically accessible and acceptable.	Robertson, Galdas et al. 2009, Wilkins, 2010

Again the typologies have been ranked based on their usefulness to an intervention design (See Figure 17). This was depending on strength of evidence base for intervention causing a beneficial recovery or clinical outcome (or not), and the extent of program theory to help explain what are key active components and how they interact.

Figure 17: Adaption of Figure 14 to highlight an examination of how useful the typologies of interventions identified that target men experiencing depression/reduced wellbeing can be for this intervention development.



A core feature of depression interventions targeted at men was making them gender sensitive. There were various approaches used to make an intervention gender sensitive. There was no clear approach that seemed more effective than another. Core strategies were around navigating aspects likely to be more undesirable to men, or promoting aspects that were likely to be more desirable to foster ownership. Consideration of the physical setting was important too, and should be considered a 'safe space' that was easily accessible to men.

5.7. Interventions that target people experiencing depression of any gender.

Similar to the tables above, Table 15 includes findings from expert opinion, policy makers and some empirical evidence e.g. randomized controlled trials.

Table 15: Typology of interventions that target persons experiencing depression.

Overarching Intervention category: Peer support		
Sub category:	Further details:	References:
Peer Support Workers	Paid employed as peer support worker within healthcare service. Inconsistent findings and use varied outcome measures, however suggestion that can be beneficial.	Chapman, Blash et al. 2018, Ibrahim, 2019
Peer support as features of interventions	Group and one-one peer support features within a healthcare intervention. Evidence of benefit, particularly on recovery orientated outcomes.	Lloyd-Evans, Mayo-Wilson et al. 2014 Pistrang, 2008
Overarching Intervention category: Psychological features or cognitive behaviour elements (CBT) within an intervention		
Sub category:	Further details:	References:
Behavioural activation	A self-help treatment combining goal setting and activity scheduling to increase meaning full activity	Ekers, Webster et al. 2014
Problem-solving therapy	Focuses on training in adaptive problem-solving attitudes and skills to enhance positive well-being and coping skills. Has shown to be effective in reducing depression symptoms when compared to no intervention	Bell and D'Zurilla 2009

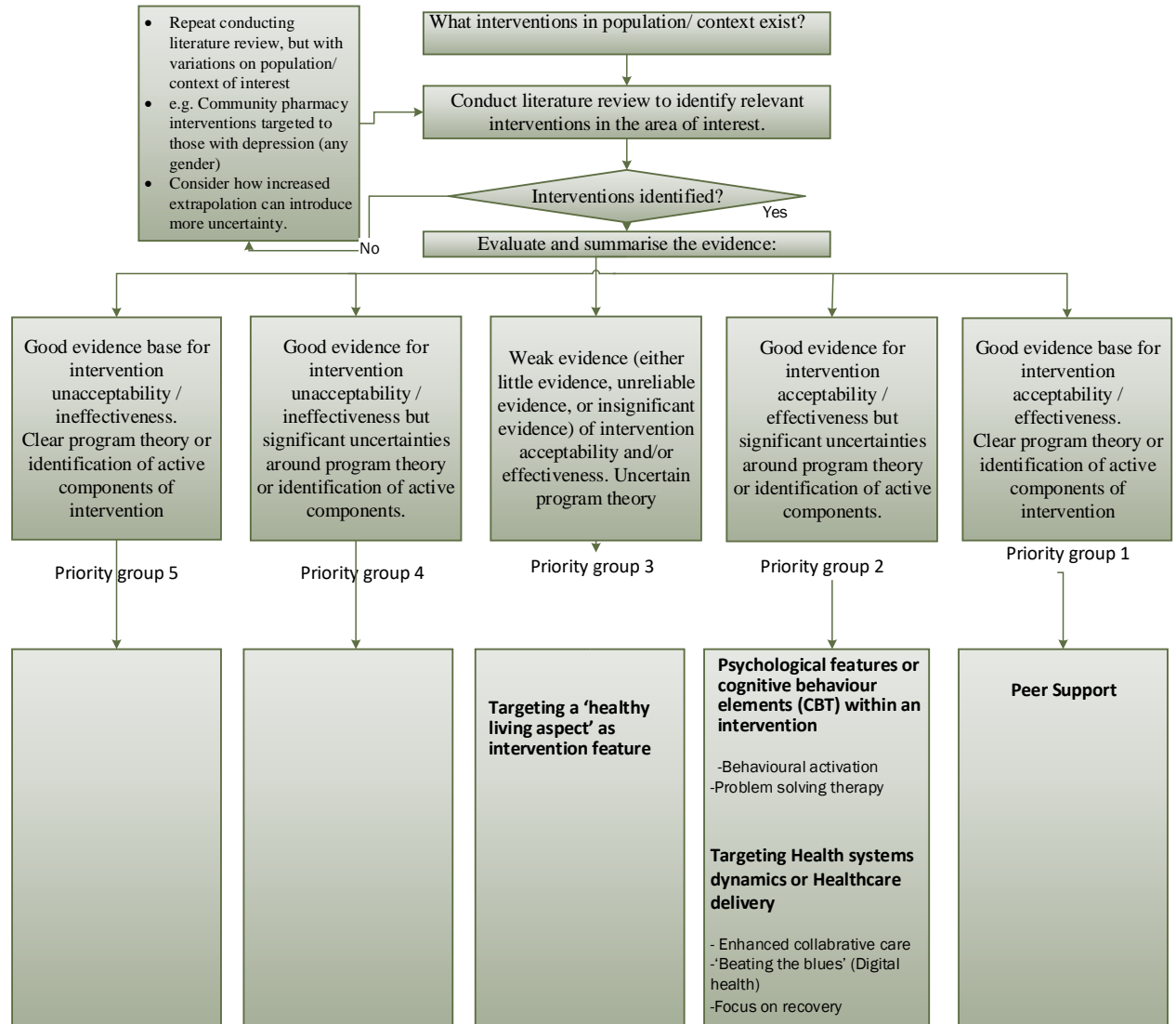
Overarching Intervention category: Targeting Health systems dynamics or Healthcare delivery		
Sub category:	Further details:	References:
Enhanced collaborative care	Systematic reviews show evidence for improved clinical outcomes in depression symptoms, and satisfaction of care.	Thota, Sipe et al. 2012
	Often case manager is a feature – named healthcare professional has overall responsibility for patients care. Little program theory on collaborative care, and what are key elements.	
Digital health	Digital health interventions, particularly that involve components of psychoeducation (e.g. beating the blues) have shown to be acceptable, and effective compared to no treatment.	Venkatesan, Rahimi et al. 2020, Buss, 2020
Focus on recovery orientated practices	To shift healthcare away from the traditional dominant focus on treating depression and measuring an effect based on measurable clinical outcomes, and shifting focus on a recovery orientated practice that focuses on person and core aspects within their life that lead to their personal recovery.	Leamy, Bird et al., 2011, Slade, Amering et al. 2014
Overarching Intervention category: Targeting a ‘healthy living aspect’ as intervention feature		
Sub category:	Further details:	References:
Physical activity	Delivered as a program of exercise. RCTs showed significant reduction in depression symptoms, particularly when compared against control groups that did no exercise.	Drew, Morgan et al. 2020, Kvam, 2016
Healthy diet	Dietary counselling, dietary education, goal settings, meetings/group sessions.	Firth, Marx et al. 2019

<p>'Positive Psychology Interventions'</p>	<p>Interventions that focus on fostering positive wellbeing e.g. optimism, connection, acts of kindness. Moderate evidence of short term effectiveness in improving depression symptoms, however large heterogeneity. Those programs that focused on multi aspects of wellbeing had greater effect on improving wellbeing and depression symptoms, compared to those focusing on one aspect.</p>	<p>Carr, Cullen et al. 2021, Bolier, 2013</p>
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It is important to highlight that the typologies are classified based on an overall characteristic or focus but there is likely to be overlap e.g. peer support is distinct to positive psychology interventions but they could also have similar processes e.g. increasing connections, optimism etc.

In terms of the evidence base for effectiveness, peer support, collaborative care and behavioural activation have a reasonably strong evidence base. There is also a large consensus that mental healthcare should have a more person-centred recovery orientation. Overall peer support had the best evidence base and the most comprehensive program theory. Basing an intervention around peer support could show promise. This is highlighted in Figure 18. These findings need to be taken with caution as it is not known what this means within a community pharmacy context, and how acceptable and effective these interventions are to men with depression within a community pharmacy context.

Figure 18: Adaption of Figure 14 to highlight an examination of how useful the typologies of interventions identified that target those experiencing depression/reduced wellbeing can be for this intervention development.



5.8. Findings from men's health

This section will not be presented as a typology chart, as many core aspects, such as delivering gender sensitive interventions have already been addressed in section 5.6; interventions for depression or wellbeing targeted at men. An exploration of the literature in men's health has led to some details that can help expand findings so far. It is known that gender sensitive interventions are important (Smith and Robertson 2008, Englar-

Carlson, 2013, Robertson, 2015, Robertson, 2008). Similarly to findings in the section on men's mental health (section 5.6), having a task focused element was important, and often this could then facilitated engaging in less desirable behaviours such as emotional expression so long as this was not the primary or initial focus (Robertson, 2008, Lefkowich, 2017, Galdas, Darwin et al. 2014).

Aspects emphasised in the literature from men's health in general are that it is important men are accepted, do not feel judged, and feel they can find personalised care (Lefkowich, Richardson et al. 2017). Importantly core messages are that men are a homogenous group and no 'one size' will fit all (Robertson, 2008, Galdas, 2005).

5.9. Summary of typology findings.

There is no one type of intervention typology that has a compelling evidence base for effectiveness in both clinical and patient recovery outcomes, a good evidence base for acceptability, and a good program theory.

Adaptation of existing interventions to a new context is best done when a well- developed program theory exists. This allows for identification of what features need to be adapted, and what are the key mechanisms that need to be retained, and if a change in delivery compromises or does not compromise core components of the intervention and how they interact.

Peer support was identified as having the largest evidence base looking at both effectiveness, acceptability, and program theory. The next section takes a more in depth look on peer support program theory, to understand if this can provide use for the development of an complex intervention and support its theory-based development approach.

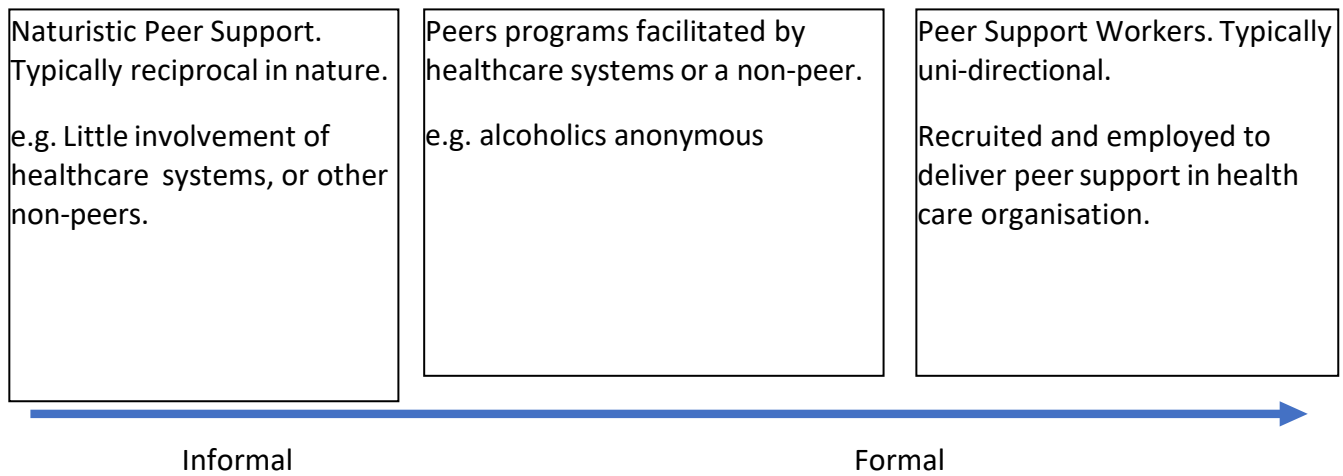
5.10. A focus on peer support in depression.

The use of peer support in mental health is well established. Peer support involves some type of an assisting relationship that occurs between two (or more) people with shared lived experience (Kent 2019).

Key goals of a peer support service in mental health could be empathetically providing low level psychological support, or intervention, such as self-management advice or signposting to resources (Campos, Sousa et al. 2016, Chinman, George et al. 2014).

Although peer support is a multifaceted concept there are some broad distinctions based on the modality of peer support ('group' or 'one to one'), the delivery setting (face-to-face, online) and if it occurs within a continuum of formality. Figure 19 highlights this continuum of formality. While some literature discussed these as theoretically distinct groups (Slade, Amering et al. 2014, Lloyd-Evans, Mayo-Wilson et al. 2014), it is still possible for overlap, and for peer support interactions to occur over a continuum of formality (illustrated in Figure 19).

Figure 19: Peer Support and levels of Formality. The boxes indicate peer support described as distinct formalities. The arrow highlights that formality could also be considered as a continuum.



Evidence looking into the effectiveness of peer support in mental health is mixed. Most reviews combine studies of individual and group face-to-face peer support interventions, within different levels of formalities (e.g. formalised and naturalistic) which may account for mixed findings.

The most consistent finding is that peer support can improve recovery orientated outcomes. In particular peer support can promote hope, (Repper and Carter 2011, Fuhr, Salisbury et al. 2014, Lloyd-Evans, Mayo-Wilson et al. 2014), self-esteem, and self- efficacy (Repper and Carter 2011, Campos, Sousa et al. 2016, Mancini 2018, Burke, Pyle et al. 2019). Peer support can also be empowering (Patrick W. Corrigan 2006, Resnick and Rosenheck 2008), but this is not a significant result in all studies (Burke, Pyle et al. 2019). This same study was also unable to draw conclusions on the effects of peer support on internalized stigma due to mixed results (Burke, Pyle et al. 2019).

Findings have also been shown for clinical outcomes. O'Connell (O'Connell, Sledge et al. 2018) found that peer support interventions delivered to those hospitalised with mood disorders has reduced readmissions. Yet others have found weak evidence or no evidence for this (Lloyd-Evans, Mayo-Wilson et al. 2014). A meta-analysis (Pfeiffer, Heisler et al. 2011) also found peer support caused a small but significant reduction in depression symptoms in depressed patients. Yet systematic reviews found peer support had little or no effect on depressive symptoms (Lloyd-Evans, Mayo-Wilson et al. 2014, Fuhr, 2014).

These conflicting results may in part be due to large heterogeneity on how peer support interventions were delivered (Pfeiffer, Heisler et al. 2011). Heterogeneity on how peer support interventions are delivered, and the multifaceted nature of peer support has led to difficulties in evaluating the effectiveness of peer support. (Lloyd-Evans, Mayo-Wilson et al. 2014, Burke, Pyle et al. 2019).

A narrower systematic review focusing on one-one peer support services within mental health services (formalised peer support) found peer support had a modest positive impact on self-reported recovery and empowerment (White, Foster et al. 2020). There was no significant impact on clinical outcomes (White, Foster et al. 2020). In this systematic review, not all participants included had depression, although all had a mental health condition. Therefore, caution needs to be taken when using this evidence to analyse the effectiveness of peer support in depression. Another caution is that only three studies were in a UK setting, with the majority conducted in the United States of America (USA). Health systems operate differently in different countries (e.g. USA is privatised, unlike the UK). However, these findings give a similar picture to that shown from the broader reviews discussed above.

Peer support can also benefit the peer providing support. Peers that have supported others have had increased sense of self-esteem and self-worth; through being aware they can give something back and feeling needed they can construct a more positive and meaningful identity (Slade, Amering et al. 2008, Kent, 2019, Peersman and Fletcher 2019).

Providing support can also positively influence their own reflections. It can lead to coherence upon their journey, helping them reframe their experiences, and reflect where they are in their recovery journey (Schwartz and Sendor 1999). Overall giving peer support can increase wellbeing, and has been shown to decrease depression symptoms (Lloyd-Evans, Mayo-Wilson et al. 2014, Repper, 2011).

Peer Support Program theory

A core assumption underlying the program theory of peer support is that peer support is a unique form of service delivery, and that the peer support aspect of the interventions make the intervention different when compared to the intervention provided by non-peers.

This seems a reasonable assumption. A peer can acquire an experiential knowledge and an awareness of the recovery journey through their own lived experience and interactions with the health care system (Oborn, Barrett et al. 2019, Austin, 2014). This lived experience is a distinct knowledge. It is different to knowledge acquired from clinical training (Mead, 2006, Oborn, 2019, Kent 2019, Repper, 2011). Similar aspects such as trust, shared lived-experiences, credibility and role modelling are considered to be core aspects of peer support(which could not be replicated within non-peer interactions (Davidson, Chinman et al. 2006, Cook 2011).

Peer support is thought to benefit peers through three mechanisms. A direct effect, by decreasing isolation, and increase information and self-management strategies (Dennis 2003, Repper and Carter 2011, Cabassa, Camacho et al. 2017). Secondly, peer support can provide a buffering effect to stresses by improving attitudes and beliefs (Dennis 2003, Repper and Carter 2011, Cabassa, Camacho et al. 2017). For example, via social comparison a peer can emotionally redefine a stressor viewing it as more normative (Gidugu, Rogers et al. 2015). Thirdly peer support can have a mediating effect on behaviour by providing a positive role model, for example providing an example of recovery can instil hope (Dennis 2003, Cabassa, 2017, Peersman, 2019).

A broader aspect of peer support program theory is that usage of peer support in clinical settings can facilitate recovery-orientated practices, which can be beneficial to care (van Weeghel, van Zelst et al. 2019, Repper, 2011, Slade, 2014). In recent years there has been a shift from a traditional biomedical models of depression treatments to a more recovery-oriented practices within healthcare policy (Shepherd, Boardman et al. 2010).

Disadvantages of Peer support

While giving peer support can be beneficial there are also barriers and potential disadvantages. Work looking at peer support workers, those that are employed as peers to work in a clinical setting, have reported concerns around being overburdened and feeling out of their depth (Rebeiro Gruhl, LaCarte et al. 2016, Chapman, 2018, Vandewalle, 2016).

Providing support can be detrimental or incur costs if the supporter becomes overly emotionally involved in the problems of who they are supporting (Burke, Pyle et al. 2018, Vandewalle, 2016). Ideally peers should be supported to manage or avoid these costs, rather than discouraged from becoming peers due to these potential risks (Rebeiro Gruhl, LaCarte et al. 2016).

The disadvantages of receiving peer support has not been extensively researched (Peersman, 2019, Alvarez, 2015). Yet it may be that there are risks to receiving help (Alvarez and van Leeuwen 2015). Workplace studies have shown it can result in reduced status, independence, and self-competence (Deelstra, Peeters et al. 2003), particularly if the help cannot be 'paid back' (Alvarez and van Leeuwen 2015). It is not clear if these findings are transferable to peer support in mental health. It is however known that people are less inclined to seek help for mental health conditions if they perceive that asking for help could threaten their social status, for example men can delay help-seeking in depression when they see it as a threat to their masculine status (Rice, Aucote et al. 2017, Johnson, 2010, O'Brien, 2005).

Another risk from peer support is the dissemination of inappropriate information and harmful ideas. There are a few well-documented and publicized negative examples, such as pro-anorexia, pro-self harm, and pro-suicide groups that are unregulated, which have resulted in negative health outcomes, including death (Mento, Silvestri et al. 2021,

Mars, Heron et al. 2015, Padmanathan, 2018). The use of facilitators or moderators have been incorporated into some peer support models as a way of managing these risks, and this is a feature often seen in clinical settings (Ali, Farrer et al. 2015).

In summary there are potential risks to peer support interactions, and there are examples of how these risks have been managed and minimalized.

Peer support; is this community pharmacy?

It would be appropriate at this point to reflect if community pharmacy is a suitable setting for a peer support intervention. Is having a peer support scheme delivered through a community pharmacy setting desirable and acceptable to males experiencing depression? There have been no examples of community pharmacy interventions or consultations integrating peer support either in men's depression, or in depression. Therefore, at current these questions are all unknowns, and would require further research.

What does exist however is a growing evidence base for peer support operating within mainstream healthcare, and this has caused both challenges and opportunities (Rebeiro Gruhl, LaCarte et al. 2016).

Challenges are that this can cause 'over-formulization' of peer support, and undermine aspects such as peer support authenticity (Gillard 2019). Yet work exploring integration of peer support into health care systems have shown that integral components and

mechanisms, such as authenticity can still exist when peer support operates within a healthcare setting, and that it has been acceptable (Kent 2019). It would be important that core values of peer support such as mutuality, and valuing experiential knowledge are not compromised when delivered in a healthcare setting (Gillard, Foster et al. 2017).

A key advantage of peer support within the NHS has been that the integration of experiential and nuanced knowledge from lived experience into mainstream healthcare has been credited as a way to support both clinical and personal recovery (Kent 2019). Western healthcare has been criticised for overly focusing on clinical recovery (Slade, Amering et al. 2008, Ng, Bourke et al. 2016). Community pharmacy is a sector that to date has also predominantly taken an illness management approach (Watkins, McKee et al. 2017, Knox, 2016, Knox, 2015, Chong, 2013) and if incorporating peer support can facilitate recovery orientated practices then this potentially could benefit both pharmacy as a sector, and those experiencing depression. Promoting peer support in general has also been put into NHS policy. Therefore, it may be possible that community pharmacy has a part to play in supporting this policy.

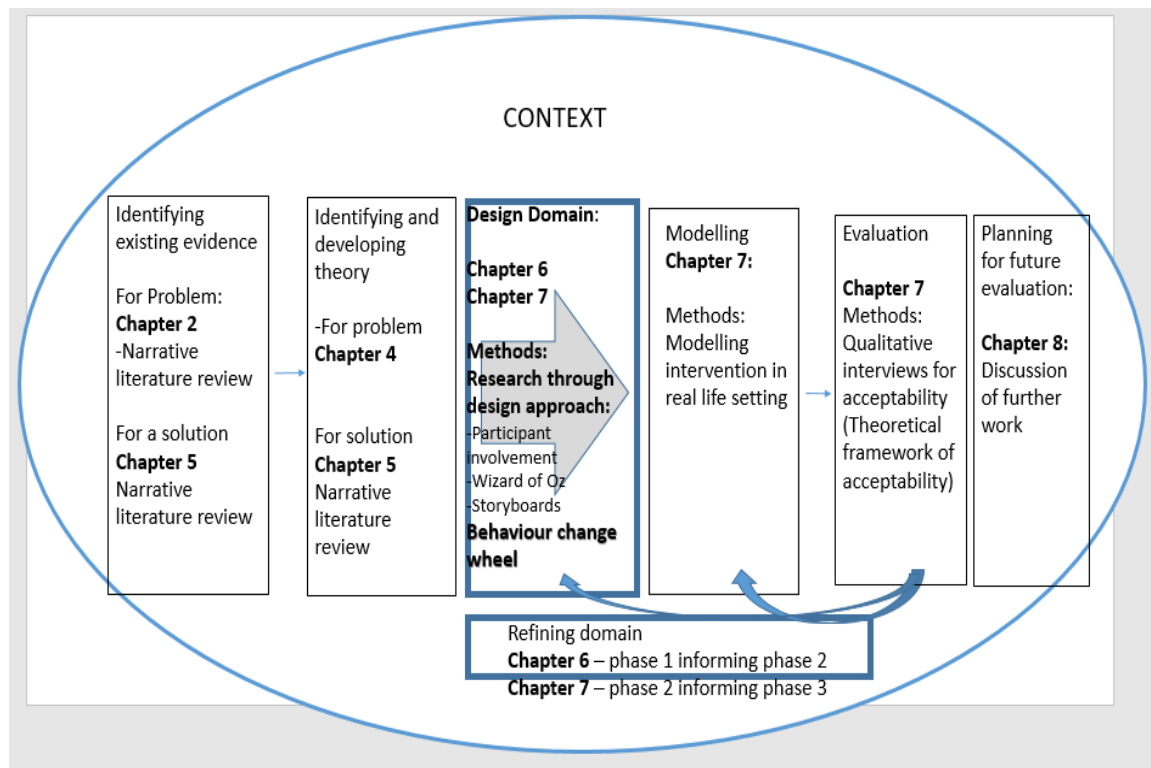
5.11. Summary

In conclusion the work in this chapter has explored the existing literature to identify any relevant interventions and/or program theory that could be used to help underpin the design activities that occur in chapter 6. There was no one typology type that had a compelling evidence base of beneficial personal and clinical outcomes, accompanied by a comprehensive program theory, in the population of interest. Therefore there is uncertainty on what might be key active components to include in the intervention design. Despite this uncertainty active components and program theory of similar populations or settings have been discussed, with a focus on peer support. Chapter 6 will now focus on design, and incorporating behaviour theory into the design to support a theory-based approach to intervention development.

Chapter 6: Design Rationale for the Complex Intervention

6.1. Introduction.

Figure 20: Introduction to chapter 6; highlighting the purpose, and situating it within the thesis schematic.



As highlighted in Figure 20, the work of chapter 6 centres around the design domain, and refining design. While most of the steps in the thesis schematic form part of the MRC guidance, the design domain is absent in the MRC guidance on developing complex interventions, yet it is the belief within this thesis that this is a key stage in development.

Chapter 6 builds on the work of previous chapters and focuses on the intervention design. This is done by using the behavioural change wheel to underpin an research through design experiment.

6.2. Applying the Behaviour Change Wheel in the design process

Figure 21: Stages of the Behaviour Change Wheel

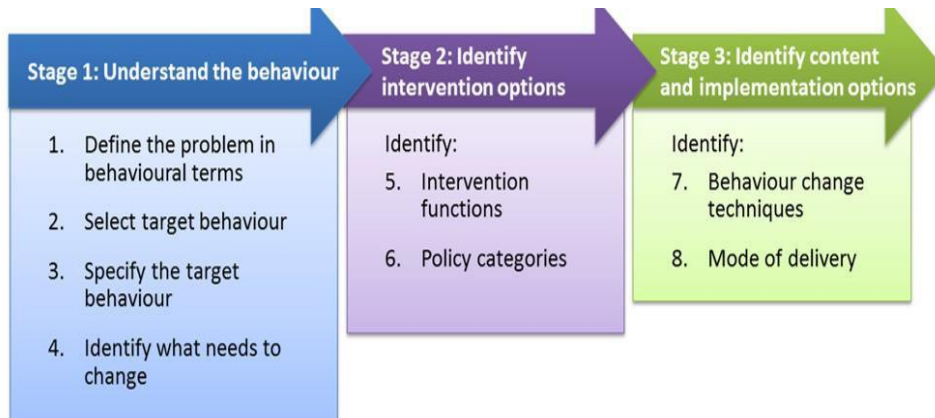


Figure 21 highlights the stages, and subsequent steps for applying the behaviour change wheel process. All steps and stages were followed except for policy categories. The decision to not apply this step was because most policy options were outside of the scope of what this research project could address due to resources and time constraints. The remainder of 6.2 discusses the behaviour change wheel stages and subsequent steps as highlighted in Figure 21.

Applying the behaviour change wheel required various judgments to be made, and each stage and step is discussed below. Judgments were made by the research team, which included a community pharmacist, a male with experience of depression, and a professor of social pharmacy with expertise in leadership of the profession.

Stage 1: Understand the Behaviour

Step 1: Define the problem in behaviour terms

The desired outcome of this complex intervention is that:

Men who have been diagnosed with unipolar depression and have been prescribed an antidepressant to manage this condition (termed the target patients) have an optimal experience with antidepressants. In particular, this intervention seeks to improve recovery-orientated outcomes e.g. empowerment, sense of hope, decreased stigma, and increase access to information and support.

This outcome can be defined and re-expressed as a behaviour term. This is shown in Table 16. Defining a problem in terms of behavioural terms helps to indicate what behaviour(s) to target when designing the complex intervention (Michie, van Stralen et al. 2011).

Table 16: Defining the problem in behavioural terms

Undesirable behaviour	Desirable behaviour
The target patients do not assess the benefits of taking the antidepressants.	The target patients assess the benefits of taking the antidepressants.
The target patients do not identify or evaluate any barriers that may hinder him from initiating or continuing antidepressants treatment, and/or is not able to seek advice and support in relation to these barriers	The target patients identify barriers that may hinder him from initiating or continuing antidepressants treatment.
	The target patients can access advice/support in relation to minimising these barriers.
The target patient does not make an informed decision about using or not using antidepressant medication	The target patients make an informed decision to take (or not take) the treatment as prescribed throughout the treatment period.

Behaviours do not exist in a vacuum. They interact as part of a system. The next step is about considering these behaviours within a system, and selecting target behaviour(s) that the complex intervention focuses on.

Step 2: Select the target behaviour

To select the target behaviour a generation process was done using findings in chapter 4 (primary research) and chapter 2 (literature), and a mind map was used to consider how potential target behaviours interact as part of a behavioural system. Figure 22 illustrates part of this process.

From the list of behaviour changes generated from work in Figure 22, the author made a judgment on how promising the identified behaviours might be to focus on. Each target behaviour was assessed based on the four categories highlighted in Table 17. The intention was that the highest scoring target behaviour areas would be selected for the intervention focus.

Figure 22: Generation of ideas for potential target behaviours while considering systems of behaviours

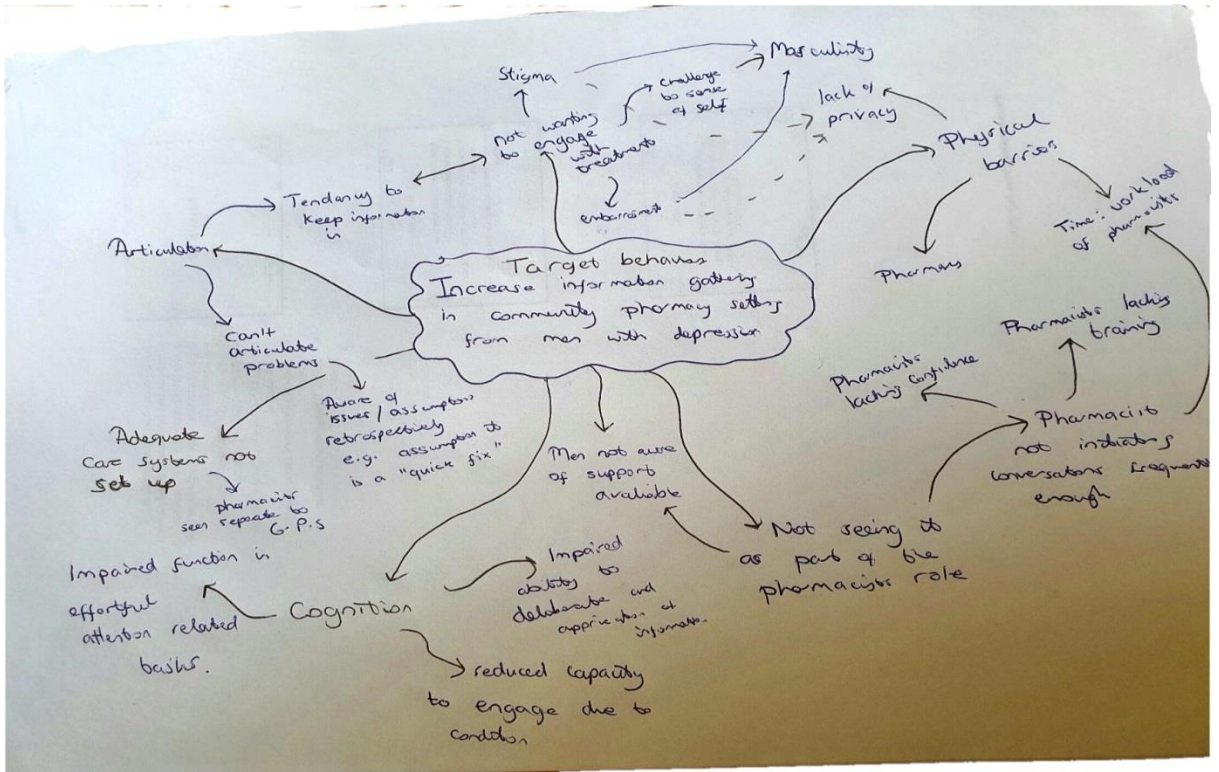


Table 17: Analysis and scoring of potential target behaviours

*Spill over score: Is changing this behaviour likely to have positive effects within behavioural system?

Categories to judge potential target behaviour on, rate then score as:					
Unacceptable =1 Unpromising but worth considering =2 Promising =3 Very promising =4					
Potential target behaviours (as identified from chapter 2 and 4)	Impact of behaviour change	Likelihood of changing behaviour	Spill over score*	Measurement score (How easy to measure?)	Total score
Increase information gathering behaviour of target patient with community pharmacist	promising	promising	promising	unpromising but worth considering	11
Increase information gathering behaviour of patient with peers	promising	promising	promising	unpromising but worth considering	11
Engaging with AD treatment, including information gathering is seen as acceptable and not threatening to one's self-esteem or masculinity	promising	promising	promising	unpromising but worth considering	11
Pharmacist proactively approach men to discuss information/support needs	promising	promising	promising	unpromising but worth considering	11

GPs and pharmacists use formalised communication channels to link patient care	promising	unpromising but worth considering	promising	unpromising but worth considering	10
Increase target patients cognitive ability to function in tasks requiring effortful attention	promising	unpromising but worth considering	promising	unpromising but worth considering	10
Men given opportunities to discuss medication/ concerns (or re-discuss following a GP consultation) with pharmacist	promising	promising	promising	unpromising but worth considering	11

There is no limit on the number of behaviours that can be specified to change, however it is advised to limit the intervention to just targeting a few behaviours (Michie, van Stralen et al. 2011). The risk of targeting too many behaviours is that interventions become over complicated or unfocused (Michie, van Stralen et al. 2011). The results showed that no potential target behaviours were a clear priority. Most were a combination of ‘promising’ and ‘unpromising but worth considering’. As there were no clear priority areas judgments were made by author on those that scored the highest as to which would be the target behaviour areas for the intervention focus. Four target behaviours were identified and these were further specified using behaviour clarification as highlighted in Table 18.

Step 3 Specify the target behaviour

It was decided to focus on four behaviours for the intervention (these 4 behaviours have some degree of overlap). These behaviours are further specified in Table 18. One of these target behaviours had more of a cognitive focus than a behaviour focus. This the behaviour No 4: ‘Engaging with treatment (including seeking advice) is not threatening to target patients’ self-esteem, or masculinity, and is viewed as beneficial’.

Step 4 Identify what needs to change, using the COM-B model.

The COM-B framework can be used to identify what behaviours need to change, and this underpins the design. The work in chapter 2,4 and 5 is used to identify what behaviours are relevant and linked to the COM-B model for the four target behaviours specified in Table 18. This work is presented in Table 19. Alternative behaviours are also considered as behaviours operate within a system. During this process ideas were also generated, and they also feature in Table 19.

Table 18: Specifying the target behaviour. Key: AD= antidepressants

Target behaviour	1	2	3	4
	The target patients reflects on any concerns or assumptions about initiating or continuing AD	The target patients identifies barriers that may hinder him from initiating or continuing AD treatment.	Community pharmacist provide the target patients with opportunities to discuss medication and minimise identified barriers	Engaging with treatment (including seeking advice) is not negatively impactful to target patients' sense of self (e.g. not damaging to one's self-esteem, target patient does not self-stigmatise etc.)
Who needs to perform the behaviour?	The target patients	The target patients	Community pharmacist	Engaging with treatment
What do they need to do differently to achieve the desired change?	Reflect on information or support needs Know what are their information or support needs	Know their information or support needs Articulate information or support needs Identify barriers	More proactive or routine offering of service or opportunities for discussion. Services positioned as part of NHS collaborative care. Package consultation in gender sensitive ways e.g. task focused, rather than discussing emotions Recovery orientated consultations ? Incorporating lived experience into consultations	Reflect and identify any negative emotions or views (e.g. threat to masculinity, embarrassment etc.) Reframe any stigmatized views ? Access peer support to normalise situation, and increase sense of hope
Where do they need to	Community pharmacy	Community	Community pharmacy	Places where medication taken or discussed.

do it?	setting.	pharmacy setting.	setting (NB this can be remote i.e. telephone)	? In a system that can enable peer to peer interactions
When/how often?	When target patient initiating AD treatment. During patient AD treatment particularly at points when reviewing treatment options	When newly starts AD, also at adhoc time points once stabilised on AD therapy	When target patient initiating treatment. During patient AD treatment particularly at points when reviewing treatment options or plans	When newly starts AD, also at adhoc time points once stabilised on AD therapy
With whom do they need to do it?	Alone With pharmacist/ HCP	Alone With Pharmacist/HCP	With target patient	Alone With peer if needed

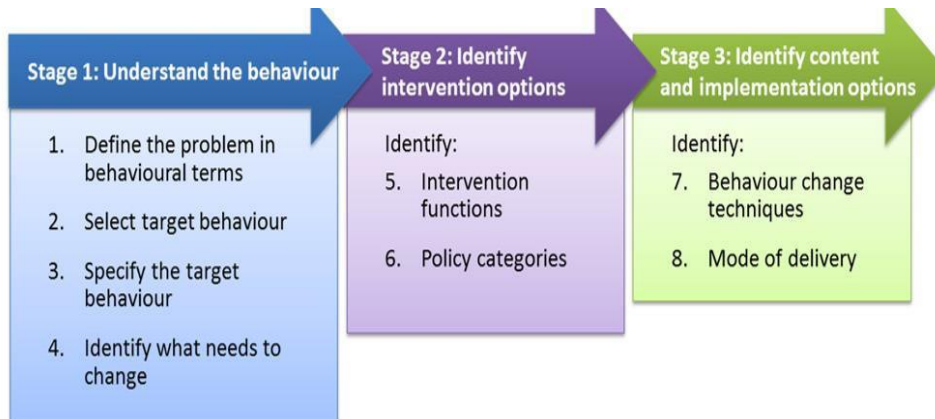
Table 19: Identifying what needs to change, using the COM-B framework.

COM-B component		Consideration of behaviour Key: (-): Alternative behaviours that might be competing with target behaviour. CP: Community pharmacist	Target behaviour relevance			
			1	2	3	4
Capacity	Physical capacity (e.g. physical skill, strength etc.)	Unlikely to be significantly important. Would be important if patient has a physical disability that affects ability to communicate or get to pharmacy and community pharmacist should seek to make appropriate adaptations.	N/A – assuming community pharmacy can make relevant adaptations as per disability requirements.			
	Psychological capacity (e.g. knowledge or psychological skills to engage in mental process)	Participant supported in engaging in analytical reflection of information needs as this ability can be hindered in depression. (-) Participant may favour actions that have a lower cognitive load i.e. just taking antidepressants, rather than discussing taking them	✓	✓		
		Men know that part of the pharmacists role is to support them with their medication, and condition, and that this is in partnership with other CPs		✓	✓	✓
		CP know that target patients could benefit from discussions about their views/concerns around ADs (-) CP lack confidence in their abilities			✓	
		CP have skills, confidence, and training to have gender sensitive discussions with men around their views of AD treatment			✓	
Example Ideas: -A service such as peer support where insights or information realised from experience can be shared						

-The target patients identifies barriers that may hinder him from initiating or continuing AD treatment.						
COM-B component (cont.)		Consideration of behaviour (cont.)	1	2	3	4
Opportunity	Physical Opportunity	Have private consultation rooms/ privacy (-) Consultation rooms busy or not used	✓	✓	✓	✓
		Time available with pharmacist			✓	✓
	Social opportunity	Create a favourable social context and opportunities for men to engage with pharmacist. (- For men fitting a model of hegemonic masculinity this social opportunity should not threaten one's masculine status	✓	✓	✓	✓
		A trigger moment, or dedicated time/space for target patients to reflect on information or support needs	✓	✓		✓
		Have support from others to engage in target behaviours (e.g. significant others, other CPs etc.)	✓	✓	✓	✓
		Have access to both professional knowledge and lived experience/tacit knowledge		✓	✓	✓
<p>Example ideas</p> <p>A service run from the pharmacy which operates in private area (e.g. consultation room)</p> <p>Create routine, or established service within a favourable, gender sensitive social context.</p>						

COM-B component (cont.)		Consideration of behaviour (cont.)	1	2	3	4
Motivation	Reflective motivation (self conscious)	Target patients feel they want to discuss their medication or concerns and understand potential benefits of doing so (or disadvantages of not doing) (-) target patient does not want to discuss AD medication	✓	✓	✓	✓
		Target patients and CPs understand that there is benefit in discussing concerns at any stage of treatment (e.g. not just at start)	✓	✓	✓	✓
		CPs are in routine of supporting target patients and have a strategy for how to do it (i.e. can offer a specific service etc.)			✓	
	Automatic motivation	Reduce emotional reactions to taking ADs e.g. sense of feeling needs to take AD as at rock bottom etc, helping men see that they do have a choice to take ADs (-) Target patient driven by negative emotions	✓			✓
<p>Example ideas</p> <p>-Positive role modelling, giving sense of hope to those newly starting</p>						

6.3. Stage 2: Identify intervention options



Step 5: Intervention functions

After identifying what needs to change to enable the behaviour, the advice is to also consider the full range of intervention options. Michie et al. (Michie, van Stralen et al. 2011) have developed a matrix of links between COM-B and intervention functions. This work has been adapted and presented in Table 20. All shaded areas represent areas where Michie et al. have linked as relevant intervention functions. The darker shaded areas represent areas where the intervention function is likely to be more promising as an intervention option. Table 21 justifies these judgments using the APEASE criteria, which are affordability, practicality, effectiveness, acceptability, safety, equity.

Informed by the behaviour change wheel, the core functions of the intervention would be education, environmental restructuring, enablement, and modelling. These intervention functions will underpin the next stage of the design work (section 6.2). Step 3 further identifies what behaviour change techniques could feature in an intervention based on the intervention functions.

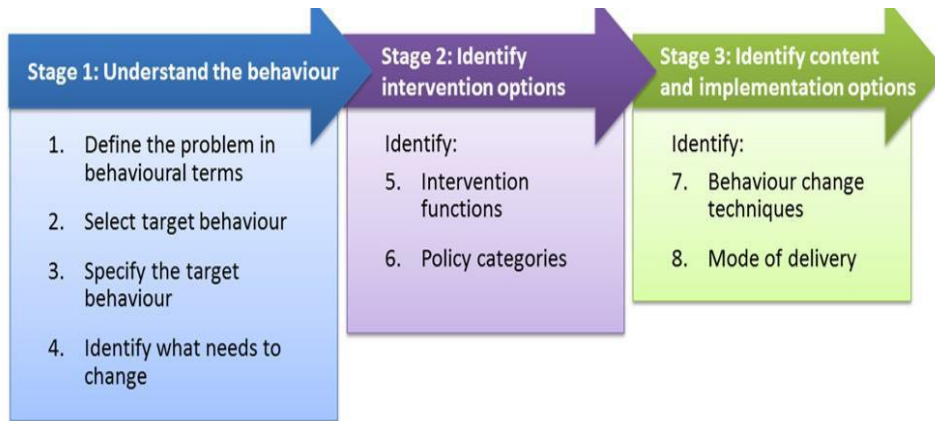
Table 20: Matrix of links between COM-B and intervention functions, adapted from Michie et al. 2011

		Intervention Functions								
		Education	Persuasion	Incentivisation	Coercion	Training	Restrictions	Environmental Restructuring	Modelling	Enablement
COM-B components	Physical capacity									
	Psychological capacity									
	Physical opportunity									
	Social opportunity									
	Automatic motivation									
	Reflective motivation									

Table 21: Evaluation of potential intervention functions judged using the APEASE criteria.

Intervention function	Judgments considering APEASE criteria
Education	Potential to be acceptable, effective and affordable.
Persuasion	Unlikely to be effective as less acceptable in this context/setting, little detail on how to do ethically.
Incentivisation	Potential issue with managing equability and affordability issues.
Coercion	Not acceptable in community pharmacy setting.
Training	Yes – although not suitable for target behaviours 1,2 or 4.
Restrictions	Not practical – no options to restrict in this context.
Environmental Restructuring	Yes – particularly around privacy issues – likely to be cost effective as private areas exist.
Modelling	Likely to be effective and acceptable.
Enablement	Potential, although less clarity on what this could be as a practical service provision.

6.4. Stage 3: Identify content options



Step 7: Identify the behaviour change techniques.

Step 7 gives more clarification about what components may be important to include in a complex intervention. Michie et al. have a long list of behaviour change techniques that can be considered for an intervention function (see: (Michie, Atkins et al. 2014)). From this list some behaviour change techniques have been chosen.

These choices were based on what aligned with the conclusions from Chapter 5. The core conclusion from chapter 5 was that no intervention type was identified as having a compelling evidence and good program theory, particularly not in the setting or population of interest. Despite this, findings from chapter 5 were still able to offer some direction. Specifically that an intervention should be multifaceted, featuring multiple intervention functions, and be gender sensitive. A peer support service was also identified as a potential direction.

Table 22 highlights the chosen behaviour change techniques, and these will underpin the design parameters in section 6.2, where a RtD approach is used to generate knowledge and present an intervention protocol as part of a research contribution.

Table 22: Chosen behaviour change techniques to underpin intervention design

Intervention function	Potential behavioural change techniques chosen
Education	Information about health consequences Feedback on outcomes of the behaviour
Environmental restructuring	Restructuring the physical environment (or use of the environment)
Modelling	Demonstration of desirable behaviour
Enablement	Social support Problem solving

Step 8: Consider mode of delivery

The final stage of the behaviour change wheel is to consider the mode of delivery. Considerations are whether it could be delivered face-to-face, or at distance, and at what level i.e. population level, individual level. As a peer support intervention had been identified as a potential intervention, this step focuses on the mode of delivery of a peer support intervention.

As shown in Table 23 a face-to-face mode of delivery may be problematic within a community pharmacy setting due to space, and this would not be cost effective to rectify. Another potential mode of delivery is distance, using remote consultation.

At the time this research was being designed and conducted (pre COVID-19) remote consultations were not the norm (Brant, Atherton et al. 2016), although the technology to do remote consultations existed. There had been some healthcare studies that had explored remote consultations (Marziniak, Bricchetto et al. 2018, Lamb, Pachana et al.2019) but there was relatively little data and guidance on conducting remote consultations in primary care healthcare settings (Brant, Atherton et al. 2016, Donaghy, Atherton et al. 2019).

Due to pragmatic responses to COVID-19 i.e. legally enforced lockdowns and social

distancing, there was a rapid increase and normalization of remote consultations, both within the work place setting, within social settings and within healthcare. Since 2020 NHS England and NHS Improvement published guidance on using online consultations in general practice (England, 2020). Similarly pharmacy specific training on remote consultations have been made part of core training within the community pharmacy contractual framework quality scheme (PSNC, 2022).

Remote consultations offer potential benefits such as flexibility, easier access, cost and time savings, and can offer a way that larger groups can meet without the need for a large physical space, or the need to be in the same geographical location.

Table 23 Consideration of mode of delivery for a peer support service in a community pharmacy setting.

Mode of delivery		Does the mode of delivery meet the APEASE criteria?:	
Face-to-Face	Individual	<p>Limited private space.</p> <p>Face-to-face peer support requires peers in close geographical proximity. This may not be desirable.</p> <p>Benefits are that face-to-face is a natural method of communication, and supports physical interactions.</p>	
	Group		
Distance	Population level	Broadcast media (TV,radio)	<p>Not relevant mode of delivery as will not be able to address the multiple identified behaviour change techniques.</p>
		Outdoor media (Posters, billboards)	
		Print media	
	Digital media	<p>Potential, however individual level more likely to be appropriate.</p>	
	Individual level	Phone (e.g., help lines, text services)	<p>Would need participants to have a phone, otherwise equity concerns. Would need to consider data security if personal phones used to interact with a peer.</p> <p>Distance increases the pool of potential service users for a peer support service.</p>
	Individually accessed computer program	<p>Consideration of costs to set up/design, although running costs tend to be lower.</p>	

There are potential limitations with remote consultations. Firstly there is a need for internet to access remote consultations. There is the concern raised that because of this, remote consultations risk increasing health inequalities (Parker, Figures et al. 2021). People with mental health problems have been shown to have poorer access to internet, including no internet access compared to those without mental health problems (Robotham, Satkunanathan et al. 2016, Too, Leach et al. 2020). Therefore this may be a particular issue to consider for this population.

Another issue is data security. There is a higher risk in remote multi-user systems of data entering the public domain. It is assumed this would be an unlikely outcome, but the potential for this risk could be an off-putting barrier for those who desire stronger data security. The findings from chapter 2 and 4, specifically phenomena of secrecy and stigma in men's depression suggest that data security may be particularly important to consider.

Another potential mode of delivery for this service is to be part face-to-face, and part distance, using remote consultation for the peer support element but having the data accessible within the community pharmacy. This then places control of data within community pharmacy networks. This addresses the issue of those without access to the internet, or are unable to access in a confidential location, and it means greater control of data which may be important for some target patients. It also keeps the interactions with the community pharmacist as face-to-face interactions. This would be (at the time this study was designed) the normative way of communication. It may be appropriate to keep these interactions between target patient and community pharmacist as face-to-face as this mode is more suitable for complex discussions (Donaghy, Atherton et al. 2019). A behaviour target of this intervention is to facilitate discussions and reflections, which is a complex process. A possible design parameter for the mode of delivery is to explore face-to-face community pharmacy consultations with remote peer interactions to incorporate lived experience elements into community pharmacy consultations.

Remote consultations can be synchronous or asynchronous. A significant benefit of asynchronous communication is that it allows increased flexibility with scheduling compared to remote synchronous communication, and this can facilitate work flow and save time (Jhala and Menon 2021). Work considering facilitators and barriers to community pharmacy service implementation has often advised potential designers to consider the barrier of time, and how to minimise these issues (Weir, Newham et al. 2019, Hattingh, Sim et al. 2020). An asynchronous peer support potentially could be easier to implement. Therefore asynchronous communication will feature as a design parameter.

Asynchronous communication is not suitable in urgent situations because there is a time gap in the communication (de Jong, Ros et al. 2014). Therefore it needs to be considered if any urgent information may be addressed in this service. The hybrid approach (also using face-to-face) could negate this concern.

Another benefit of asynchronous communication is that it offers the potential to limit forms of harm from peer interactions. There have been some particularly high-profile examples of damaging peer support messages, for example pro anorexia ('ana') websites (Mento, Silvestri et al. 2021) self-harm messages, and pro-suicide networks (Mars, Heron et al. 2015, Padmanathan, 2018). These forms of harm would not be expected in a peer support service, however it is possible. In an intervention developed around therapeutically sharing recovery narratives developers spoke about how occurrences did happen where they had to make judgments and exclude some narratives as it was considered that it could cause a form of harm (Slade, Rennick- Egglestone et al. 2021). Having asynchronous communication allows this safety netting over this potential form of harm. Therefore this reasoning, and mainly the opportunities that asynchronous communication brings justifies why asynchronous remote communication will be set as a design parameter.

6.5. Conclusion following the behaviour change wheel:

This is an exploratory study. At this stage of the study the intention was to set design parameters, rather than make decisions. Therefore the design parameters are that intervention should be multifaceted, and seeks to lead to the following behaviours:

- Community pharmacist provides the target patients with opportunities to discuss medication.
- Male prescribed antidepressants reflects on any concerns or assumptions about initiating or continuing antidepressant treatment.
- Male prescribed antidepressants identifies barriers that may hinder him from initiating or continuing antidepressant treatment.
- Engaging with treatment (including seeking advice) is not negatively impactful to patient's sense of self.

These could be achieved by creating a service for community pharmacists and male patients to interact. This can be used as a platform for these patients to reflect on their information needs. Based on the behaviour change wheel this will involve environmental restructuring, where a community pharmacist restructures how they use the environment (i.e. invite men into consultation rooms). It should also involve enablement (i.e. creating this social opportunity for men to have a discussion with the community pharmacist), providing an opportunity to reflect on any concerns or assumptions. Findings from chapter 4 suggest such interactions do not always happen, and men's psychological state may hinder this from happening. Men also reflected on things they had learned that may have been useful to know at the beginning, but it was only through experience that they were able to know this useful knowledge. Potentially the incorporation of a peer support scheme, or incorporation of experiential lived experience into community pharmacy

consultations may be beneficial for this reason.

This further links into enablement, as findings from chapter 2 and 4 suggest men do not have easy access to this support. This could involve education, information about health consequences and feedback on outcomes of the behaviour. It can also involve modelling and demonstration of desirable behaviour i.e. normalisation of taking antidepressants, and normalisation of having problems or needing to ask questions about medication.

Problem solving may also be an useful behaviour technique. It is important this can be delivered in a gender sensitive way.

Based on work in step 8 of the behaviour change wheel, having a face-to-face peer support service within a community pharmacy setting could be problematic. A potential design idea could be to deliver face-to-face community pharmacy consultations that included remote interactions to incorporate peer elements or lived experience elements into community pharmacy consultations. A design prototype will be explored using RtD based on these design parameters.

6.6. Lessons learned from rejected approaches; intervention mapping and its contribution to this thesis.

This brief section highlights an initial, and later rejected, method termed intervention mapping. Intervention mapping is a protocol to aid development of health promotion interventions. It promotes a theory and evidence based approach (see <https://interventionmapping.com/> for further details).

In this thesis intervention mapping was rejected as it was difficult to move on from intervention mapping towards a design, and have it underpin the design prototype. In comparison the behaviour change wheel was more practical, and encouraged the consideration of behaviours as a system, and to systematically consider all intervention functions, before identifying most promising intervention functions.

Although intervention mapping was a rejected method, the work on creating the matrix of objectives did help influence the design process by providing clarity and articulation about objectives for the complex intervention, and this work was later used in step 1 in the behaviour change wheel process. The matrix of objectives is presented in Table 24. Work by Santana et al. (Santina, Lauzier et al. 2018), who developed a community pharmacy based intervention to optimise patients use of antidepressants was particularly influential in helping articulate change objectives, and this was used to help create the matrix presented below.

Table 24: Matrix of objectives. KEY: AD = Antidepressants HCP= Healthcare professional.

Performance Objectives	Influencing Factors for target patient: Male with depression prescribed antidepressants.			
	Knowledge	Attitude	Self-Efficacy	Intention
<p><i>Target patient makes an informed decision to initiate AD</i></p>	<p>K1. Target patient knows that he can speak to a pharmacist if he has any information or support needs.</p>	<p>A1. Target patient recognizes potential benefits of consulting with a pharmacist at different points during treatment.</p>	<p>SE1. Target patient can recognise potential psychological or social barriers that may hinder him from taking AD as prescribed and able to address or reframe these barriers.</p>	<p>I1. Target patient expresses a positive intention to initiate treatment.</p>
	<p>K2. Target patient knows the general mechanism of action of the AD.</p>	<p>A2. Target patient believes taking antidepressants is not a cause for self-stigmatization, nor a threat to one's masculinity.</p>		<p>I2. Target patient expresses neutral or positive views around antidepressants as a therapy.</p>
	<p>K3. Target patient knows the different phases of treatment.</p>	<p>A3. Target patient has realistic expectations about the benefits of the ADs and duration of treatment.</p>		
	<p>K4. Target patient knows the non-pharmacological measures that may be used in addition or as an alternative to AD.</p>			
	<p>K5. Target patient knows potential benefits of AD and when it is expected they may occur.</p>			
	<p>K6. Target patient knows possible side effects of AD, and approx. how likely they are.</p>			

<p><i>Target patient assesses benefits of taking AD.</i></p>	<p><i>K1, K2, K3, K4, K5, K6</i></p>	<p><i>A1, A2, A3</i></p>		<p><i>I1, I2</i></p>
		<p>A4. <i>Target patient is able to perceive benefits of taking antidepressants and weight these against any costs (e.g. side effects).</i></p>		
		<p>A5. <i>Target patient recognises benefits of taking the AD as prescribed throughout the treatment period.</i></p>		
<p><i>Target patient makes an informed decision to persist with AD for treatment duration OR to switch treatment as appropriate with HCP</i></p>	<p><i>K1, K2, K3, K4, K5, K6</i></p>	<p><i>A1, A2, A3, A4, A5.</i></p>	<p>SE2. <i>Target patient identifies strategies to overcome these side effects and makes use of them.</i></p>	<p>I3. <i>Target patient expresses intention to continue the treatment despite side effects OR expresses intention to explore other options with community pharmacists</i></p>
	<p>K7 <i>Target patient identifies any side-effects the experiences from the AD.</i></p>			
	<p>K8 <i>Target patient knows the potential risks associated with premature discontinuation of AD treatment.</i></p>			
		<p>A6. <i>Target patient recognizes the benefits and barriers of continuing the treatment for the prescribed period.</i></p>	<p>SE3. <i>Target patient identifies barriers that may hinder him from continuing treatment</i> SE4. <i>Target patient identifies strategies to overcome these barriers and makes use of them</i></p>	<p>I4. <i>Target patient expresses a positive intention to continue treatment until review OR expresses intention to explore other options</i></p>

6.7. Phase 1: Pre-pilot sensitizing study using iterative modelling and thinking aloud method; the design decisions and learning points.

Introduction and aims

This section focuses on phase 1 (pre-pilot). Phase 1 work is a key part of the design domain and uses a RtD approach. The design work in phase 1 will be used to develop the intervention used in phase 2 and 3.

Another purpose of phase 1 is to evaluate a method called the retrospective think-aloud method, and its suitability for use in phase 3 (modelling out the intervention in its real life context). The retrospective think-aloud method involves participants watching back their participation in various intervention designs and talking through their thoughts, and cognitive processes. It is a form of a method termed think-aloud, however the retrospective method is performed shortly after the event, so not to interrupt the task performed. The benefit of this approach is that it can provide insights. The variation on the traditional think-aloud method makes it less obtrusive to the task. While retrospective think-aloud has been termed as a variation on think-aloud, there is some interchangeability, with some experiments utilising the think-aloud method straight after tasks, or a hybrid approach, rather than concurrently (Sadasivam, Delaughter et al. 2011, Alhadreti, 2018, Paz and Pow-Sang 2015). Think-aloud, and retrospective think- aloud methods, have been used in intervention development and pharmacy research (Pasterfield, Clarke et al. 2019, Sadasivam, 2011), and its suitability as a method will be considered in this subchapter (see aim 3 below).

In summary the aims for Phase 1 are:

- Aim 1: Using RtD approach to help describe if any rationale, theory, or goal of the elements could be essential to the intervention design.
- Aim 2: Make design decisions on modes of deliveries, procedures, and activities for the complex intervention that will be further explored in phase 2 and 3.
- Aim 3: Decide if the think-aloud method should be a method used in later phases of the study design.

Method and ethical considerations

Ethical approval was given from the University of Nottingham School of Pharmacy ethics. Participants were recruited via poster recruitment in the University of Nottingham. Eligible participants were those who were healthy males, 18 years or older, who identified as being 'stressed' or having experienced 'stress'. All participants were given a participant

information sheet (appendix 7) explaining the study, and signed consent before participating (appendix 8). They received a £5 voucher for participation. This was also run as part of an MPharm student dissertation project. Participants were aware of this.

Three participants were recruited. A fourth participant made initial contact but did not partake in the study. Two participants disclosed during the study that they had experience of using antidepressants to treat depression.

Initially a small focus group discussion was held with participants, lead researcher (thesis author and a pharmacist) and assistant researcher (the MPharm dissertation student).

Participants were asked to contribute to a potential intervention design, and model out potential protocols for the design of a peer support scheme operating within a community pharmacy setting. They were given the design parameters identified in chapter 6.1 and encouraged to discuss potential protocol designs, which they would then model. Following this focus group, 4 design models were identified and participants modelled out these different protocol designs for this service (see Table 25 for overview). Participants were either a peer 1 (a peer newly starting antidepressants) or a panel member (a peer with more experience of taking antidepressants).

Table 25: Design ideas modelled out in study

Protocol design ideas for remote communication:	
Design 1	Panel member records a reflective video of their experiences with antidepressants and depression. Peer 1 watches this video and remotely feedbacks to panel member what aspects useful to them/why. This process integrated into community pharmacist consultations
Design 2	Peer 1 records a question to panel member, shown to panel member, who responds, peer 1 watches response and sends 'thank you thread' to panel member. Process is integrated into community pharmacist consultations.
Design 3	Platform to access a peer reflection, matched to certain characteristics or certain side effects pertinent to them from a collection of videos or audios. This is a signposting tool to be used in community pharmacy consultations
Design 4	Variations of above designs using audio and/or writing (i.e. no visual communication)

Participants were put in different rooms and interacted with each other via asynchronous recordings. In each room there was either the PhD author or the dissertation MPharm student who role played being the community pharmacist. The 'Wizard of Oz' approach was used throughout the modelling which means favouring using low cost, easy to implement techniques that simulates more complex prototypes or systems at the design stage, particularly when some designs were problematic to model out quickly or inexpensively. For example in design 3 it was not possible to make an interactive website. Instead a PowerPoint presentation was used to simulate a website and research team were able to add headings as relevant to give the impression of a populated website. Similarly to mimic a system where data could be securely transferred, stored, and destroyed, recordings were done using camera recording onto a SD card and the researcher team transferring the SD cards to the different rooms, and then securely deleting them. This avoided the need to program an appropriate system before designs could be trialled.

Participants were recorded while modelling the intervention designs. After completing the peer support interactions participants were asked about their views of the different approaches. They were also asked to vocalise their thought processes during the intervention, while watching the process back on video. All participant's feedback was audio recorded, transcribed, and coded.

Results and discussion for intervention design

Findings from the initial focus group:

Peer support, and peer support operating within a community pharmacy setting was seen as a promising intervention by all participants. However, an important learning point that came about through the designing is the need to navigate around a resistant mind-set.

Participant 3 "I've found that you have a mind-set where you don't want to listen "

This needs to be considered within the design. Participants spoke about a tendency of not listening, 'disengagement triggers' and not wanting to reach out to others when depressed. 'Disengagement triggers', were described as any unauthenticity from service providers, such as 'tick box' filling exercises or 'scripts' , or sensing peer support as reinforcing 'categorisation' or unauthenticity.

Participant 1 “.I had to talk to a counsellor and they would tell me the same thing over and over and over again, and would be the same facts, and they would be reading off a script, and that is similar situation when you see a questionnaire, and that’s how I would see it as; it’s a script, it’s one of those standard things that to go through.”

While peer support could be of value care would need to be taken to not trivialising one’s experience, or the complexity of their situation by suggesting what makes someone a ‘peer’ is that they have depression.

Participant3: “Telling me that you’re telling someone that someone else has it or it’s something that people go through, I see it as a categorisation yet again. Yes, just like saying ‘it’s one of those things’ , in fact I would see it as I’m not interested by it “

Findings from modelling and comparing Designs 1-4 (see table 25)

The findings from modelling out the designs suggested in the initial focus groups enforced the key learning discussed above; a need to navigate around a resistant mind set in depression. Participants favoured designing peer support interventions that had a clear link to a purpose, and supporting another. Specifically a design focusing the peer support task on helping another, and having tailored interactions, focused around specific questions was seen as a way to navigate around a resistant mind-set, and therefore facilitate engagement. This led to participants being more focused and engaged in intervention designs where they could see that their engagement benefited someone else. For these reasons both design 1 and 2 were preferred.

Participant 3: “You can easily just say ‘yeah fine, fine’ but if you know you're talking to someone else who is possibly going to benefit, and you know that it is going to help them in some respects then it helps you to talk, it helped me talk because there is the motive at the end of it. – “

A second important learning was that design 2 was preferred to design 1 and 3. In design 1 and 3 a peer support video was created without this being targeted to a known peer. This was problematic. Firstly, it led to unstructured and non-personalised responses.

Secondly, and particularly for design 1, there was concern that this structure led to negative wellbeing. By recalling experiences, some participants negatively ruminated, and the unstructured task was attributed as a reason for this; it was too demanding to produce a video without knowing how to focus the video, and to whom they were aiming the video at.

Participant3: “[Design 2] wasn't like reminiscing, it was more like I'm saying what I said. It wasn't going into depth, whereas the [design 1] can end up going into depth because there was no structure nothing to tell me what to do and when, so you can end up going on and on and on and going deeper and deeper and deeper and that way it's (laughs) it sort of makes it all really weird and you get to a stage where you're like I can't continue any more and you don't like it, whereas this way it was better”

While design 1 was preferred there were some improvements suggested. When no guidance was given to the participants on how to structure the peer support videos, or clarity on the purpose of the peer support interactions it led to difficulties and hesitations. This led to frustrations or dissatisfaction for both peer 1 and panel member upon hearing the responses. Some level of facilitation would be an important aspect of the design; it was important that peers were prompted to give enough information and clarity on their question, and also facilitation for the peer who was responding as a panel member.

Participant2: “It was just telling me how the drug works but then again that could be because when I gave my first video I didn't know what to say because I could have given him more background on what I was doing and everything else, the whole situation here, but he responded to what I have said which was about the medication and me being scared of that medication and not knowing what it was do, and I

didn't give him enough information, so clearly he answered to what I have said. "

Design 4 was a variation of the designs 1-3 but by using different interaction formats (e.g. video, audio, written text). Participants valued the concept of a peer support scheme, yet spoke about designing aspects to protect their identity, such as not showing their face, pixilation of their face, and need for secure data transmission.

Interestingly when participants went about the design and modelling process all did opt to show their face, however it was emphasized that a having options was an important feature of a preferred design. Therefore an asynchronous peer support scheme could primarily feature communication via asynchronous video, but it would also be important to provide options, and take steps to protect participants' confidentiality.

The key learning points and design decisions are summarised in Table 26, and Table 27 which demonstrates how learning points lead to design decisions.

Table 26: Key learnings linked to design prototypes

RtD activity	Key learning points:
<p>Initial focus group: Focus group between researcher (pharmacist), assistant researcher (student pharmacist) and 3 men identifying as experiencing stress</p>	<ul style="list-style-type: none"> • Peer support service using remote communication in community setting could be promising. • Disengagement needs to be considered in design; avoid ‘disengagement triggers’. • The need navigate around a resistant mind-set.
<p>Design 1: Panel member records a reflective video of their experiences with antidepressants and depression. Peer 1 watches this video and remotely feedbacks to panel member what aspects useful to them/why. Integrate into community pharmacy consultations.</p>	<ul style="list-style-type: none"> • The connection to supporting another favourable - facilitate navigating around resistant mind-set. • Task focused favourable – way around resistant mind-set. • Concern that this design could lead to negative wellbeing through reminiscing – by asking the peer to recall past events lead to unstructured recall of experiences and negative mind-set.
<p>Design 2: Peer 1 records a question to panel member, shown to panel member, who responds, peer 1 watches response and sends ‘thank you end thread’ to panel member. This process is integrated into a community pharmacist consultation</p>	<ul style="list-style-type: none"> • A focused peer support intervention linked to a purpose, and supporting another is a potentially beneficial design. • Requirement for some level of structure and facilitation
<p>Design 3: Platform to access a peer reflection, matched to certain characteristics or certain side effects pertinent to them from a collection of videos or audios. This is a signposting tool to be used in community pharmacy consultations</p>	<ul style="list-style-type: none"> • Concern that may not support authentic interactions – risk of ‘categorisations’ and felt more likely to lead to disengagement compared with design 1 and 2.
<p>Design 4: Variations of above designs using audio and/or writing (i.e. no visual communication)</p>	<ul style="list-style-type: none"> • Disclosure of mental health status is a concern for some. • Having options for how to interact can help alleviate some concerns. • Showing face is acceptable to some.

Table 27: Mapping the key learning points to design decisions:

	<i>Key learning points:</i>		<i>Design decisions:</i>	
Initial focus group	Peer support service using remote communication in community setting could be promising.	→	Continue to focus design around remote asynchronous peer support service and mock out using Wizard of Oz technique the 4 designs ideas discussed in the focus group.	1
	Disengagement needs to be considered in design; avoid 'disengagement triggers'.	→	Remove questionnaires matching peers to panel members Protocol design having a peer asking a tailored question, and a second peer giving a tailored response is favoured design.	2
	Navigate around a resistant mindset- important feature for design.	→		
Design 1	The connection to supporting another favourable - facilitate navigating around resistant mind-set.	→	Protocol design having a peer asking a tailored question, and a second peer giving a tailored response is favoured design.	3
	Task focused favourable – navigating around resistant mind-set.	→		
	Concern that this design could lead to negative wellbeing through reminiscing – by asking the peer to recall past events lead to unstructured recall of experiences and negative mind-set.	→	Reject design 1 and 3. Take design 2 forward to next phase (chapter 7).	4
Design 2	A focused peer support intervention linked to a purpose, and supporting another is a potentially beneficial design	→	Refine design 2 to include more facilitation from pharmacist (briefing, debriefing etc.)	5
	Requirement for some level of structure and facilitation	→		
Design 3	Concern that may not support authentic interactions – risk of 'categorisations' and felt more likely to lead to disengagement compared with design 1 and 2.	→	Default option to be video asynchronous interaction yet to include participation and consent options e.g. record audio if preferred.	6
Design 4	Having options for how to interact can help alleviate some concerns.	→	To provide further clarity to future participants on data security (e.g. end-end encrypted videos etc.)	7
	Recording video showing face is acceptable to some	→		
	Disclosure of mental health status is a concern for some.	→		

Based on this work key design decisions about the protocol that would feature in phase 2 (storyboard) and phase 3 (modelling in real life setting) have been made. These are relevant for this chapter's aims 1 and 2.

In terms of aim 3, this was to decide if the think-aloud method should be a method used in later phases of the study design. In phase 1 the retrospective think-aloud method was used. This method had advantages such as prompting information. However this method did not aid the capturing data around participants reflections of the service, which is required for answering the research question.

Also, to accommodate this method the whole prototype consultation needed recording. Consultations with pharmacists would not be routinely recorded, and having the consultation video recorded could influence data. It had the further disadvantage of being time consuming. This is already a recognised limitation of the retrospective think-aloud method (Paz and Pow-Sang 2015, Alhadreti and Mayhew 2018). Therefore the decision was made to not continue the retrospective think-aloud method in the next phases of the study design.

Finally, it is important to reflect that these participants were recruited as men who had experienced 'stress' rather than men who were taking antidepressants. This may limit the value of phase 1 experiment, however two men disclosed during the experiment that they had previously taken antidepressants (although not currently taking).

Originally, participants who were experiencing depression were desired to be recruited as eligible participants, however the school ethics committee did not grant ethical approval to recruit those that were experiencing depression, nor had previously had depression and now recovered. The options at this stage were to seek ethical approval from the UK's research ethics committees (REC) and NHS Health Research Authority (HRA), or to recruit healthy males, that identified with having reduced wellbeing, but are healthy participants.

Recruiting participants who had lived experience of depression, and treating depression would be the most desirable option, yet if this meant following the REC route it was problematic. The REC ethical approval process is a multi-stage process that typically takes months to complete. Additionally the current HRA/REC ethical processes do not synergise with iterative and evolving study designs as they often require and approve predefined protocols and outcomes designs (Stevenson, Gibson et al. 2015).

In this early stage, it was important to identify and test a wide range of approaches iteratively before committing to one. Additionally the purpose of this phase was to inform subsequent phases. This meant it was a time sensitive stage. A long delay (that applying for REC ethics may have caused) could compromise phase 1's usefulness, and the project timescale. Particularly so because subsequent phases would need REC approval to recruit the participants of interest. For these reasons, the decision was made to not apply for REC ethics in this initial stage, and to obtain School of Pharmacy research ethics.

Conclusion

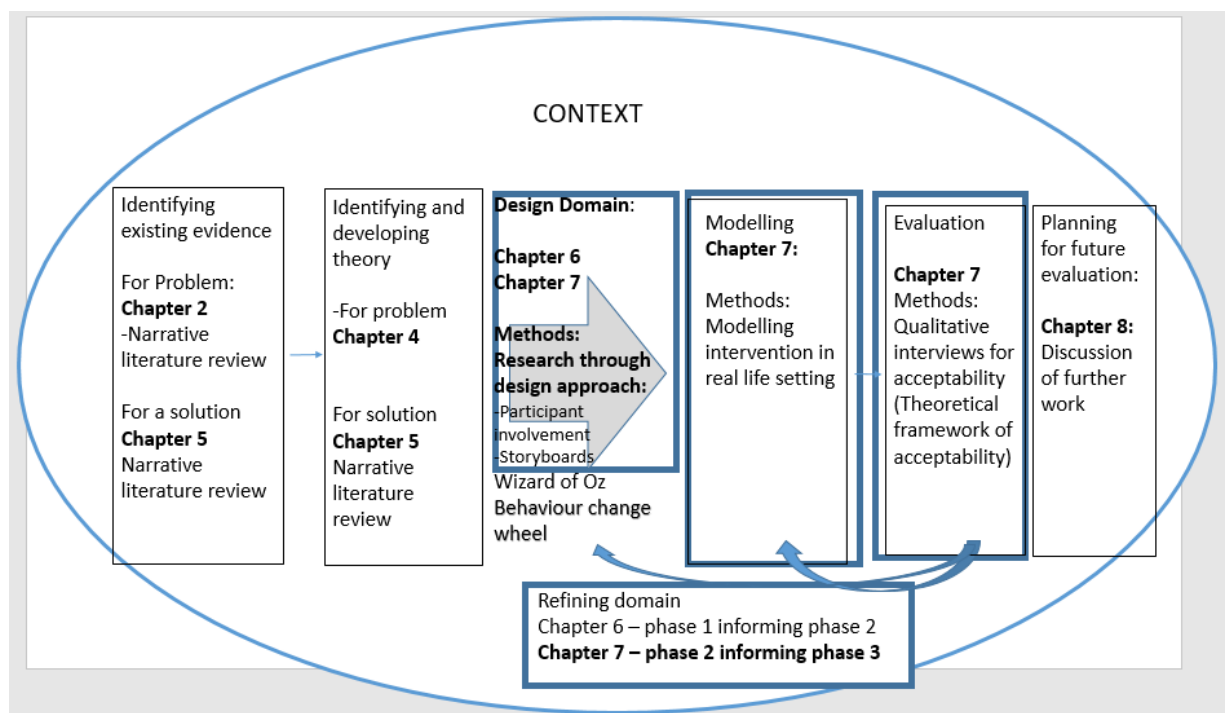
Various design decisions have been made in phase 1. These have been used to create protocol parameters for pre-modelling interview phase 2, and the intervention modelled in phase 3. The GUIDED template has been completed to outline the key development decisions made. In terms of methods, the retrospective method will not feature as a method for phase 3, based on evaluations of its value in this chapter.

The intervention will seek to (i) improve recovery-orientated outcomes, and (ii) improve health literacy for the target patients. It will be further developed in chapter 7 (phase 2 and 3).

Chapter 7: Modelling, Evaluating and Refining the Complex Intervention

7.1. . Introduction and aims.

Figure 23: Introduction to chapter 7; highlighting the purpose, and situating it within the thesis schematic.



Chapter 7 is the largest research study in this thesis. As highlighted in Figure 23, the work looks at design work, modelling, evaluating and refining an intervention. Specifically this qualitative research chapter utilises the views of both male peers, and community pharmacists to refine and evaluate the complex intervention developed in chapter 6 (phase 1). It begins by gathering male participants views on the intervention using a storyboard method and capturing views on prospective acceptability, and further refinements (phase 2). The intervention is then modelled out in its real world setting and retrospective views of acceptability are assessed (phase 3). The theoretical framework of acceptability is used to facilitate data analysis and findings.

The aims for chapter 7 are to:

- Aim 1: Evaluate the piloted complex intervention's acceptability (prospective and retrospective) to service users.
- Aim 2: Develop program theory; understand what type of interactions, support, and knowledge exchange occurs within this complex intervention pilot service.
- Aim 3: Consider what further work or refinements are required.

7.2. Participants recruitment

Eligibility

Both community pharmacists (termed pharmacist participants) and men who are treating depression with antidepressants (termed peer participants) are the participants of interest in this chapter 7 study. Table 28 and 29 highlight the eligibility criteria of each of the participant groups, respectively. The research in this chapter was run as two phases, and builds on the work from phase 1 in chapter 6. Phase 2 was an interview with peer participants before the piloted intervention, and phase 3 was a post pilot interview with peer and pharmacist participants.

For Phase 2 (pre-pilot) only peer participants were recruited.

For Phase 3 (pilot study), pharmacist participants and peer participants were recruited. Peer participants were further classified as either peer 1 or a panel member.

Table 28: Eligibility criteria for Peer Participants.

Inclusion criteria	Exclusion criteria
Male (Those born as male sex, and currently identify as being male.)	Female
Aged 18-65 years	Over 65 years, or under 18 years
Prescribed a selective serotonin reuptake inhibitor (SSRI) antidepressant to treat unipolar depression (SSRI prescribed to treat anxiety or obsessive compulsive disorder with associated depression are still eligible)	Patients with bipolar depression, dementia and/or psychosis
Fluent in English (written and oral)	Have a mental or physical illness or disability that means their participation in the research project is not appropriate
Agree to protocol and sign consent form	
Have medications dispensed at one of the community pharmacies participating in the study and view it as an accessible location	
Will be termed 'peer 1' participant if taken current antidepressant for less than 3 months. Will be termed 'panel member' participant if taken current antidepressant for over 3 months	

Table 29: Eligibility criteria for Pharmacist Participants.

Inclusion criteria	Exclusion criteria
Community pharmacist	Not on GPhC register
Employed in one of the participating community pharmacies that have agreed to model intervention	Employed in a non-community pharmacy role or non-patient facing role
Fluent in English (written and oral)	Have a mental or physical illness or disability that means their participation in the research project is not appropriate
Agree to protocol and sign consent form	

^a Decision on what ‘appropriate’ means is made between the research team and the potential participant, although the research team will make the final decision.

Recruitment: Stakeholder, Peers & Pharmacists

Pharmacy stakeholder

A UK community pharmacy company was approached as a stakeholder. Five of their UK community pharmacy branches were involved in the study. These pharmacies are called the participating pharmacies.

Peer Participants

Peer participants were recruited from the pool of participants that were recruited for the study in chapter 4 (see 4.2 Ethics and Methods). Peer participants who wanted to partake in both phases 2 and 3 had to be recruited from a stakeholder pharmacy, and consider this pharmacy as their regular pharmacy and accessible to them (i.e. they would be willing to travel to this location).

Peer participants were aware of the linked study at the stage of recruitment, and that there was no obligation to partake in subsequent studies. Table 4 (in chapter 3) highlights the number of participants recruited for each phase.

Pharmacist participants

Employees of the participating pharmacies were invited to be participants. This occurred either by telephone or email. It was made clear that their decision on participation would not affect their employment.

Four pharmacists were recruited and did the pilot intervention. However, one pharmacist involved in modelling later left community pharmacy to become a primary care network pharmacist, and due to this, and other time commitments they declined to take part in the data collection in phase 3.









7.3. Overview of method

Both phase 2 and phase 3 involved an audio recorded qualitative interview with the researcher. All Peer participants in phases 2 and 3 had met the researcher previously when taking part in the linked study reported in chapter 4. Therefore, there was already some level of rapport, yet care was still taken to re-establish an interview relationship and put to participants at ease. Interviews took place in a private quiet location, and lone working was avoided.

Phase 2 method:

The purpose of phase 2 was to measure prospective-acceptability of intervention, and to further develop the intervention prior to phase 3. Peer Participants were shown a storyboard of an intervention (Figure 24). They were asked for feedback, particularly around acceptability of the intervention, and any improvements. These interviews ranged from 9-25 minutes. The phase 2 interviews were combined with the member checking process for the chapter 4 study. This was designed in such a way to optimise time management, while being mindful of research fatigue.

Figure 24: Storyboard of intervention for Phase 2

Nathan 1 st visit	'Introduction Question' media			
	Nathan has started antidepressants. He discusses with pharmacist about how he feels about taking them, and given opportunity to ask a question to a peer who has been in this stage before.		Nathan records a video message asking a question or proposing a topic to the peer. Video encrypted and uploaded to secure server.	
John 1 st visit	'Response' media		'Pharmacist facilitator response'	
	John takes antidepressants and is in remission. During consultation he watches Nathan's 'introduction question' media		John records a (short) video message reply. Media encrypted and uploaded to secure server	
Nathan 2 nd visit 1-2 weeks after 1 st	'Acknowledgment' media			
	Nathan watches John's 'response' media		Nathan records a feedback response where he reflects upon the response video. Media encrypted and uploaded to secure server.	
John 2 nd visit 1-2 weeks after 1 st	'End-thread thank you'			
	John watches back the 'acknowledgment' media		John can type an 'end-thread' thank you note that Nathan can read.	

Phase 3 method:

Phase 3 involved modelling the intervention in real life at the participating pharmacies. For peer participants, this involved 2 visits. After the second visit peer participants completed a semi-structured audio recorded interview. Their retrospective views of the intervention's acceptability were captured. The steps for the intervention are outlined in the intervention overview. Peer participants were either termed 'peer 1' or 'panel member' based on how long they had been taking their current antidepressant (see peer eligibility).

For pharmacist participants, this involved running the service in their participating pharmacy. All pharmacist participants were involved in at least one intervention, and a semi-structured interview was conducted after phase 3 had been completed.

7.4. Intervention Overview:

The intervention overview is presented using the template for intervention description and replication (TIDieR), as shown in Table 30, and in the storyboard shown in Figure 24.

Table 30: Outline of intervention using the TIDieR template

BRIEF NAME
An asynchronous peer-support intervention for men with unipolar depression, for use in community pharmacy: Development of a complex intervention.
WHY Describe rationale, theory, or goal of the elements essential to the intervention.
<p>Relevant theory/ rationale:</p> <ul style="list-style-type: none"> - Theory of Masculinity - COM-B system and Behaviour Change Wheel. - Recovery framework <p>Core elements:</p> <ul style="list-style-type: none"> - Peer support (male-to-male) - Linking lived experience with community pharmacy consultations - Task focused, gender sensitive approach - Providing platform for patients to ask questions and get support - Asynchronous communication with feedback
Intervention material
<p>Prior to the intervention, all participants briefed on intervention and its purpose. Pharmacist participants received training on the intervention protocol. This involved instructions on how to use the phones, passwords, and how to securely delete data files. They also received training on suicide awareness, including asking direct questions around suicide if they were concerned about suicide, and asked to reflect on how they felt about asking about suicide intent.</p> <p>Pharmacists were given face-to-face training on how to deliver the intervention and required to complete CPPE training packages on safeguarding, and advised to complete CPPE training on 'consulting with people with mental health problems' (https://www.cppe.ac.uk/). This website is often used by community pharmacy professionals, and pharmacists were familiar with it, and logistics of using e.g. log in details, navigation of website etc. Pharmacist participants were also made aware of pharmacist support charity (https://pharmacistsupport.org/) that they could access if felt need support for any issue.</p> <p>Peer participants were not given any formal training on peer support. All peer participants offered a debriefing after participation, including signposting to relevant support resources.</p>

Intervention Procedures:

Peer participants (1 and 2) have 2 visits to their pharmacy (approx. 10minutes each). There is a 1-2 week interlude between visit 1 and 2.

In participating pharmacy A, peer 1 has a discussion with pharmacist on any concerns or questions about antidepressants. A recording of these is made. This recording is termed the **'introduction question media'**. This was recorded by pharmacist, encrypted, and securely transferred to another participating pharmacy.

In participating pharmacy B, panel member has a briefing with pharmacist. Pharmacist decrypts media and plays to panel member. Panel member records a **'response media'**. Pharmacist records and can input in discussion if beneficial. Pharmacist encrypts media and securely transfers back to participating pharmacy A. Decrypted media is securely destroyed.

In participating pharmacy A (visit 2), pharmacist decrypts media, shows to peer 1, and discusses how they feel. Peer 1 makes **'acknowledgment media'** for panel member, to thank, and highlight what they found useful or insightful about 'response media'. Pharmacist securely destroys decrypted media. Debriefing between peer 1 and pharmacist occurs and issues discussed as relevant.

In participating pharmacy B (visit 2), pharmacist decrypts 'acknowledgment media' and shows to panel member. Pharmacist securely destroys decrypted media. Debriefing occurs between panel member and pharmacist to discuss issues as relevant.

See also storyboard schematic Figure 24 for a visual representation of the service.

Who Provided?

The research team organised appointments. Pharmacist participants briefed peer participants on the purpose of the intervention, recorded media, and facilitated peer participants to consider questions, or consider responses where appropriate. Pharmacist recorded participants media (audio or video), encrypted media, securely transferred media, decrypted media, and securely deleted media. Pharmacist participants debriefed peer participants. Peer participants produced the media content.

How? Describe the intervention modes of delivery (e.g. face-to-face or by some other mechanism, such as internet etc.) and whether it was provided individually or in a group.

Interactions between the peer and pharmacist were face-to-face. Interactions between peers were remote and asynchronous taking place in their respective pharmacies.

Where?
All interactions occurred in pharmacy consultation rooms in the participating pharmacy (this is also the peer participant's local pharmacy/used pharmacy).
When? and How Much?
One intervention involved 2 visits to pharmacy, each lasting approx. 10 minutes over 1-2 weeks.
Tailoring?
Participants can choose to respond via video, audio, or text.
Modifications?
Pharmacist participants asked to brief participants that media should be about 2-3 minutes long, and not over 5 minutes. This was because one recording from a participant (who did not have these instructions) was too long (over 15 minutes) and had to be edited. Pharmacist participants asked to check all media securely transferred before deleting. This was because one media file was securely deleted before being fully transferred. This data was unrecoverable.
How Well? If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.
1 media response file was recorded but securely deleted before successfully transferred to the participating pharmacy. This file could not be retrieved. 1 media response file was too long, and an edited version used (discussed further in section 7.8)

7.5. Ethics

The UK Research Ethics Committee and University of Nottingham granted ethical approval [Ref: 17/EM/0264]. Participants signed a consent form that had tiered levels of consent (see appendix 8). They were offered a £10 voucher for participation in two visits. Participants agreed, prior to participation, that their confidentiality could be breached to access a professional (e.g. GP) if the research team had safeguarding concerns, either about them or another in their care.

Video and audio data was produced in this chapter as part of the modelling of the service. The media contained confidential information and in some cases a recording of participants faces and voices.

In all interactions the recording of media was managed by the pharmacist. All media was recorded using password protected devices. The media was recorded within an end-to-end encryption program, and securely transferred. Once data was successfully transferred it was securely deleted. Password protected mobile phones were used to record the audio or video, and this media was transferred using WhatsApp. Consent was not authorized for WhatsApp to save media outside of the WhatsApp chats, nor to back- up cloud storage. Pharmacists were also responsible for charging the mobile phones, storing them in a locked cabinet when not in use, and securely deleting any media from the phone using a secure delete application installed on the phone.

7.6. Data analysis

Table 31 highlights participant details, and media files produced.

Table 31: Participant details, and media files.

	No of participants interviewed	Age range / mean age	No. of media files produced
Phase 2 (Prospective acceptability)	14 male participants	mean = 49 years (range 28-61 years).	N/A
Phase 3 (Retrospective acceptability)	11 male participants (peer 1 =1, panel members=10) 3 pharmacist participants	mean age = 46 years (range 24-61 years)	21 (NB one file was securely deleted before completed and could not be retrieved)

Interviews from phases 2 and 3 were transcribed verbatim, and analysed using thematic analysis (e.g. see (Braun and Clarke 2006)). NVivo12 was used for analysis. Coding was deductive, based on theoretical framework of acceptability proposed by Sekhon et al. (Sekhon, Cartwright et al. 2017).

The media files produced from the intervention were transcribed verbatim and analysed using content analysis. To aggregate across all experiences and understand what responses may occur, ten panel member participants were shown the same peer 1 'introduction question media'. This peer was given pseudonym 'James'. Using this model, five key variables were examined: (1) Interaction patterns (e.g. media length and format); (2) Responses to questions asked in the introduction media; (3) Supportive content of peer messages (4) Components of peer message where personal insights were shared; and (5) Medical advice content from the peers. James was recruited as a participant but was also a member of the research design team and PPI. His initial views were recorded to help in the design of the intervention, but he was not recruited for the acceptability interviews.

Finally, a case study was done on one of the panel member's responses around the concept of introducing bias.

7.7. Qualitative interviews - Results and Discussion.

The results for acceptability of the intervention are discussed below using tables to highlight overall findings and accompanied text to provide further discussion and supporting quotations. The results are structured based on the seven constructs of the thematic framework for acceptability: **affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.**

For linguistic clarity; when the term 'participants' is used it refers to both the peer participants, and the pharmacist participants. When the term 'peer participants' is used it refers to peer 1 and panel member participants. For each of the core themes of acceptability (based on the framework for acceptability) the data is presented in Tables 32-38, followed by text passages to provide more in- depth detail with associated illustrative quotes.

Affective attitude.

Affective attitude is how an individual feels about taking part in the intervention. There were a range of affective attitudes. These ranged from highly positive, to negative. An overview of this theme is presented in Table 32.

Table 32: Summary of findings for Affective Attitude theme

Sub-themes	Details
Range of attitudes	<ul style="list-style-type: none"> • Range of affective attitudes from very strongly positive, to negative. Most were in-between. • Balancing of various beliefs and concerns when determining their overall affective attitude.
Refinements (what participants would change)	<ul style="list-style-type: none"> • No clear consensus on aspects to be refined or changed. Below are some of the points: <ul style="list-style-type: none"> -Asynchronous element – switch to live synchronous communication -Option to link to a more ‘traditional’ peer support service as an add on to this intervention -Stronger links to GP or prescriber -Focus on men’s depression, but peers not needed to be male -Remove pharmacist video -Acknowledgment media not necessary
Core elements or aspects participants would like to keep	<ul style="list-style-type: none"> • Below are key points: <ul style="list-style-type: none"> - Peer support - Question and concern focus, rather than an in-depth peer relationship -Seen as initial step for both accessing peer support and initial confidence for starting medication - Providing opportunity to ask questions - Male to male aspect -Acknowledgment media important feature
View shifts of acceptability with retrospective views more positive compared to prospective views.	<ul style="list-style-type: none"> • Some participants having a more positive shift in affective attitude after intervention.

When comparing the two participants that had the most polar views on affective attitudes (strongly positive vs negative), there were significant differences in levels of self-stigma and views of peer support. The participant, who had a clear negative prospective affective attitude for the intervention, self-stigmatised for taking antidepressants. He also had concerns about peer support, not valuing peer input above professional input,

Gerry (prospective): " I would want to go to the pharmacist or my ideal person, I personally wouldn't want to speak to some Joe who's been on what might or might not have been on the same type of antidepressants, same dosage, might have completely different reasons, he might think they were good, he might think they were bad, but I wouldn't... for me it would be maybe only slightly better than reading the comment section of a website."

When exploring his views of acceptability after the intervention, he held a more positive view on overall acceptability, feeling it could be beneficial to some men, and be a more accessible way to access peer support.

Gerry (retrospective): "Yes well as I say I was touched, if I'm being honest surprised and pleased... that what I did not really see as being advice or support, more answering questions, evidently assuming our friend was telling the truth was of use, and helpful, and of comfort, and relief to him."

He however did not feel if he was newly starting antidepressants he wouldn't do this service, and he did not think he had benefited significantly by partaking.

In comparison the participant who had a very positive affective attitude both prospectively and retrospectively believed strongly in peer support, and viewed peer support (both providing and receiving) as linking to his concept of recovery.

Clint (retrospective): "It is nice to think that if you can just put that seed in you then...it has a chance to grow but without

that seed then it is up to that persons you know whether they want to get better or not, so this is a great exercise, so I felt pretty good.”

Most participants had an overall positive affective attitude on the intervention, but with some reservations, or aspects that they would change. These are highlighted in Table 32. There was limited consensus on what aspects participants would want to change. Sometimes there was a direct contrast between what a participant felt was an active component of the intervention, and what another participant felt could be changed. An example was the asynchronous element. One participant highlighting it as a key element both from a logistical perspective, and a way to facilitate communication on sensitive issues, such as effects on libido.

John (prospective): “I think from a positive point of view the fact that you can form your question, or your comments and then get a response sometime later in a confidential way is a very positive thing, very positive.”

Another participant felt it hindered interactions, compromising nonverbal communication, and obstructed elaborations. He suggested changing it to face-to-face communication.

Andrew (prospective): “ The big drawback with this is ‘here is your question’ back comes the answer. It is very clunky very remote, and not connected.”

As discussed in this thesis, the research was conducted pre-covid-19, and at this time remote consultations either synchronous or asynchronous were not the norm.

The overall finding was that most participants balanced various beliefs, motivations, and concerns, when determining their overall affective attitude. As an overall trend the retrospective views (views after the intervention) were more positive compared to prospective views of acceptability (views before doing the intervention). These are explored further in the remaining six themes.

Burden

The next theme to explore is what aspects of the intervention was burdensome and if this influenced acceptability. Table 33 highlights these findings.

Table 33: Summary of findings for Burden theme

Sub-themes:	Details
Characteristics of the disease increased burden	<ul style="list-style-type: none"> ● Difficult to interact, engage and open-up when depressed. ● Some participants discussed increased paranoia and concealment when depressed.
Data security as a burdening concern	<ul style="list-style-type: none"> ● Concern on data security: Participants need to know data is secure and protected. ● Logistics to encrypt and securely destroy data not burdensome (software programs used)
Recording content as a burden	<ul style="list-style-type: none"> ● Rumination as potential risk for panel member. ● Being recorded and saying ‘wrong thing’ was a concern - having pharmacist present helped alleviate these concerns. ● Concern about a recording existing (linked to data security above). ● The act of recording media can elicit negative emotions e.g. awkwardness, intimidating. ● Smart phones considered less intimidating recording device (e.g. compared to tripod cameras etc). ● Poor audio quality problematic. ● Role of pharmacist – debriefing.
Asynchronous communication had some burdensome aspects	<ul style="list-style-type: none"> ● Restrictive interaction. ● Unknown time delays for replies. ● Less logistically burdensome, and less intimidating.
Time burden	<ul style="list-style-type: none"> ● Pharmacists have busy workload. ● Average of 10 min consultations plausible to manage.

Due to the nature of depression, activities can become burdensome. Participants spoke about lower motivation and a tendency to be insular, which could make participation for one with depression more of a burden than would be expected for the general population. This is in line with the wider literature, and while there are numerous examples of this population partaking and engaging in healthcare interventions; overall activities, and engagement can be more burdensome to this population due to depression (NICE 2009, Rennick-Egglestone, Knowles et al. 2016, Grahek, Shenhav et al. 2019).

Andrew (retrospective): "Bearing in mind the condition that is being talked about when people are unmotivated because I can sit here now and be quite jolly talking about the phone, but when I was starting out in the other individual's position, it is a very difficult thing to do."

Grahek et al. (Grahek, Shenhav et al. 2019) use the term *effort costs* to represent the intensification of physical or mental activities needed to reach a goal, such as the participation in a healthcare intervention or service. To partake in this service requires increased effort costs. Increased effort cost could be problematic in depression. A greater ease of disengagement from goals has been shown in individuals experiencing depression compared to healthy controls (Dickson, Moberly et al. 2016). Therefore, this effort cost is important to consider as it may cause burden, and those with depression may be at higher risk of disengagement if these activities are considered burdensome.

As well as effort costs, some participants reflected that during their initial depression there was a tendency for paranoia, and limited disclosure. Making a recording about their depression could be challenging for these reasons and create an insecurity. This was linked to data management and data security. Data security was a burdening concern, and is a concept echoed later in themes of ethicality and opportunity costs.

Edward (prospective): "As someone who suffers from depression I think if you are being videoed you do not know where that goes and there is the constant worry that you have something of you somewhere that anyone can watch and it will make you feel even more... not depressed, but kind of anxious about it."

Participants would need to know that data was secure, protected, and that data would not be used for unintended purposes. A secure system needed to be used, and participants would need to be reassured and informed about this system.

Harry (prospective): " I think there would have to be a lot of trust because especially with things being on the internet my fear is it will get used for something outside of its intended purpose. If it is recorded encrypted, sent, then done – fine."

Another burden highlighted, and already identified previously in chapter 6 (phase 1), was that revisiting one's depression posed a potential risk to panel members. Revisiting how they felt or taking on another's problems were highlighted as potential burden risks.

Bennie (prospective): " I suppose one could argue that he [panel member] still has a need for the antidepressants and therefore if he is reminded of certain things, depressing things or depressive feelings, all these sorts of questions bubble stuff up, that's what I meant when I said he has more to lose than to gain."

After the intervention participants were specifically asked about this and no participants highlighted that they felt worse after doing the intervention. However it was still highlighted as important to consider. It was suggested the pharmacist had a key role in supporting peers after they had been involved in the service. A debriefing was held as part of the research study, and it was suggested that this debriefing should form part of the service to link with larger discussions, and be an opportunity to link back with GPs. Linking pharmacy services within wider healthcare, and providing joined up mental health services is important (Scahill, Fowler et al. 2015, Hossain, Fernandez-Llimos et al. 2017, Wilkins and Kemple 2010.), and would be an important area to focus on for future development of this intervention.

For some participants the recording process was a burden. Some found it initially intimidating, although for most the build-up was worse than the actual process.

Edward (prospective): " I did find it quite intimidating initially."

Researcher: "Okay, can you explain further about that?"

Edward: "Yes, saying the wrong thing, being recorded as well, as I said before the whole stress of what my voice sounds like that's weird, I still don't know what it sounds like. So, I think the whole build up is worse rather than the actual process of it."

Mobile phones were used to record media. Those who had envisioned large cameras, tripods, and microphones saw these devices as less intimidating. However, as a minor burden, the quality of the media was poor, particularly the audio. Some participants commented they had to listen to the recording multiple times to hear what had been said.

For some the asynchronous and retrospective aspect was seen as a less burdensome way to access a peer support system. It was seen as a first step, being less intimidating than face-to-face, and a way to build up initial confidence in taking antidepressants.

Barry (prospective): “That would be alright. There is something about that that has a personal side of it but also it feels quite safe.”

Remote asynchronous communication was also seen as logistically less burdensome. Reasons for this were that the pharmacy was an accessible location they would visit anyway, and that the asynchronous element meant it would be easier to partake without meeting particular time frames.

Lawrence (retrospective): “I can't see one-to-ones going on because I just don't see how it's going to work, and I don't think people would then want to take part. Because it takes up too much time out of their working day, or whatever, and there would be a cost wouldn't there? So that is the only way you can do it really.”

Another burden to consider is a time burden. This service is an addition to standard care, and therefore participation does carry an additional time burden.

The pharmacist participants felt that the length of time each consultation took (about 10mins) made it a plausible service to operate but highlighted it could be a burden because of their high workload and demand for time, particularly if it was not seen as financially viable, or not supported by their managers or company owners.

Pharmacist 2 (retrospective): “Nowadays everyone is looking how basically financially viable a service can be. Going a bit off topic here but with the stop smoking service some pharmacists are not being bothered by it because when they look at the time

being spent with a 12-week program, it is like minimum wage. So sometimes they look at it like that.”

For the peer participants, most felt the services time burden was not a significant barrier to its acceptability, and felt the asynchronous structure allowed a greater flexibility for scheduling. Although it was suggested that the asynchronous element could result in more time burden if peer participants needed further clarification, which otherwise could have been addressed during a real time consultation.

The operationalisation of community pharmacy innovative services has been highlighted as a principal factor that can influence implementation success (Weir, Newham et al. 2019). Therefore the finding that the time burden did not compromise the acceptability is positive, however future implementation work should consider what remuneration would be required and if this was a cost effective service, in line with the MRC guidance (Skivington, Matthews et al. 2021, Craig, 2008).

Perceived effectiveness

Table 34 highlights a summary of findings for perceived effectiveness.

Table 34: Summary of findings for Perceived Effectiveness theme

Sub-themes	Details
Providing emotional support	<ul style="list-style-type: none"> • Initial confidence for engaging in both peer support, and treatments. • Increased emotional support between pharmacists and the peers involved. • Not effective for providing deeper social connections between peers.
Information sharing	<ul style="list-style-type: none"> • More tailored, specific questions answered. • Lack of opportunity for clarification from peers. • Pharmacist role in supporting comprehension of information.
Different views on purpose led to differences in perceived effectiveness	<ul style="list-style-type: none"> • Those that saw this as a ‘top level’ or ‘stepping stone’ to further support felt intervention effective. Those that felt effectiveness was limited were seeking a ‘deeper’ interaction

<p>Accessible/Increasing opportunity for peer support</p>	<ul style="list-style-type: none"> • Offering through pharmacy increased opportunity to access peer support. • Felt the service was offering something different to what was already there. • Asynchronous and remote elements made peer support more accessible. • The focus on a task rather than an emotional disclosure focus made it more acceptable for some.
<p>Panel members benefits to providing peer support</p>	<ul style="list-style-type: none"> • Altruistic benefits. • Opportunity for reflection on current condition.
<p>Improving pharmacist consultations</p>	<ul style="list-style-type: none"> • Experiential/tacit knowledge incorporation; pharmacist felt this added to their consultations. • Therapeutic relationships between pharmacists and peers created.
<p>Time delay – hinder or help intervention effectiveness?</p>	<ul style="list-style-type: none"> • Time delay between peer communications may limit effectiveness. • May also increase effectiveness by enabling a peer experiencing depression to take in information in staggered timeframes.

All participants saw a core purpose of the intervention was to provide authentic peer support. The participants felt the service was successful in this purpose.

Barry (retrospective): "The big benefit of this you are actually speaking to someone who is in the same boat as you are."

However, there were different interpretations, particularly between the peer participants, on what the outcomes or effects from this peer support should be. This influenced their perceived effectiveness of the service.

Receiving emotional support was a perceived and realised effect of this service. This took the form of providing hope and reassurance through role modelling, and upward social comparisons.

Fred reflected on his initial concerns about taking antidepressants, and how role modelling could provide emotional support and potentially help manage concerns about taking antidepressants.

Fred (retrospective): "There was a bit of fear there. So yes, it would be nice, this interaction, this modelling, it would be nice to know that if you are brave then it does work out."

Providing positive role modelling has been highlighted as a core part of program theory for peer support in depression (Dennis 2003, Festinger, 1954, Proudfoot, Jayawant et al. 2012). Most felt the service effectively enabled this.

The sharing of health and self-management information was also a perceived effect of this service. This has also been highlighted as a core aspect of peer support program theory (Dennis 2003, Proudfoot, Jayawant et al. 2012). In this intervention getting direct answers to personalised questions was seen as an advantage, which otherwise could be hard to get with other strategies such as internet searching, or hearing stories about a 'friend of a friend'.

Harry (prospective): " People google they get a whole load of answers, that is not useful to anybody, this is more tailored."

Studies looking into consumer-operated mental health service programs, in which peer support is a function, have shown that peer support can empower patients to play a more active role in their own self-care (Rogers, Teague et al. 2007, Pfeiffer, Heisler et al. 2011). The opportunity that this service provides for patients to access lived experience tailored in response to their specific questions or concerns may empower patients to play a more active role in their own self-care.

However, the asynchronous element, and focus on a question-response-

acknowledgement dynamic with short direct media responses may not facilitate deeper social connections. Those peer participants that saw this as a core outcome felt the service was compromised.

Andrew (prospective): "The initial time, very short answer, mine was three minutes, very short, altogether that whole thing we have had less than five minutes interaction at the moment that is really, really short. I don't know what his depression is... my depression is a huge thing. That is where the benefits of something like that can come in, so yes, the time constraints were something which may just negate its usefulness."

From the literature, one recognised mechanism of peer support in depression is that it can decrease isolation, particularly by enabling cohesiveness and a sense of universality (Rogers, Teague et al. 2007, Pfeiffer, 2011). It may be that this type of peer support service does not facilitate this, or particularly not to the expectations of some participants. Similarly, it was felt by some that asynchronous communication could hinder information exchange between peers, particularly for information that may require a dynamic interplay or dialogue.

Winston/Pharmacist 3 (prospective): "You have to ask questions, you might think of something different after you send the video off, you might change your mind, you might want more support. It is short, and it is not a full relationship."

Yet for others this was not an issue. They were not looking for a 'full relationship'. Instead they felt the purpose of this service was to provide 'high level' support, meaning it was not about going into depth, and analysing another's depression. It was about providing initial reassurance to male patients about taking medication, either through addressing questions, or being a role model or social comparison, to address issues such as stigma. For these peers the asynchronous communication style, and a focus on direct questions did not compromise the service's effectiveness.

Harry (retrospective): "If it is at the level of the person I spoke to who set the questions, then this is ideal for that. They are not going to look into anything more than- just a bit of reassurance and someone to sort of say this is how I felt, this is perfectly normal."

This could be in line with the literature that suggests in peer services it is the overall perception of support that has a stronger influence on patient outcomes, such as reduced stress, rather than the actual support provided (Robinson, Raine et al. 2015, Wethington, 1986). Therefore, if this service meets the perceived needs of the participants, then these benefits of peer support could still operate even if it is not considered a 'full relationship'.

Offering a peer support that did not seek to engage peers in a deep social connection was even seen as advantageous for some, who explained they may feel overwhelmed, particularly when they were at a stage when they were trying to understand their own problems and situation. The focus on a direct question and answer interaction was seen as a beneficial component for this purpose.

Kevin (prospective): "I don't really want to go into too many details. You know about hospitals and all this rubbish. Because that's nothing to do with it. Whether the guys in a wheelchair or he's not or whatever. Do you know what I mean? Whether he's a brain surgeon, or whatever he's doing, I'm not interested. He's answered the questions, that's all I want to know."

It is known that some features of gender sensitive interventions deliberately create a situation where men can retain the masculine embodiment of control so that they can relax other masculine traits such as emotional control (De Visser, Smith et al. 2009, Robertson, 2015, Conrad, 2010). In this service having a task focus, rather than an emotional disclosure focus, or a focus on creating an intimate peer relationship may be an advantage so long as this aligns with the perceived intervention purpose for the participants.

The asynchronous element was also highlighted as a way that could facilitate communication on sensitive issues, as discussed previously in the **Affective attitude** and **burden** themes.

Participants felt that there was a place for a peer support service that was accessible and seeking to provide the *'initial confidence'* required to take antidepressants, or could be used as a first *'stepping stone'* on one's recovery journey, particularly when aspects such as stigma, and navigating masculinity came into play.

Clint (prospective): "You have got to make it as light-hearted as possible because these people are depressed, half of them want help desperately but because of their age, the family, the way they have been brought up they are scared and they are scared of losing their masculinity. So make it little pigeon steps to start with. Like this. Great idea."

It is known from the literature that self-stigma and conforming to aspects of hegemonic masculinity can be a barrier towards seeking help both from professionals and peers (Addis and Mahalik 2003, O'Brien, 2005, Seidler, 2016). The intention was that this intervention should be gender sensitive and be non-threatening to those who endorse hegemonic masculinity. The comments above seem to support this.

Core components such as the asynchronous element, and the focus on direct communication facilitated this in being effective for this purpose, but not for a *'deeper'* peer support relationship. It was suggested that this could be the first step, but with potential to link to other services later.

Fred (Prospective): "I think for that initial confidence to progress with the it is enough. I think I definitely needed more for that long term help. [...] I don't know if that might be something that could be offered if it was on an NHS platform it could plug you into other likeminded groups. Things like it would be a 2-3months thing, you get over the first hurdle then have options later, that kind of thing."

Following on from this theme, another way the intervention was perceived as being effective was that it provided opportunity for men to access peer support, and increased their access to resources. Many men commented that they were not aware of peer support services, or how to access them.

Kevin (Retrospective): “I wouldn't have a clue so unless you'd set this up for me...and also I've asked all the questions I need to. I wouldn't know would I? It would just be speaking to the doctor. So no, no, I wouldn't have a clue. I'd just be carrying on doing what I'm doing now. So I wouldn't have any questions asked.”

Kevin's comments also suggest that he may not have considered speaking to the pharmacist. Findings from the literature suggest patients may underutilise the community pharmacist (Murphy, Martin-Misener et al. 2016, Boardman, 2005), yet they are receptive to doing so in the right context (Saramunee, Krska et al. 2015, Mey, 2013). Findings from the chapter 4 study, specific to men with depression, also support this finding.

Those that had accessed peer support, or were aware of peer support options, felt the focus of this intervention for concerns and questions around the medication was offering something different to what was available already. Participants felt there was a need for this, as the decision to take antidepressants could be a difficult one, and this was often not adequately addressed in other support services such as counselling.

Clint (Retrospective): “I have not seen this before. I mean if I had gone to the doctors this is the couple of years back and he or she had said to me you know 'are you worried about these, about taking them' to let me show you there is a site to go on, or you know I can play this video and blah blah blah, if I was thinking no I do not want to take them it might of helped me get into it maybe a bit sooner.”

Another perceived effect of this service was the benefit it provided the panel member (the peer providing the peer support). Peer participants spoke of an altruistic benefit. This resulted in the feeling of being valued, empowered, and had a positive effect on wellbeing.

Edward (Retrospective): “Knowing that something I said someone actually took notice to it, which I think when you do suffer with things like depression I think sometimes you feel like you're not being heard. It just feels like you are in a room, you could be

shouting out at the top of your lungs and nobody is listening.
So yes that was kind of nice to know that something you
actually said has been heard.”

This finding is supported by the wider literature which suggests that providing peer support in mental health can be beneficial by providing altruism (Pfeiffer, Heisler et al. 2011) and giving meaning to their suffering by using it as a mechanism to give back (Pfeiffer, Heisler et al. 2011, Repper, 2011). These positive benefits were particularly thought to be important in a population experiencing depression.

John (Prospective): “I think it is nice to know that you have made some... that you have helped somebody in some way. Positive reinforcement, don't forget people who are dealing with depression often feel quite bad about themselves and have feelings of negativity so any positive reinforcement is going to be of value. So yes I think that that is an important part of the process.”

For most participants, the feedback component was a core component that enhanced this altruistic benefit, and their sense of feeling as a valued expert from experience. Therefore for these participants the feedback mechanism (‘Acknowledgment media’) was an important part of the intervention program theory.

Barry (Retrospective): “When he came back and said the part about try different medications... different antidepressants, that was a buzz to get that back. As I say it's probably the only one thing experience wise that I can actually give him that the GP might not be able to.”

It also provided these peer participants an opportunity, or a platform to review where they were in their depression journey.

Andrew (retrospective): “Yes I have been able to look at it and revisit...yes I think revisit. Because it has been going on now for some time and I am thinking am I now really depressed, am I just rolling along, there is an argument perhaps that maybe I am just rolling along but I do not know, so yes. It was quite good for me to actually think about where I am.”

This comment illustrates how self-reflection about one’s own progression can be positive, and providing a stimulus and opportunity for this can be important, particularly as interpreting if one is in remission can be subjective.

Yet for a minority, providing peer support had a negligible or unnoticeable impact on their own wellbeing or recovery journey.

Gerry (retrospective): “I felt alright. I don't feel considerably better, I did not feel considerably worse. It has not had much of an effect in a conscious way [...] Because as I see it I was just speaking about my experiences, it’s not as though it was therapy or something like that so I think it has not really affected anything.”

Turning now to the role of the pharmacist, and having the service operate at the pharmacy; participants highlighted the importance of the service having a moderation aspect to it. This was so information could be vetted to ensure a safe environment, but more particularly when knowledge may require both comprehension and application, for example side effects which may affect some, but not others.

Pharmacist 1 (prospective): “He then kind of asked me, ‘is that right?’ So it triggered off a bit more of the science behind it, rather than someone else's views on them.”

Similarly participants also recognised that some questions and answers were not ‘black and white’. The effectiveness of the service depends on the questions asked.

Dichotomous thinking or questioning may not be useful in this service, and the pharmacist was seen as having a role in helping peer 1 participants consider their questions, and the

interpretation and contextualisation of answers.

Barry (prospective): “I am on 20 mg and did you drop down after six months?’ ‘No, I went up’. It's not a helpful answer. It’s an answer...it is the right answer, but that was that person's needs, it might not be yours, so it's probably not a very valid question in the first place to ask, that sort of thing.”

Pharmacist participants saw value in being able to incorporate real life experience into their consultation. They felt this helped open up conversations between them and participants, supporting further discussion of information, potentially leading indirectly to higher health literacy for peer participants. This service had an effect of creating or enhancing a therapeutic relationship between the pharmacist and participants.

Pharmacist 1 (prospective): “So he's open about all of it. About his personal life. I think that's good, the fact that he can talk to someone about it. I think it's changed the relationship between me and the gentleman who was new to starting them.”

The importance of partnership building and enhancing therapeutic relationships for patients in depression has been highlighted in work exploring general health consultations (Mead and Bower 2000) and also in work around community pharmacist consultations (Chong, 2014, Mey, 2013, O'Reilly, Wong et al. 2015). The finding that this service can facilitate this is an important part of its program theory.

This is particularly important as many of the participants prior to partaking in the intervention did not have a therapeutic relationship with their pharmacist. This intervention helped raise awareness of the pharmacist as a healthcare resource.

Andrew (prospective): “I wouldn't have had any idea that I could have spoken to the pharmacist, that I could speak to pharmacists... strangely enough the person who probably knows all about the medicine I would not have actually thought I could ask them about the medicine.”

An enhanced therapeutic relationship with the pharmacist was seen as a beneficial

outcome of the service, and in a wider sense it potentially increased further contact and support points for men with depression.

Duncan (retrospective): "It is another point of contact, the pharmacy. It is great to have another local point of contact where perhaps you can't go through dragging yourself to the GP for whatever reason but if you are coming to pick up your medication that is a great intervention point for people who are struggling."

While most participants held this view, there was one deviant case. One interviewee alluded to the notion of embarrassment; for him having a pharmacist knowing about his depression was undesirable. He did reason that a greater pharmacist involvement could be a good thing for his care, but this was after an initial sense of embarrassment and in his words 'shame'.

Gerry (prospective): "So having a relationship with your pharmacist that's not just saying how are you, picking up your pill and getting the hell out of there is probably no bad thing."

This deviant case is also discussed further in '**opportunity costs**'.

The time scale of the intervention, particularly the interlude between peer response was a component that led to differing views on intervention effectiveness. Some participants felt the time interlude (around 1-2 weeks) between peer 1's initial video, and the panel member's response was problematic and potentially limited the interventions effectiveness, particularly for information sharing purposes, or providing the 'initial confidence' to start medication.

Gerry (prospective): "A lot could happen and yes that is my fear, although it is not that long it does seem quite a long time; and long enough for someone to either think... to make up their own minds about whether they're going to go on them. By the time the answers come through he may have done some

soul-searching, spoken to some friends, googled it, and come to his own conclusion anyway.”

Yet Kevin, the peer participant who had been taking antidepressants for the least amount of time (nine days at time of interview) felt the staggered response made the intervention more acceptable and effective for him. Kevin expressed initial concern about being given information or accessing peer support too early, as he wanted time to process his own thoughts.

Kevin (retrospective): “I've noticed a lot the last week and yeah I think it was right to do that. I don't see the point in doing something like that straight away. I think that would just be a waste of time [...] waiting that time and everything, it's alright. Yeah it was good. To do it all in one go, I wouldn't want to do that.”

Participants highlighted that consideration needs to be given to one's ability to take on information in their depressed state. Andrew explains how in depression there can be a tendency to not take things on board, even while giving the impression of taking things on board.

Andrew (prospective): “When you are told things and you go in... so say you're in position of a pharmacist; I will believe anything that you say, and I would agree with you and say 'yes yes' 'once a day' 'yeah yeah' and then go off round the corner and be [Andrew makes ohhh sound while tapping fingers on his lips]. There is an element of doing that.”

In the example above Andrew illustrates a person who is pretending to agree with the pharmacist, but once they are in their own space they resist taking information on board, which he explained is how he used to be when he was first taking antidepressants. Another interviewee confirmed this behaviour, but felt the peer element of the service could negate these behaviours.

Lawrence (retrospective): “When you're in [Depression] ... it's like in and out the other ear. You know those things don't... I don't know

what it is [...] No. You're speaking to someone. I think that James will listen to me because he's been told that I've been depressed."

Ethicality

Table 35: Findings for ethicality theme

Sub-theme results	Details
Support in depression valued	<ul style="list-style-type: none"> • A serious and impactful disease. • Support and not feeling alone can result in positive outcomes. • Desire to help others, to 'repay' help that was offered to them, to stop others going through what they went through.
Peer support as a concept valued	<ul style="list-style-type: none"> • Overall peer support (and a service underpinned by this concept) seen positively. • Deviant case highlighted.
Pharmacists – improve consultations	<ul style="list-style-type: none"> • A desire to improve consultations, fits into pharmacist's professional values.
Focus on male depression	<ul style="list-style-type: none"> • Views that men had different social pressures. Felt more isolated as male, hard to find support networks. • None felt a male focus conflicted with their ethicality, but some ambivalent views on the need to focus on men.
e-health	<ul style="list-style-type: none"> • For a minority; concern about e-health concepts, high profile digital manipulations, or data security breaches referenced e.g. Facebook-Cambridge Analytica scandal 2018 etc.

This is about how the intervention fits in with one's value system. Table 35 highlights overall findings. In all cases, the informants reported that depression was a serious

disease, and one that can negatively progress. They welcomed an intervention aiming to reduce the potential negative consequences of depression.

Clint (retrospective): “It is the bleakness of it, [...] is so huge when people are going through and it, there is no escape. But it is nice to think you know that people don't have to feel like, that it doesn't have to go onto more serious problems [...] but obviously that is the whole point of this exercise.”

Participants justified a need for support in this area on a society level, highlighting the economic cost of depression. They also justified the need on a personal level, either referencing their own struggles, or the struggles of close friends. Particularly they felt this service could enable them to repay back the help that was offered to them, or stop someone else suffering what they went through.

Fred (retrospective): “Because it was anxious for me back in 2003 time, it was a very anxious time for me, and if I could reassure somebody else then it is a nice feeling.”

The peer support element of this service fitted well with participants value systems. Peer participants saw value with sharing their nuanced knowledge, and their own lessons learned, and creating a connection.

Duncan (retrospective): “It is a real person who has or has been through depression and it is part of that realisation. Trying to make a connection that you are not on your own.”

Yet as already discussed, one peer participant held a more negative view on peer support. He did not envision value; reasoning experiences can be so different.

Pharmacist participants valued the opportunity to incorporate lived experience into healthcare consultations. Pharmacist 1 gives an example of when her knowledge of the antidepressant's pharmacokinetic properties, and a peer's experiential knowledge were combined.

Pharmacist 1 (retrospective): “To have someone else's response and say, ‘actually I find it better after food’. It was, it's just someone else's opinion I guess who is actually taking them. Like I personally don't take them so I wouldn't know the ins and outs of how it feels to take them [...]it is getting more of a personal side of it.”

In doing so the pharmacist participants felt they could deliver better consultations, that empowered patients, and this fitted into their professional value system.

Pharmacist 3/Winston (prospective): “It's like us as healthcare professionals saying we are not necessarily the experts all the time, our advice is as equally as useful as another patient's. So it's taking them seriously and saying that that they are useful parts of the process. It empowers [...] it would empower me that my opinion is useful and important and I have been taken seriously, so that's what I like about it most.”

Having a focus on antidepressants was also seen positively. Most participants felt there was lots of insight to be shared on taking antidepressants. Interventions giving voice to more balanced views, and focusing on dealing with issues around antidepressants, rather than promoting or not promoting antidepressants was seen as important.

John (prospective): “I don't think there is an advocacy for antidepressants, I think it is about how you deal with them when you are on them and what it might be to help you go forwards.”

Participants referenced how peer support could support normalisation and how dealing with stigma, low self-worth, negative media stories, and issues relating to masculinity were reasons why there were needs for this service, and why it fitted into their value system.

Winston/Pharmacist 3 (prospective): “I would have... you feel a bit mad, you know you have been given these drugs you are told you are mad. Well the doctor hasn't said that, but it is symbolic of

that, and it would be nice to speak to somebody else so you don't feel like you are the only person who has been through it, which sounds a bit of a cliché but I actually think it would be important.”

A focus on the male population fitted well for most participants’ value systems. This was because it was felt that men handled depression differently. Participants highlighted some maladaptive behaviours, or discussed certain social influences, or pressures due to gender.

Bennie (prospective): “I think it is entirely appropriate. I don't want to be too stereotypical and I'm not familiar enough with it all, but I think it is possible that men may share the same sort of feelings, the same sort of reasons for wanting to go on or needing to go on antidepressants, and probably relate to each other more readily.”

Frustration was expressed by some participants on toxic hegemonic masculinity and they believed that this was linked to negative mental wellbeing. Interventions that considered and sought to address such issue were seen as positive.

Clint (prospective): “And I'm happy to do this to show other men stop being big girls blouses. All you builders and big men out there take advice, and stick to it.

Another issue experienced by some of the male participants was that they had felt more isolated due to their gender. They felt it was harder to build up support networks. A service that could link men experiencing depression to another was valued.

Fred (retrospective): “I feel positive about it especially because it does seem really tricky for guys to have that place to talk about things and to sort of feel vulnerable and open up and that kind of stuff.”

A small number of participants were more ambivalent on the focus on men, unsure if it would matter in terms of peer support, yet most participants (peer participants and

pharmacists) saw a benefit to a male focused peer support service.

In terms of e-health and digital systems, there were examples of how high profile negative news stories caused conflict with one's value systems in relation to using e-health. For example Gerry, the participant who held the most negative views of peer support, linked an awareness of negative news stories (of people with malicious intent) to his concerns about this peer support service.

Gerry (prospective): "Make sure that he is not saying anything too..., not intending to be glib, that he's not trying to make you kill yourself, because that is a thing that does go into your head, that all the internet and all that malarkey is full of people goading other people on to do things that will actually end up making things worse."

Similarly some participants had concerns on communicating digitally, and recording sensitive information. Underpinning this view was concerns about data privacy, with participants referencing high profile data management breaches and data manipulations.

John (prospective): "I think people may be concerned about the privacy of information. Especially when you hear stories about whole elections being rigged, Facebook's losing millions of people's data all that sort of thing, so how the information is controlled and protected would be a big issue."

Intervention coherence

Table 36 Findings for Intervention coherence theme:

Sub-theme results	Details
Protocol and procedures coherent	<ul style="list-style-type: none"> • Steps in service were logical to participants • Pharmacists able to explain and conduct service.
Purposes of service and desired outcomes of service not clear for some.	<ul style="list-style-type: none"> • Different views – some seeking a deeper, more involved peer interaction than offered, others seeing it as a ‘top-level’ interaction and seeing this as desirable.
Consideration of real-life implementation, and healthcare collaboration	<ul style="list-style-type: none"> • Existing resources e.g. patient medication record search functions could be used • Current model not linked with other healthcare providers – the need to establish service within a care system was identified.
Feedback response (the response from peer 1 to panel member) not coherent to all in prospective interviews	<ul style="list-style-type: none"> • This caused most confusion when explaining the service. • Lexicon ‘feedback’ may not be appropriate.
Responsibilities and boundaries for participants	<ul style="list-style-type: none"> • Pharmacist need to consider boundaries if moving from facilitation to a therapeutic relationship. • Panel members felt responsibility for their information.

The flow of the intervention (The intervention protocol) was coherent for most in this study. The pharmacists felt they were able to explain how to do the service to the

respective peer 1s and panel members and were able to facilitate the consultation.

Researcher: “So how did you feel about explaining to them what they were going to do?”

Pharmacist 1: “Yes, pretty comfortable. It's quite a straightforward thing. You're asking questions and you get answers back. Yeah it was pretty good, comfortable.”

The peer participants understood the protocol steps and flow.

Andrew (Prospective): “Yes the process, the flow of it, it is logical, it is a logical way of doing it.”

Participants had different views on what the intended purpose, and the aims for the peer support should be. This would be important to address because it influenced views on the value of the service, and participants understanding of the service structure, as discussed previously in **perceived effectiveness**.

Some participants questioned how the intervention would operate if it were to be a real service. Pharmacist participants felt confident that they could identify participants who had been taking antidepressants from patient pharmacy medication records, and likened this to services that they currently did, such as the new medication service.

However it was suggested that this intervention could be improved by linking to the GPs, both in terms of GPs being able to refer patients to the service, and having a debriefing pathway, linking to GPs

Duncan (retrospective): “There is a danger that there are silos of information that the pharmacist has some information the GP has some information and they are not being shared, there is no collation of that experience and what the person is going through, so yes you have to be quite careful that the person being helped, that everybody knows what is going on.”

As mentioned, provided linked mental healthcare services is important, and participants saw value in linking to wider healthcare providers such as GPs, and there was a concern that if this was not in place patient care could be compromised.

The 'feedback media' was an element not initially understood by some participants. However retrospectively the feedback element was seen as a core aspect that helped connect the service, particularly for the panel member participants.

It was suggested that the lexicon 'feedback' may not be appropriate and leading to the confusion, rather than the actual process. Therefore the term 'feedback media' could be changed to 'response media'.

The responsibilities and boundaries of the peers and the pharmacists is something that came up in relation to intervention coherence. Some panel member participants were concerned about how their information may be interpreted, for example inadvertently giving incorrect information, or their messages being interpreted as an absolute truth by the reciprocal peer. This could suggest that these panel members felt a responsibility, and this was possibly amplified by the asynchronous communication because they would not be part of the interaction between the reciprocal peer and their pharmacist. They did not know how the peer 1 interpreted their information during the consultation, and what discussions occurred between that peer and their pharmacist. This sub-theme is discussed further in the self-efficacy theme.

For the pharmacists role, neither the peer or pharmacist participants saw this role as being a counsellor or clinical psychologist, but felt it may be difficult to understand where boundaries lay.

John (prospective): "You are effectively moving from facilitation to a therapeutic relationship and that is actually quite difficult to create the boundaries [...] if a facilitator is there to impart information and answer questions then that is fine, but it is when there is issues of clinical concern that come through whether pharmacist may get drawn into psychological aspects or discussions, so I think that is an issue."

Opportunity costs

Opportunity costs is a component of acceptability which covers the extent to which benefits, profits, or values must be given up to engage in an intervention. Findings are highlighted in Table 37.

Table 37: Findings for Opportunity Cost theme

Sub theme results	Details
Partaking in intervention meant not doing other activities.	<ul style="list-style-type: none"> • Pharmacist had high workloads. (Also see burden – time) • Pharmacists would need to be remunerated for it to be a viable service.
Loss of anonymity	<ul style="list-style-type: none"> • Participation required a loss of anonymity (to various extents). • This had potential to change the relationship with the pharmacist; one participant uncomfortable knowing the pharmacist is aware of their depression. • Also linked to data security and interactions when depressed in ‘burden’. There was trust in an ‘NHS system’

Opportunity cost can also be judged by what other interventions or activities participants might not partake in because they are partaking in this service. As this service was in addition to standard care this aspect was less relevant for peer participants as a cost. Many peer participants did not have access to or awareness of alternative acceptable peer support (see perceived effectiveness above), and for these the opportunity provided to access peer support was a benefit rather than an opportunity cost.

For pharmacist participants, involvement time, while mentioned under burden, also became an opportunity cost. The pharmacists had a high workload and taking part meant taking time away from other activities, therefore representing an opportunity cost. As mentioned, time as a barrier has been shown consistently in literature considering barriers and facilitators for community pharmacy services (Hossain, 2017 Hattingh, 2017, Hattingh, Sim et al. 2020).

Another opportunity cost, particularly for peer participants, was that partaking in this service resulted in a loss of anonymity. Participation resulted in a recording existing of participant, and this recording transferred within an information technology (IT) system. This was an issue for those concerned about potential loss of anonymity, and influenced if

they would want to partake.

Gerry (prospective): “I want my voice to go through a billion pounds worth of technology to completely disguise it, and make me sound like a woman from the Caribbean, so that it removed all trace of me.”

It was suggested that the condition of depression made these concerns worse, particularly as keeping things ‘inward’ and not wanting to open up were characteristics highlighted by peer participants.

Fred: “I guess I was paranoid and that kind of thing. I don’t know if that’s a symptom of the depression, I assume it is. [...] I am generally quite happy to speak to people, but it is just committing it to an IT system, and that trust in the system and the paranoia that potentially...”

Researcher: “So having the data on the system?”

Fred: “Hum.”

Yet other participants were pragmatic about the potential break of anonymity, and placed helping others, or receiving help as a greater benefit.

Lawrence (retrospective): “I wouldn't want other people to see me on TV. But this is different. This is not on TV. This is to help somebody else. If I can help somebody else, I'll help them. So I don't have any problems with that at all. None whatsoever.”

Some participants felt this service offered them more anonymity and confidentiality compared to other options, such as talking to friends or accessing self-help groups.

Kevin (retrospective): “There’s a male at the end giving me the answers what I want. I could get the same answers from a friend but I

don't talk to other people about medication and stuff. So get the answers from another male, it's ok, yeah it was good.”

It was important to participants that they were offered the choice between video or audio messaging. The audio option was preferred by those who were most concerned about privacy and anonymity. Yet some of these participants felt the video option would benefit them more, but did not choose this option because of concerns about security, or would need to be reassured about these issues before choosing video messaging.

Fred (retrospective): “Yeah I feel really conflicted, because like I said the privacy thing, if I could get over that and if I was confident in the system, I think video would be really nice, much better, so yes I would like that. I think especially now after the first interview, I would like to see the video, the video would be nicer.”

To reduce the concerns around the potential loss of anonymity participants wanted to know that the IT systems were secure, that data would not be used for other purposes, and that they were unlikely to be matched to peers that they may interact with in other contexts such as neighbours or work colleagues.

Edward (Retrospective): “You might know someone in passing to say hello but you might not want to say ‘you know what I am suffering from really bad anxiety issues, I am on these medications, its driving me potty, I have all these side effects. You don’t really want your next door neighbour to turn around and say really how’s everything going? ‘Well’...”

Running the service within the NHS was seen as positive, it increased participants confidence in the operations and security because they already had confidence and felt a part of this system.

Barry (retrospective): “I think so, as long it is as it is in the NHS care system it's fine.”

Although interestingly 1-2 years before these interviews there had been a high profile cyber-security attack on NHS (O'Dowd 2017). Barry explained further about how a '*NHS badge*' for him may subconsciously increase his confidence in the service, and the authority of the information.

Another consequence of this intervention is that it changes the relationship between the participant and their pharmacist. For most this was either welcomed, or not an issue, yet for one participant this was undesirable. It was a perceived threat to his anonymity and caused embarrassment.

Gerry (retrospective): "I don't know why. I felt embarrassed and I don't know why. Because...it's nothing to do with her [Pharmacist], it's more the sense of turning what's a very superficial relationship into...it's not a direct parallel because she knows what medication I am on, none of this will come as a surprise, but part of me probably incorrectly, goes into the pharmacy, they give you the pills, and you go out thinking they will lose track of who is on what."

Self-efficacy.

All participants were able to complete the intervention (their self-efficacy). Table 38 highlights key findings.

Table 38: Findings for Self-efficacy

Self-efficacy.	
Able to provide peer support within this service	<ul style="list-style-type: none">• Panel member able to use lived experience to answer questions.• Some felt need to 'safety net' responses
Consultation logistics	<ul style="list-style-type: none">• 4-5 questions appropriate.• Panel member participants placed importance on answering all questions• Pharmacist role in helping peer 1 consolidate core questions.

Panel member participants felt they were able to use their knowledge or own experiences to answer peer 1 questions, and also to suggest questions that a peer 1 might not think to ask, such as discussing with prescriber how long they may be on antidepressants. Typically 4-5 questions were asked by peer 1 in the introduction media, this allowed panel member's enough opportunity to provide their insights and support, but not too many that it was challenging for panel member's, or lost its impact for peer 1's.

Barry (retrospective): "There's not a lot I don't know about experiences with antidepressants, but it was nice I was able to... I remember thinking that is four questions; what! [Barry laughs] No more questions. But it was enough to make me feel like I could give him back some feedback, and one of four really helped him."

There was an importance placed on answering all questions, both by peer 1 and panel members. The asynchronous element of the intervention meant questions were asked without opportunity for further clarification. Panel members had to adapt to this mechanism of communication.

Andrew (retrospective): “The only bit is that I did have to listen to it all two-three times, which would I have done if I could see him or not because I wanted to pick out what he was actually asking.”

Some re-listened to media, made notes (participants suggested pen and paper should be part of the equipment required for this intervention), or were prompted by the pharmacist to ensure all questions were answered. The pharmacist also helped the peer 1’s, facilitating the process of considering their information needs, and what they wanted to ask.

Kevin: “Yeah there's a lot of different questions, but also the lady there was reminding me and asking me stuff so that was helpful.”

Researcher: “ The pharmacist?”

Kevin: “Yeah because obviously like I say when I've been going to appointments at the hospital I come out and think I didn't ask that question and all my questions are answered now apart from the driving.”

Only one interaction was not suitable to be show to peer 1 due to its length, and lack of focus on answering questions, (discussed further in content analysis section). Overall panel members spoke about a concern of how peer 1 may interpret their asynchronous response, particularly because the panel member could not pick up on nuances in conversations, or provide further clarification.

Andrew (retrospective): “From the reassuring side of view, because of the remoteness of it, because there was no immediate interaction, so the real time is not there you are not quite sure of how it is being received at the other end.”

Linked to this (discussed in ‘intervention coherence’) was a concern if a peer 1 may seek ‘*black and white*’ answers, and what were suitable questions. Similarly some panel members felt a responsibility for the information they imparted, and how it was interpreted by the peer 1 participants. This led to judgment and balance on the part of the panel members. Lawrence, who had a negative experience with the NHS during his care, spoke about conflicts with being an authentic peer and providing supportive information.

Lawrence (retrospective): “So you can't say to [Peer 1] something to make them feel better so they do it and they get better. You tell them what happened to you. You can only tell them that. [...] my first two experiences, if it had been left to the NHS, I wouldn't be here. I wouldn't be here. I wouldn't tell him that. So I when I say ‘don't lie’, he never asked; I didn't tell him.”

Sometimes panel members would include safety netting in their answers such as ‘check with your GP’, or appreciated the pharmacist confirming their information. For one participant, the concern about answering questions, and particularly that he may give wrong information was a source of potential anxiety. For him having the pharmacist present at the time of him recording his response helped him manage negative rumination.

Edward (prospective): “The whole internal thought of did I say the right thing, could I have said more, could I have said this. And then obviously the internal fight thinking actually the pharmacist said that that was okay, that was the right thing that I could have said. And then that was it really, it was just because knowing the pharmacist agreed and said yes, you said everything that you know, probably the best. It was really good.”

While most participants did not report this anxiety, this view is important to be aware of as those with depression can be more prone to negative rumination (Olatunji, Naragon-Gainey et al. 2013), and impaired cognitive functions can mean compromised ability to objectively appraise (Hammar and Årdal 2009, Grahek, Shenhav et al. 2019) even when in remission (Hasselbalch, Knorr et al. 2011). Therefore the role for pharmacist in validating

responses, may be an important program theory for patients who may react like Edward.

Peer participants felt they were able to record media without significant preparation or training. This did result in media with hesitations (umms and ahhs) but that was not seen as a disadvantage.

Harry (retrospective): “I might not have umm-d and ahuh-d so much, trying to think on my feet. But again, maybe that is what makes it natural perhaps, if you are just talking about how you feel.”

Some participants felt initially intimidated or awkward by being recorded (audio or video) but spoke about how they overcame this once they started talking. Concern was raised about how recording the introduction media may be particularly challenging for the peer 1, who is newly starting antidepressants, because at that point they would not have seen the panel member

Fred (prospective): “I think I would find it difficult to do that. To send something into an unknown, because I would not have necessarily have seen [Panel member] at that point, so putting my mind back in to where it was I would feel a bit vulnerable, just sort of sent it out there, into nowhere, not having seen [Panel member] at that point.”

As discussed previously some participants felt awkward by being recorded but spoke about how they overcame this once they started talking. There is concern that those newly starting antidepressants may find it harder to overcome these feelings. It was also highlighted that when suffering depression symptoms there can be a tendency be insular, focus on solving problems themselves, and resist taking in information.

Andrew (prospective): “The advice you’re given can go in one ear and out the other for any number of reasons. With the nature of depression you just do not believe it, you just do not believe that there is any way out of the hole that you are in.”

However, Kevin, the patient who had been taking antidepressants for the least amount of time felt able to partake, with positive outcomes from the experience. Features such as

having a pharmacist present to help him consider questions, having a focus on questions rather than an in-depth peer connection, and an asynchronous element, which allowed him to stagger the process and stagger taking in information made it more acceptable to him, and easier for him to participate.

There was a common view that this service would not be for everyone; some suggestions were that one's suitability to participate should be considered, and that a debriefing should occur after participation.

Next the results from the content analysis will be explored, and these findings can also be triangulated back to some of the interview findings discussed.

7.8. Content Analysis – Results and Discussion.

Results:

The content of the response media produced in this pilot was explored using content analysis. To facilitate a comparison between responses, only the responses from the panel members to peer 1 'James' media was used in the content analysis. Ten panel members responded to peer 1 'James' media, however one file was securely destroyed before being transferred and was lost.

The text transcripts from the nine responses were examined for five key variables. These were:

- (1) Interaction patterns (e.g. media length and format).
- (2) Responses to questions asked in the introduction media.
- (3) Supportive content of peer messages.
- (4) Components of peer message where personal insights were shared.
- (5) Medical advice content from the peers.

For variable 2, questions that had similar themes were grouped together. Three question themes were identified; side effects, stopping antidepressants and missed doses.

Results for variable 1 (interaction patterns):

The mean length of responses was 3 minutes 01 seconds, and a range of 2 minutes 15 - 3 minutes 48 seconds. There was one outlier which was 16 minutes 30 seconds long. This was an example where the intervention was not delivered as planned. In this case the file did not adhere to this protocol, and resulted in adaptation of the file, where only the first 3 minutes were played back to the peer 1. This editing of peer response media was also a non-adherence to protocol.

Results for variables 2-5:

Tables 39-50 below highlight the relevant texts categorised to the appropriate variables, and how many panel members response medias featured the coded variable.

Table 39: Responses of panel member participants to question 1 in the 'James' the introduction media.

<p>Question 1: Side- effects.</p>	<p>'So, when you started taking antidepressants what were the side-effects like? How long did they last for, do you still have many of them? Have they been worth it? Were they a short term thing that disappears? Was it worth the process? Do they still carry on afterwards?'</p>	
<p>Response media</p>	<p>Coded transcript</p>	<p>Theme(s)</p>
<p>Respondent ID: 1 Modality: Video Total Duration: 3 min 11</p>	<p>(a) I think your first question was side effects. I haven't noticed any side effects as such, I'm not sure what they say they will be, but I don't suffer any side effects, there's no drowsiness or anything like that. There is perhaps the loss of a sexual drive if I can say that. I am not sure if that is tied into the depression, or what have you, but I believe that is down to the tablets, but that is just something that I have, but I think for the tablets to be working it's probably worth it at the moment.</p>	<p>Side effects Weigh up side effects against taking medication (to get better)</p>
<p>Respondent ID: 2 Modality: Video Total Duration: 3 min 16</p>	<p>(a) Yes there are some slight side effects in the first few weeks, which means you are a little bit up and down. It's a bit of a roller-coaster but stick with it because when the antidepressants start to kick in you will get an overwhelming feeling of being happy to be here again, depending on how bad your depression is. Side effects like you've asked last about...for me it was about two weeks.</p>	<p>Side effects Weigh up side effects against taking medication (to get better) Discussed dealing with intolerable side effects</p>
	<p>(b) Side effects don't carry on for after the two weeks but a little bit of the sex drive, being a man, it dampens it a little bit. Doesn't destroy it, but it dampens it a little bit. c) and I asked my GP lots of questions and stuff like that, he told me how long it might take.</p>	

<p>Respondent ID: 3 Modality: Audio Total Duration: 16 min 30</p>	<p>(a) This current course that I started taking last year, I have not observed any side-effects at all. I suppose it was a little easier because I had taken them before, I might have expected to... if there was something little bit different then I would know, have noticed it. (b) I try to be aware of any side effects, but I can't think of any noticeable side effects that it had, apart from making me feel better.</p>	<p>No side effects</p>
<p>Respondent ID: 4 Modality: Audio Total Duration: 3 minutes 48</p>	<p>(a) I would suggest that the side effects I think they depend on the antidepressant that you are on. I have had side effects previously of being sick, ache and general lethargy, I think that is the right word, but the antidepressants I am on at the moment I haven't really had any side effects with. Again I think it is really trial and error, if you have too many side effects its best to go to the pharmacist or the doctor and tell them what you are suffering from and to see if there is any better medication that could benefit you. (b) If you do suffer lots of side effects say to the doctor about it and hopefully, they can refer you onto something that may have no side effects which is what I did. (c) I do take other medications so a lot of side effects I suffer from are from my other medications and not generally my antidepressants.</p>	<p>Side effects Discussed dealing with intolerable side effects</p>
<p>Respondent ID: 5 Modality: Audio Total Duration: 2minutes 15.</p>	<p>(a) Some of the side effects which I got were to do with sleep, I think my sleep was affected while I was depressed, and then when I took the antidepressants my sleep was, kind of got worse at the start, I think it may have lasted for four or five nights, and I do remember thinking if it was worth it, and if I should keep going, but I did keep going, and it was worth it, and it did get a lot better and they didn't continue, those side effects didn't continue, my sleep got a lot better. So after - I think after those four or five days my sleep did get better, so it was worth it and it is worth continuing.</p>	<p>Side effects Side effects went away/got better Weigh up side effects against taking medication</p>

<p>Respondent ID: 6</p> <p>Modality: Audio Total</p> <p>Duration: 2 minutes</p> <p>50</p>	<p>(a)I've never experienced any side effects that I knew were directly attributable to the antidepressants. There's something else that- another medical thing has cropped off recently where the person I saw thought that potentially it might be caused by the interaction - different medication I was on, which is one of the things that has made me try and wean myself off stuff. But I suppose ultimately it is a balancing up thing between are the side effects more bearable than, you know, what you are on the antidepressants for in the first place.</p>	<p>No side effects</p> <p>Weigh up side effects against taking medication (to get better)</p>
<p>Respondent ID: 7</p> <p>Modality: Video Total</p> <p>Duration: 3 min 25</p>	<p>(a)In terms of the side effects - yeah there are some interesting ones and some not so interesting ones. So the interesting ones; forgetfulness and foggy brain sometimes. The worst one is that I have had to had go to the toilet maybe four times a night (laugh). That has got better, but it changed my routine, you wake up more therefore you need the toilet more. Little tip; maybe don't have cups of tea before you go to bed. But you do get used to it.</p>	<p>Side effects</p> <p>Side effects went away/got better</p>
<p>Respondent ID: 8</p> <p>Modality: Video</p> <p>Total Duration: 3 min 41</p>	<p>(a) In my circumstances I didn't ask about any side effects because that didn't enter my mind. All I wanted to do was get better.</p> <p>b) I didn't suffer any side effects and in my experience, the side effects if there are any they will be minimal. At the end of the day you need to get better, so you need to get the drugs into your system as soon as possible so they can start having an effect and then get back to normal. That is my experience.</p>	<p>No side effects</p> <p>Weigh up side effects against taking medication (to get better)</p>
<p>Respondent ID: 9</p> <p>Modality: Audio</p> <p>Total Duration: 3 min</p>	<p>(a)The main side effects when taking the medication to start with were a bit of stomach upset, and tightness, almost like wind in the stomach and bit of constipation. That goes quite quickly. I feel I gained some weight as well, which I'm not sure if it was to do with the medication or what. I also experienced a bit of headaches, I'd describe as fuzziness in the head but that lasted a matter of a few weeks and eased off. None of these effects have lasted more than a few weeks. There was quite a profound effect on libido, that does tend to continue on, I think that's probably an issue that was the most concern.</p>	<p>Side effects</p> <p>Found side effects went away/got better</p>

Table 40: Number of panel member's media responses containing each theme from Table 39

Theme:	Number of panel members that expressed this theme:
No side effects	3
Side effects	Loss of libido (3), 'Foggy' brain / 'Fuzziness' in head (2), Stomach / GI upsets (2), Sleep disturbances (1), increased urination (1), Side effects, but not specified (2)
Weigh up side effects against taking medication (to get better)	5
Found side effects went away/got better	4
Discussed dealing with intolerable side effects (e.g. change antidepressant, speaking to GP, pharmacist)	3 (NB one was from the corrupt video, no transcript possible)

Table 41: Responses of panel member participants to question 2 in the 'James' the introduction media.

Question 2 Stopping antidepressants	I might stop taking them at some point, in fact I hope I will be able to stop... Have you tried stopping what does it feel like to stop? Does it take a long time? does it feel bad to do it? Theme	
Response media details	Coded transcript	Theme
Respondent ID: 1 Modality: Video Total Duration: 3 min 10	(a)As far as giving up, I haven't thought about giving up at the moment, so I haven't tried to stop it or reducing them.	Not stopped
Respondent ID: 2 Modality: Video	(a)Coming off them, yes quite easy because when you are up, the fact that you are happy again because you are on the antidepressants, coming off them is a lot easier than you think. Everything at the moment, well while you are in depression, and anxious and worried, everything is blown out of proportion. As soon as the antidepressants start kicking in, things become clearer, you can start thinking straighter and these questions will be answered near enough for themselves.	Suggest stopping antidepressants (AD) successful/non problematic Give encouragement reassurance about stopping
Respondent ID: 3 Modality: Audio	N/A	

<p>Respondent ID: 4 Modality: Audio</p>	<p>(a)I will say that if you do stop taking them, I wouldn't stop taking anything straight away, I would wean yourself off anything, as if you stop taking something straight away you will find that you have very bad side effects; nausea, feeling very sick generally and it could be a lot worse. (b) Pharmacist: Have you ever tried to stop your antidepressant? ID 4: I have yes. And I had very bad side effects from that issue. That is one of the things I would say, if you do stop taking anything it is best to wean yourself off them and talk to the pharmacist or doctor previously.</p>	<p>Discuss reducing dose/ issues about stopping suddenly Suggest stopping ADs was problematic Advise about talking to GP/Pharmacist about stopping</p>
<p>Respondent ID: 5 Modality: Audio</p>	<p>(a)Stopping...yeah I think, I can't quite remember the dose I was on the first I took them but the dose comes down in stages, and then you don't really notice that you are coming down because you feel so much better anyway. So that was a good thing.</p>	<p>Discuss reducing dose/ issues about stopping suddenly Suggest stopping ADs was successful/non problematic Give encouragement/ reassurance about stopping</p>
<p>Respondent ID: 6 Modality: Audio</p>	<p>(a)number two, how easy is it to stop. Well my experience is that I am very good at weaning myself down to an absolutely minimal dosage and then invariably as soon as I am off them I absolutely feel the effects of coming off them, so then my GP puts me up to a high dosage again. So what I am at the moment on is a fairly minimal dosage. So in answer to your question, yeah in my experience it is not easy to stop, but then again you have got to weigh up what the lesser of the two evils is.</p>	<p>Discuss reducing dose/ issues about stopping suddenly Suggest stopping ADs was problematic Advise about needing to be in right place before stopping</p>

<p>Respondent ID: 7 Modality: Video</p>	<p>(a)I have tried to reduce it a few times, not because I have any desire to come off of it or because I feel it is bad to take antidepressants. I think it's just I would like to try and reduce it just to see if I can, mentally maybe I might be feeling better, well enough to not take medication, but when I've tried to do it in the past maybe I've tried to come off it too quickly, I've had tremors, shakes, and sort of brain sparks, you get this funny feeling in the head from time to time, which kind of tells me I need to come off it more slowly, or go back on it again and try it again later.</p>	<p>Suggest stopping ADs was problematic Discuss reducing dose/ issues about stopping suddenly Advise about needing to be in right place before stopping</p>
<p>Respondent ID: 8 Modality: Video</p>	<p>(a)The second issue you asked about was stopping them. Yes I have weaned myself off the medication a couple of times over a long period of time, but for various reasons I started taking them again. The way I weaned myself off was a very slow process. I soon realised I needed to go back on the medication again. I have no desire to wean myself off now.</p>	<p>Discuss reducing dose/ issues about stopping suddenly Advise about needing to be in right place before stopping</p>
<p>Respondent ID: 9</p>	<p>N/A</p>	

Table 42: Number of panel member's media responses containing each theme from Table 41

Theme:	Number of panel members that expressed this theme:
Discuss reducing dose/ issues about stopping suddenly	5
Suggest stopping ADs was problematic	3
Suggest stopping ADs was successful/non problematic	2
Give encouragement/reassurance about stopping	2
Advise about needing to be in right place before stopping	3
Not stopped	1
Advise about talking to GP/Pharmacist about stopping	1

Table 43; Responses of panel member participants to question 3 in the 'James' the introduction media.

Question 3 Missed doses	What happens if you forget to take them does not have bad consequences if you forget to take them or do you have to be really rigorous, or does it not matter quite so much if I miss the odd one?	
Response media details	Coded transcript	Theme
Respondent ID: 1 Modality: Video Total Duration: 3 min 10	I know that sometimes...the question that you asked was happens if I forget or if I miss the odd one, that does happen although I am quite good I think at keeping track of it. If I do forget, or I do miss the odd one nothing actually happens, it's ok, I don't need to take one to catch up, I've just missed it, but I just keep on taking them.	Reassurance to peer about missing doses Missed doses in past Discuss not having issues from missing (singular) dose
Respondent ID: 2 Modality: Video	Ah yes I have done that quite a few times myself and because you have to build them up in the system as long as you do, as long as you don't miss more than two days...I have been two days without them without feeling too much of a side effect, I would say....I was a bit down that day until I took the antidepressants, and everything was fine, so I would suggest taking them rigorously every single day, but don't worry about it if you miss one, but make sure you take it as soon as you remember.	Missed doses in past Discuss not having issues from missing (singular) dose Reassurance to peer about missing doses Discuss issues they had from missing dose Advice about missed dose Importance of taking regularly
Respondent ID: 3 Modality: Audio	there is no strictness on the regime, if you do not take a tablet every day it does not really matter, as long as you try and be regular obviously	Reassurance to peer about missing doses Importance of taking regularly Discuss not having issues from missing (singular) dose

Respondent ID: 4 Modality: Audio	ID4: I think if you forget to take your medication, when you do remember you need to take it I would take it	Advice about missed dose Reassurance to peer about missing doses
	but don't take too many if that's the right Pharmacist : Ah-huh. ID4: If you just continue as best you can. I think if you have missed it for a day I wouldn't worry too much about it. Just continue taking it from the following day, and continue on as normal. The way I best do my medication is I actually keep my medication all together for a week, I work which worth of medication and I put it in a little planner and also a little bag which I put next to the fridge knowing that I need to get a drink when I need to take my medication so I always see it as soon as I take it. So I never forget everyday that I need to take my medication.	Importance of taking regularly Share practical advice/tips for remembering medications
Respondent ID: 5 Modality: Audio	I personally didn't forget to take the pill, so I'm not sure about that one,	Not missed dose
Respondent ID: 6 Modality: Audio	If you forget, okay a couple of things a) more often than not you will notice if you forget because, you know, your state will alert you to the fact that you have forgotten it. If you don't notice it then well that's fantastic. On the odd occasions where I've forgotten and haven't felt the effects of having forgotten then it's almost like a pat on the back, that maybe I am not as reliant on them as I think I are. Or there are these great things, that you can't see because you are only hearing my voice, but there are these great pill containers which I am sure your local pharmacy will be pleased to sell you.	Reassurance to peer about missing doses Missed doses in past Discuss not having issues from missing (singular) dose Share practical advice/tips for remembering medications

<p>Respondent ID: 7 Modality: Video</p>	<p>It's um...bit of a problem to start with, remembering to take your tablet, but you get into the routine of taking it. So every day I get up, have a cup of tea, and take my tablet, don't even think about it. Just becomes part of my daily routine. I have no problem taking it. I have forgot to take my tablet a few times and again I have noticed quite quickly, within the day I will get the sparks in my head. It is not a horrible feeling, it is just bit of a weird sensation and it reminds me that I need to take the medication.</p>	<p>Missed doses in past Discuss issues they had from missing dose</p> <p>Reassurance to peer about missing doses</p>
<p>Respondent ID: 8 Modality: Video</p>	<p>The third question you asked was the issue to do with missing a dose. I don't worry about that. I miss a dose now and again, just forget sometimes or too busy and I don't find a problem, it doesn't have an effect at all. I think if you miss more than one dose though perhaps would be more of a concern.</p>	<p>Missed doses in past</p> <p>Discuss not having issues from missing (singular) dose</p> <p>Importance of taking regularly</p>
<p>Respondent ID: 9</p>	<p>All I wanted to do was get better, so I took the drugs and in order to make sure that I took them and kept taking the right ones each day I went to a chemist and bought one of those, I call it a pill pot which has got Monday, Tuesday, Wednesday, Thursday and Friday on it. Some of them are am, pm, and then you can know if you have missed one. That will help you doing that.</p>	<p>Importance of taking regularly</p> <p>Share practical advice/tips for remembering medications</p>

Table 44: Number of panel member's media responses containing theme from Table 43

Theme:	Number of panel members that expressed this theme:
Reassurance to peer about missing doses (e.g. that it can be an issue, but managed, or singular missed dose unlikely to be problematic etc)	6
Missed doses in past	4
Share practical advice/tips for remembering medications	4
Importance of taking regularly	4
Discuss issues they had from missing dose	3
Advice about missed dose – (carry on and take next dose as normal)	3
Discuss not having issues from missing (singular) dose	2
Not missed dose	1

Table 45: Coding of panel member's response media for supportive responses

Response media details	Coded transcript	Theme
<p>Respondent ID: 1 Modality: Video Total Duration: 3 min 11</p>	<p>(a) Righto, I started taking antidepressants in Jan of 2016, so that's a year and a half now. At the moment I am still taking them, which is going well, it has been a very positive journey.</p> <p>(b) the question that you asked was happens if I forget or if I miss the odd one, that does happen although I am quite good I think at keeping track of it.</p> <p>(c) It is quite subtle and it takes a build up to get into your system and to start working. It is something that is quite hard to see first of all.</p> <p>(d) There is perhaps the loss of a sexual drive if I can say that. My own belief at the beginning was that my depression which was caused for whatever reason, I couldn't see that it could be solved medically, through medicine. But a piece of advice that I was given, which was very true was that [...]</p> <p>(f) So yes I would certainly recommend sticking with it and carrying on with it.</p> <p>(f) [Smile]</p>	<p>A focus or importance placed on answering (Peer 1's) questions.</p> <p>Provide empathy, hope reassurance, or encouragement.</p> <p>Disclose personal sensitive information about themselves.</p> <p>Acknowledging that they had negative thoughts or views about antidepressants.</p> <p>Encouraging balanced thoughts, and/or expectations.</p> <p>Sensitive phrasing or hedging phrasing.</p> <p>Video only: Visual cues / body language (e.g. thumbs up, smile)</p>
<p>Respondent ID: 2 Modality: Video Total Duration: 3 min 16</p>	<p>(a) It's a bit of a roller-coaster, but stick with it because when the antidepressants start to kick in you will get an overwhelming feeling being happy to be here again, depending on how bad your depression is. Side effects like you've asked last about...for me it was [...]</p> <p>(b) I've been on other antidepressants before, briefly I'm a musician, bit sensitive</p> <p>(c) Overall, I would say in my experience, it has saved my life. I would say, on two occasions, because without that helping hand I don't know</p>	<p>A focus or importance placed on answering (Peer 1's) questions.</p> <p>Provide empathy, hope reassurance, or encouragement.</p> <p>Disclose personal sensitive</p>

	<p>how far I would have sunk.</p> <p>(c) Ah yes I have done that quite a few times myself [Ends with a thumbs up]</p>	<p>information about themselves. Sensitive phrasing or hedging phrasing. Video only: Visual cues / body language (e.g. thumbs up, smile)</p>
<p>Respondent ID: 3 Modality: Audio Total Duration: 16 min 30</p>	<p>(a) Yes it is difficult isn't it. A lot of those questions that were being asked are the sort of questions that I asked when I was first prescribed.</p> <p>(b) I have no idea how it would work apart from the explanation given by the GP at the time. I mean they are all pertinent questions about how will it affect you, and what are the side-effects, the possible side effects.</p> <p>(c) My wife occasionally says to me 'are you sure you don't want to go to the doctor and get your tablets doubled in dosage'. Ah yeah. Am I not being very happy? No. it is not something to be frightened of it in a sense</p>	<p>Validating importance of question/ Normalising concerns. Provide empathy, hope reassurance, or encouragement. Disclose personal sensitive information about themselves. Acknowledging that they had negative thoughts or views about antidepressants. Encouraging balanced thoughts, and/or expectations. Use of humour</p>
<p>Respondent ID: 4 Modality: Audio Total Duration: 3 minutes 48</p>	<p>(a) Myself I have been taking antidepressants on and off for twenty plus years. Some have been very good, some have been extremely bad, If you just continue as best you can.</p>	<p>A focus or importance placed on answering (Peer 1's) questions.</p> <p>Provide empathy, hope reassurance, or encouragement.</p>
<p>Respondent ID: 5 Modality: Audio Total Duration:</p>	<p>(a) Yeah, I think when I started I was very nervous as well, but it was worth it, it was worth doing it.</p> <p>(b) I do remember thinking if it was worth it, and if I should keep</p>	<p>A focus or importance placed on answering (Peer 1's) questions</p>

<p>2minutes 15.</p>	<p>going, but I did keep going, and it was worth it, and it did get a lot better</p> <p>(c) the best advice I can give I think is that it is not something....there is not a massive stigma to it. It's just treatment, and it is quite common. It is a common treatment and it helps and it's good in the long run, and it is worthwhile pursuing.</p>	<p>Validating importance of question/ Normalising concerns. Provide empathy, hope reassurance, or encouragement. Disclose personal sensitive information about themselves. Acknowledging that they had negative thoughts or views about antidepressants Encouraging balanced thoughts, and/or expectations.</p>
<p>Respondent ID: 6 Modality: Audio Total Duration: 2minutes 50</p>	<p>(a) yeah in my experience it is not easy to stop, but then again you have got to weigh up what the lesser of the two evils is.</p> <p>(b) On the odd occasions where I've forgotten and haven't felt the effects of having forgotten then it's almost like a pat on the back, that maybe I am not as reliant on them as I think I am.</p>	<p>A focus or importance placed on answering (Peer 1's) questions Encouraging balanced thoughts, and/or expectations. Use of humour</p>
<p>Respondent ID: 7 Modality: Video Total Duration: 3min 25</p>	<p>(a) Hi Nathan, so I'd like to try and talk through and answer some of the questions that you have had in regards to taking your medication.</p> <p>(b) I have been on medication now for a number of years. I would say to start off that it has changed my life, um without it think I would have struggled [...]</p> <p>(c) so I would say that you are doing the right thing to start with.</p> <p>(d) I found I needed to reduce the amount of antidepressant that I was taking for myself to feel comfortable with what I am doing.</p>	<p>A focus or importance placed on answering (Peer 1's) questions Validating importance of question/ Normalising concerns. Provide empathy, hope reassurance, or encouragement. Disclose personal sensitive information about themselves. Acknowledging that they had</p>

		negative thoughts or views about antidepressants Encouraging balanced thoughts, and/or expectations.
Respondent ID: 8 Modality: Video Total Duration: 3 min 41	(a) There were three things raised in the video. One was about side effects. The other was about stopping the medication, and the third one was about missing a dose. So I'll just cover them all off one, by one. The second issue you asked about was stopping them.	A focus or importance placed on answering (Peer 1's) questions
Respondent ID: 9 Modality: Audio Total Duration: 3 min	(a) Okay, thank you for the question. (b) that didn't enter my mind. All I wanted to do was get better, so I took the drugs You have already been through the...you have already got half way, well not half, a third of the way there by actually going to the doctor and getting advice. That's the major battle.	A focus or importance placed on answering (Peer 1's) questions Provide empathy, hope reassurance, or encouragement. Disclose personal sensitive information about themselves. Encouraging balanced thoughts, and/or expectations.

Table 46: Number of panel member's media responses containing theme from Table 45.

Theme:	No of panel members that expressed theme:
A focus or importance placed on answering (Peer 1's) questions	8
Provide empathy/hope/reassurance/encouragement	8
Disclose personal sensitive information about themselves (e.g. how long have been taking, view that it has saved their life, etc.)	8
Acknowledging that they had negative thoughts or views about antidepressants	6
Validating importance of question/ Normalising concerns	5
Sensitive phrasing or hedging phrasing	4
Encouraging balanced thoughts, and/or expectations	4
Use of humour	4
From video only: Visual cues / body language (e.g. thumbs up, smile)	2

Table 47: Coding panel members' media responses for personal insights

Response media details	Coded transcript	Theme
<p>Respondent ID: 1 Modality: Video Total Duration: 3 min 10</p>	<p>(a) My own belief at the beginning was that my depression which was caused for whatever reason, I couldn't see that it could be solved medically, through medicine. But a piece of advice that I was given, which was very true was that you know I couldn't start solving problems in my life that were causing depression until I had started sorting myself out, and they do eventually start working but it is a subtle thing and it does take time. (b) So yes I would certainly recommend sticking with it and carrying on with it.</p>	<p>Taking antidepressants have been worth it/beneficial.</p> <p>Recommend taking antidepressants.</p> <p>Issues with thinking clearly when depressed.</p>
<p>Respondent ID: 2 Modality: Video</p>	<p>(a) Overall, I would say in my experience, it has saved my life. I would say, on two occasions, because without that helping hand I don't know how far I would have sunk. (b) Everything at the moment, well while you are in depression, and anxious and worried, everything is blown out of proportion. As soon as the antidepressants start kicking in, things become clearer, you can start thinking straighter and these questions will be answered near enough for themselves.</p>	<p>Taking antidepressants have been worth it/beneficial.</p> <p>Recommend taking antidepressants.</p> <p>Issues with thinking clearly when depressed.</p>
<p>Respondent ID: 3 Modality: Audio</p>	<p>(a) I did a lot of reading about it and tried to become a little bit more self-aware, which is very difficult, and tried in a small way to perceive how other people thought about me which is also quite difficult (b) that is what I would recommend to people is if you are suffering from</p>	<p>Seeking information and support (e.g. from HCP, self-reading etc.) important.</p> <p>Self awareness of their mood has been</p>

	<p>depression, and you can bring yourself to... which is very difficult I understand when you are just there on the floor...if you can bring yourself to look at the subject [...]do some reading and think about the way the mind works... I found it quite helpful, and I thought there is a lot to this.</p> <p>(c) And it gave me a little bit of ability to recognise when I was perhaps going downhill a little bit. Rather than just going down those very deep troughs it's almost like thinking 'ohh no, no, no' I have to do something else, develop some sort of mechanism for trying to level your mood as it were for want of a better phrase. But it's just not easy when you are in a very bad place try to suggest somebody that they get some books and start studying about depression, perhaps not everybody's favourite.</p> <p>(d) But yes just going back to the general questions that were there; it is not something to be frightened of it in a sense, again I did a lot of reading I found out myself if I had any questions, and I found it just smoothed the path a little.</p>	<p>important in recovery (e.g. downward spirals).</p> <p>Not stigmatising themselves/ cognitive realignment to feel comfortable with taking antidepressants.</p> <p>Recommend taking antidepressants.</p>
<p>Respondent ID: 4 Modality: Audio</p>	<p>(a) Myself I have been taking antidepressants on and off for twenty plus years. Some have been very good, some have been extremely bad, and as I say the one I am on at the moment is very good.</p> <p>(b) The only thing I would suggest is that if I was taking medication for the first time is to find out what is best for you. If you do suffer lots of side effects say to the doctor about it and hopefully they can refer you onto something that may have no side effects which is what I did.</p>	<p>Taking antidepressants have been worth it/beneficial.</p> <p>Adjustments to get right therapy</p> <p>Promoting candour Seeking information and support (e.g. from HCP, self-reading etc.) important</p>
<p>Respondent ID: 5 Modality: Audio</p>	<p>the best advice I can give I think is that it is not something....there is not a massive stigma to it. It's just treatment, and it is quite common. It is a common treatment and it helps and it's good in the long run, and it is worthwhile pursuing.</p> <p>(b) It was worth it, it was worth doing it.</p>	<p>Not stigmatising themselves/ cognitive realignment to feel comfortable with taking antidepressants.</p> <p>Taking antidepressants have been worth it/beneficial.</p> <p>Recommend taking antidepressants.</p>

<p>Respondent ID: 6 Modality: Audio</p>	<p>What else would I pass on – nothing really. Try them because ultimately if they make absolutely no difference come off them, and if they help in even small way then you know, I think that's probably better than not being on them as long as you don't experience any side effects or what not. I think that's it.</p>	<p>Recommend taking antidepressants. Adjustments to get right therapy (e.g. change antidepressant, reduce dose etc.)</p>
<p>Respondent ID: 7 Modality: Video</p>	<p>(a) It has helped to stabilise the way I feel about things, so I would say that you are doing the right thing to start with. (b) I would say to start off that it has changed my life, um without it think I would have struggled to overcome the problems that I was experiencing, which has caused my depression. (c) Just becomes part of my daily routine. I have no problem taking it. To me it's like if I had a headache I'd take paracetamol, so I take this to help me overcome the problems that I have. (d) I found I needed to reduce the amount of antidepressant that I was taking for myself to feel comfortable with what I am doing. (e) But as I said I think without it I would have struggled to be able change my lifestyle and help myself get out of depression and not go down a vicious cycle, so it is well worth continuing with it.</p>	<p>Issues with thinking clearly when depressed Taking antidepressants have been worth it/beneficial. Recommend taking antidepressants Not stigmatising themselves/ cognitive realignment to feel comfortable with taking antidepressants Adjustments to get right therapy</p>
<p>Respondent ID: 8 Modality: Video</p>	<p>N/A</p>	

<p>Respondent ID: 9</p>	<p>(a)At the end of the day you need to get better, so you need to get the drugs into your system as soon as possible so they can start having an effect and then get back to normal. That is my experience. (b)My advice to you is to listen to your doctor, and take their advice and take the medication as prescribed because that the only way you are going to get better.</p> <p>So listen to the doctor, tell them the truth, be honest with them, that's the only way they can make a proper diagnosis and then take the pills. Try not to forget them, and if they aren't having any effect tell the doctor. That would be my advice to you.</p>	<p>Recommend taking antidepressants Taking antidepressants have been worth it/beneficial.</p> <p>Issues with thinking clearly when depressed Promoting candour</p>
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Table 48: Number of panel member's media responses containing theme from Table 47.

Theme	No. of panel members that expressed the theme:
Taking antidepressants have been worth it/beneficial.	6
Recommend taking antidepressants	6
Issues with thinking clearly when depressed, and antidepressants helped them to think clearer, and solve problems/ get back to 'normal'	4
Adjustments to get right therapy (e.g. change antidepressant, reduce dose etc.)	3
Not stigmatising themselves/ cognitive realignment to feel comfortable with taking antidepressants	3
Promoting candour	2
Seeking information and support (e.g. from HCP, self-reading etc.) important	2
Self awareness of their mood has been important in recovery (e.g. downward spirals)	1
Would not recommend taking antidepressants	0

Table 49: Coding panel members' media responses for medical advice.

Response media details	Coded transcript	Theme
<p>Respondent ID: 1 Modality: Video Total Duration: 3 min 11</p>	<p>(a) I haven't noticed any side effects as such [...] I don't suffer any side effects, there's no drowsiness or anything like that. There is perhaps the loss of a sexual drive</p> <p>(b) I do miss the odd one nothing actually happens [...] I don't need to take one to catch up, I've just missed it.</p> <p>(c) ...they are not an instant result, so you don't take the tablets and you are suddenly there. It is quite subtle and it takes a build up to get into your system and to start working.</p> <p>(d) ...they do eventually start working but it is a subtle thing and it does take time.</p>	<p>Medical information given linked to their experience.</p> <p>Common side effect</p> <p>Said no issue from one missed dose.</p> <p>Advised not to double dose if missed dose.</p> <p>Discuss delayed therapeutic effect.</p>
<p>Respondent ID: 2 Modality: Video Total Duration: 3 min 16</p>	<p>(a) There are some slight side effects in the first few weeks, which means you are a little bit up and down.</p> <p>(b) ...when the antidepressants start to kick in you will get an overwhelming feeling being happy to be here again</p> <p>(c) Side effects like you've asked last about...for me it was about two weeks (d)...the sertraline that I am on at the moment it's the best I've been on for the anxiety and depression.</p> <p>(e) Side effects don't carry on for after the two weeks but a little bit of the sex drive, being a man, it dampens it a little bit.</p> <p>(f) ...antidepressants, coming off them is a lot</p>	<p>Medical information given linked to their experience.</p> <p>The effect antidepressants will have (make you happy, clear head).</p> <p>Discuss delayed therapeutic effect.</p> <p>Specifics on antidepressants mentioned (e.g. name, dose etc.)</p> <p>Potential issue from multiple missed doses</p>

	<p>easier than you think.</p> <p>(g) As soon as the antidepressants start kicking in, things become clearer, you can start thinking straighter</p> <p>(h) You have to build them up in the system as long as you do, as long as you don't miss more than two days...I have been two days without them without feeling too much of a side effect.</p>	
<p>Respondent ID: 3 Modality: Audio Total Duration: 16min 30</p>	<p>(a) I have not observed any side-effects at all.</p> <p>(b) I knew that they would take a period of time to take effect and there is no strictness on the regime, if you do not take a tablet every day it does not really matter, as long as you try and be regular obviously,</p> <p>(c) There is the dosage. I am aware that different dosages can be prescribed. what I'm thinking off is like a chemical imbalance that causes, made to need this</p>	<p>No side effects.</p> <p>Discuss delayed therapeutic effect.</p> <p>Said no issue from one missed dose.</p> <p>Medical information given linked to their experience.</p> <p>Discuss conceptually that different antidepressants and doses available (e.g. not specifically stated).</p> <p>Reason why take them/need them (chemical imbalance, need rest etc.) .</p>

<p>Respondent ID: 4 Modality: Audio Total Duration: 3 minutes 48</p>	<p>(a) I would suggest that the side effects I think they depend on the antidepressant that you are on. (b) I have had side effects previously of being sick, ache and general lethargy (c) I think it is really trial and error, if you have too many side effects its best to go to the pharmacist or the doctor and tell them what you are suffering from and to see if there is any better medication that could benefit you. (d) I wouldn't stop taking anything straight away, I would wean yourself off anything, as if you stop taking something straight away you will find that you have very bad side effects; nausea, feeling very sick generally and it could be a lot worse. (e) ID4: I think if you forget to take your medication, when you do remember you need to take it I would take it but don't take too many if that's the right</p>	<p>Medical information given linked to their experience</p> <p>Discuss conceptually that different antidepressants and doses available (e.g. not specifically stated). Common side effect. Felt prescribing right antidepressant was 'trial and error'</p> <p>Advice not to suddenly stop antidepressants, and to come off slowly.</p> <p>Take antidepressant regularly</p>
	<p>Pharmacist : Ah-huh. ID4: Just continue taking it from the following day, and continue on as normal. (f) I was taking medication for the first time is to find out what is best for you. If you do suffer lots of side effects say to the doctor about it and hopefully they can refer you onto something that may have no side effects which is what I did. (g) I think the main thing is that if you are taking anything other than antidepressants as well, I think the combination of medication you take is best to get checked first otherwise they could contradict each other.</p>	<p>Discuss conceptually that interactions can occur between antidepressants and other medications.</p> <p>To use HCP as resource, and involve in decisions, plans, or problems.</p>

<p>Respondent ID: 5 Modality: Audio Total Duration: 2minutes 15.</p>	<p>(a) Some of the side effects which I got were to do with sleep,[...] my sleep was, kind of got worse at the start, I think it may have lasted for four or five night. ...the dose comes down in stages, and then you don't really notice that you are coming down because you feel so much better anyway.</p>	<p>Medical information given linked to their experience.</p> <p>Common side effect.</p> <p>Advice not to suddenly stop antidepressants, and to come off slowly.</p> <p>The effect antidepressants will have (make you happy, clear head).</p>
<p>Respondent ID: 6 Modality: Audio Total Duration: 2minutes 50</p>	<p>(a) I've never experienced any side effects that I knew were directly attributable to the antidepressants. (b) it might be caused by the interaction - different medication I was on (c) more often than not you will notice if you forget because, you know, your state will alert you to the fact that you have forgotten it. If you don't notice it then well that's fantastic. On the odd occasions where I've forgotten and haven't felt the effects of having forgotten then it's almost like a pat on the back, that maybe I am not as reliant on them as I think I am.</p>	<p>Medical information given linked to their experience.</p> <p>No side effects.</p> <p>Medical information given not linked to their experience (e.g. statements).</p>

<p>Respondent ID: 7 Modality: Video Total Duration: 3min 25</p>	<p>(a) forgetfulness and foggy brain sometimes. The worst one is that I have had to had go to the toilet maybe four times a night (laugh). That has got better, but it changed my routine, you wake up more therefore you need the toilet more.</p> <p>(b) when I've tried to do it in the past maybe I've tried to come off it too quickly, I've had tremors, shakes, and sort of brain sparks, you get this funny feeling in the head from time to time, which kind of tells me I need to come off it more slowly, or go back on it again and try it again later.</p> <p>(c) I have forgot to take my tablet a few times and again I have noticed quite quickly, within the day I will get the sparks in my head.</p> <p>(d) I wouldn't recommend stopping the medication, just going, speaking to the doctor and see if there is a different form of antidepressant that has less of a side effect that what you're experiencing.</p>	<p>Medical information given linked to their experience.</p> <p>Common side effect</p> <p>Uncommon side effects</p> <p>Advice not to suddenly stop antidepressants, and to come off slowly</p> <p>To use HCP as resource, and involve in decisions, plans, or problems.</p>
<p>Respondent ID: 8 Modality: Video Total Duration: 3 min 41</p>	<p>(a) The main side effects when taking the medication to start with were a bit of stomach upset, and tightness, almost like wind in the stomach and bit of constipation. That goes quite quickly [...] I also experienced a bit of headaches, I'd describe as fuzziness in the head but that lasted a matter of a few weeks and eased off.</p> <p>(b) There was quite a profound effect on libido, that does tend to continue on.</p> <p>(c) I miss a dose now and again, just forget sometimes or too busy and I don't find a problem, it doesn't have an effect at all. I think if you miss more than one dose though perhaps would be more of a concern.</p> <p>(d) The way I weaned myself off was a very slow process.</p>	<p>Medical information given not linked to their experience (e.g. statements).</p> <p>Medical information given linked to their experience.</p> <p>Common side effect.</p> <p>Said no issue from one missed dose.</p> <p>Advice not to suddenly stop antidepressants, and to come off slowly</p>

<p>Respondent ID: 9 Modality: Audio Total Duration: 3 min</p>	<p>(a) If you have been prescribed antidepressants it means that you, you need rest and you need help. (b) I didn't suffer any side effects and in my experience, the side effects if there are any they will be minimal. (c) if they aren't having any effect tell the doctor.</p>	<p>Medical information given not linked to their experience (e.g. statements). Medical information given linked to their experience. No side effects. To use HCP as resource, and involve in decisions, plans, or problems.</p>
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Table 50: Number of panel member's media responses containing theme from Table 49

Media content:	Number of times content expressed:
Medical information given linked to their experience (e.g. 'the side effects, for me it was...')	8
Common side effect	5
Advice not to suddenly stop antidepressants, and to come off slowly	4
Potential issue from multiple missed doses	3
Medical information given not linked to their experience	3
To use HCP as resource, and involve in decisions, plans, or problems.	3
The effect antidepressants will have (make you happy, clear head)	3
No side effects	3
Discuss conceptually that different antidepressants and doses available (e.g. not specifically stated)	3
Discuss delayed therapeutic effect	3
Said no issue from one missed dose	3
?Reason why take them/need them (chemical imbalance, need rest etc.)	3
Discuss conceptually than interactions can occur between antidepressants and other medications.	2
Uncommon side effects	1
Specifics on antidepressants mentioned (e.g. name, dose etc.)	1
Felt prescribing right antidepressant was 'trial and error'	1
Advised not to double dose if missed dose	1
Information incorrect (unambiguously) or dangerous	0
Specifics on antidepressants interactions (e.g. name, dose etc)	0

Content analysis - discussion

In terms of modality, about half of the panel member responded via video, and half audio. It is worth noting that in the participant information (see appendix 5), the descriptor of what the study involved encourage video communication and included an explanation for why video interaction may be preferred. However, participants were free to choose any option. This shows about half were willing to produce a video.

For the second interaction pattern, the average media length was about 3 minutes, and this supports the findings from the acceptability interviews; where the time burden was considered acceptable (estimated 10mins for complete consultation).

There was one outlier, 16 minutes 30 second response. For this media response only the first 3 minutes were played back to the peer 1. This editing of peer response media was also a non-adherence to protocol and was a pragmatic response. There were some possible reasons for why one media response was significantly longer than other responses. There may have been a training issue with the reciprocal pharmacist participant. All pharmacist participants received training, but they were also told this was an exploratory study. It may be that this created a mixed message, and lack of clarity in relation to following protocol. Following this the pharmacist participant was re-briefed on expected timings of the media file. Another factor that could have caused the long response from the panel member was that this person had done a pre-acceptability interview shortly before modelling the pilot. The pilot took place in the same room as this interview (community pharmacy consultation room). They were also recording their media response with the same device used in the audio-recorded interview. It may be possible that the situation was too similar to the interview situation prior, and he was continuing the same behaviours, where he was encouraged to talk at length about his views.

While this 16 minute 30 second file was not the norm, it does highlight that there is a need to manage participants and ensure all understand the purpose and expected timings.

The next part of this discussion section moves onto discussion of variables 2-5, which were responses to questions asked in the introduction media, supportive content of peer messages, personal insights, and medical advice content from the peers.

It is important to highlight that all peer participants were taking a SSRI, yet peer 1 and panel members were not matched based on the specific antidepressant, or specific doses.

The content analysis for the questions around side effects resulted in mixed responses. The specific SSRI and the dose can influence side effects, but for all common side effects, the side effect profiles of SSRIs are similar (BNF 2021). Overall, the content analysis results are expected, in that SSRIs do not always cause side effects, and of the side effects, the common side effects were mentioned most. There was one side effect mentioned (increased urination) that is not listed as a side effect according to an authoritative medical resource, the BNF (BNF 2021). This is an example where the role of the pharmacist may

come in to help peer participants both comprehend and apply information. The interviews and the acceptability data analysis show that these types of discussions did happen, and the therapeutic relationship between peer and pharmacist was enhanced.

The analysis on medical advice and missed doses are similar examples, in that overall, the advice was appropriate (no panel members were coded as giving incorrect or dangerous medical advice), yet there may be examples where findings needed to be both comprehended and appropriately applied, which triangulates with points made in the acceptability interviews. For example, a theme that frequently appeared was panel members reassuring the peer 1 participant that missing a single dose was unlikely to be problematic. One panel member stated two days missed doses would cause issues. It is difficult to say if this advice is appropriate. Antidepressants have the potential to cause a withdrawal effect. There is no known timeframe for when withdrawal reactions occur, however a judgment can be made by considering several factors, such as the dose, the treatment duration, and the type of SSRI taken (BNF 2021, NICE, 2009). Some SSRIs, such as paroxetine have shorter half-lives, and are more likely to cause withdrawal (NICE 2009, BNF, 2021). Therefore, this is an example where the pharmacist's role might be important to help peers interpret advice and apply clinical judgments.

For most participants it was clear that they were giving medical advice relating to their experience, rather than making statements about antidepressants. Panel members are experts through experience, not necessarily clinical or scientific experts, therefore it is appropriate that their advice is presented as such (although in this study two peer participants did also have expert scientific knowledge on antidepressants). There were some content identified where medical information was given but not linked to the panel members experience (i.e making statements etc). However, all these panel members also made a clear reference to discussing their advice based on their experience in some part of their response media. The findings from the qualitative acceptability interviews also support this, where it was found that peer participants considered how their information may be interpreted by the peer 1, and there was an awareness that they were talking from their own experience. In one response media a panel member expressed the arguably well intended advice that taking medication as prescribed was the 'only way' of getting better. This example is further explored as a case study below, it provides an illustration where panel members views can be biased by their own experience, and why helping peer 1s interpret information should be part of the role of the pharmacist in this service.

As well as medical advice, self-management information was also shared. Practical advice was given on how to avoid forgetting medication. Conceptual advice was also shared that could help with self-management, or self-empowerment. For example, when responding about side effects, rather than stating side effects, some expanded further, highlighting that they balanced the side effects against the benefits of taking antidepressants, or highlighting that there were other choices such as changing antidepressants or altering doses in discussion with healthcare professionals.

In summary the sharing of health information, and self-management support information was a key aspect of perceived effectiveness in the acceptability interviews. Triangulation with the content analysis further demonstrated this information exchange occurred.

Another known mechanism of peer support is that it can provide emotional support. It was identified in the acceptability interviews that many participants believed this intervention offered this (to the level that was acceptable to them) and linked this to part of the service's effectiveness. The content analysis supported this with emotionally supportive content having the highest coding frequency. It was shown in all but one panel members' responses. Examples were displaying empathy and offering hope or encouragement. From the literature it is known that empathic understanding is important for effective emotional support (Verhaeghe, Bracke et al. 2008). The results demonstrate empathetic understanding within the responses. Panel member participants also respected James's questions, and placed an importance on answering them, and more than half validated James's question or concerns by normalising them or by highlighting these were concerns they had also had.

Positive role modelling and upward social comparisons are specifically mentioned in the literature as ways to enhance emotional support, and support recovery (Lloyd-Evans, Mayo-Wilson et al. 2014, Dennis, 2003). The content analysis showed all panel members demonstrated an upward social comparison by speaking about how antidepressants had benefited them. Therefore, the content analysis supports the acceptability interviews, to show that emotional support was provided in this service.

However, in the acceptability interviews there were differences of opinion about the desired peer 'relationship'. The content analysis suggests that while panel members did disclose personal insights and reflections, there were no examples of content intending to build further social relations or interactions. This is expected as this is not the purpose of the intervention. Literature has suggested that building trusting relationships and creating social opportunities can be part of program theory for some peer support interactions (Gillard, Gibson et al. 2015, Dennis, 2003). Therefore, this service would not be suitable for participants who were specifically seeking this type of mechanism.

In the acceptability interviews it was highlighted that pharmacist participants valued having lived experience incorporated into their consultations, and it was argued that this could help provide a recovery orientated focus to consultations. The content analysis supports this, showing personal insights within panel members responses. There were examples of nuanced experiential knowledge exchange, such as promoting candour, or highlighting helpful ways to frame the reasoning for taking antidepressants. Sharing experiential learning in mental health has been linked to recovery, by facilitating individuals to develop expanded knowledge bases on mental health management and recovery (Faulkner 2017, Lyons, 2021). Therefore, this service could help experiential knowledge exchange, and support community pharmacy in delivering recovery orientated consultations.

7.9. A focused example; introducing bias through cognitive distortion.

In this section the issue of introducing bias will be considered. A definition of bias from the Oxford Dictionary is “that which sways or influences a person in their actions or perceptions” . Further definitions talk about preconceived opinions, and “an attitude that affects outlook or behaviour, esp. by inhibiting impartial consideration or judgement.”

In the social world there are numerous types of bias, and characteristics or dimensions linked to biases. These biases can also interplay within healthcare interactions. Examples of relatively well-conceptualised and researched biases are those based on gender and race (be it conscious or unconscious). Another, relatively less researched, phenomenon is bias based on cognitive distortions, and how one’s previous experience can influence a perspective or an interpretation of a situation. In this section, an exploration and discussion on introducing bias is done using a case study.

A study example is appropriate when wanting to consider material in greater depth, and when wanting to focus on a particular phenomenon, while keeping its context (in this case the context is the response media). The findings in this section are however not generalizable. However this is not an issue, as the purpose of this section is to illustrate and explore the concept of how peer support accounts can introduce bias, and link back to previous discussions on why this service may require peer 1s to interpret and apply information to themselves, and how this should form part of the pharmacist’s facilitator role if needed.

The response media from the panel member ‘Lawrence’ has been purposefully selected due to being an example where a participant has introduced their own experiences and bias into their response to ‘James’ (peer 1).

Interpretative phenomenological analysis was used as the data analysis method. The process of data analysis is demonstrated in Table 51-52. Initially the data was read line by line, then exploratory comments were made linked to relevant lines (see Table 51). These comments were then further considered, and clustered with descriptive labels leading to the formulation of an overall theme (see Table 50). Some exploratory comments were not developed into themes if they did not link to the phenomena of interest (i.e. introducing bias via cognitive distortion). The overall themes, and consideration of the case study characteristics were triangulated with data from the semi-structured qualitative interviews.

Data Analysis

Table 51: Data analysis of Lawrence’s media response to James with exploratory comments

Speaker:	Transcript:	Exploratory comments.
Lawrence:	<p>Okay, thank you for the question. If you have been prescribed antidepressants it means that you, you need rest and you need help.</p> <p>In my circumstances I didn’t ask about any side effects because that didn’t enter my mind. All I wanted to do was get better, so I took the drugs and in order to make sure that I took them and kept taking the right ones each day I went to a chemist and bought one of those, I call it a pill pot which has got Monday, Tuesday, Wednesday, Thursday, Friday on it. Some of them are am, pm, and then you can know if you have missed one. That will help you doing that.</p> <p>I didn’t suffer any side effects and in my experience, the side effects if there are any they will be minimal.</p>	<p>Feels need to be candid. Judged ‘James’ situation as a crisis situation.</p> <p>Lawrence recounts his own situation he felt he had no choices but to take medication. View medication as core to recovery.</p> <p>Conversation leading onto practical/self-management advice.</p> <p>Medical information generalised, seeking to be reassuring?</p>
<hr/>	<p>At the end of the day you need to get better, so you need to get the drugs into your system as soon as possible so they can start having an effect and then get back to normal. That is my experience.</p>	<p>Candid approach. Link getting better to medication. View medication as core to recovery</p>
	<p>I can’t remember the other questions the man asked.</p>	<p>Lawrence wants to make sure he’s completed the task/answered all of peer 1s questions</p>

Pharmacist: That's fine, we can go back. Towards the end?

Lawrence: Yes he asked something but I can't remember.

(replayed end of the video)

Yes he wants to know one thing that I would tell him.

My advice to you is to listen to your doctor, and take their advice and take the medication as prescribed because that's the only way you are going to get better.

So listen to the doctor, tell them the truth, be honest with them, that's the only way they can make a proper diagnosis, and then take the pills

Try not to forget them, and if they aren't having any effect tell the doctor.

That would be my advice to you. You have already been through the... you have already got half way, well not half, a third of the way there by actually going to the doctor and getting advice. That's the major battle,

now listen to them, take the medication and report back to them the effects they are having to them.

Lawrence expresses strong view that medication and medical intervention needed.

? Did Lawrence struggle to communicate with his doctor.

Collaborating with the doctor.

Compassion and encouragement for James based on his own tacit knowledge/ mapping his own recovery.

Reiteration about communication between healthcare providers

Table 52: Data analysis showing emergent themes

Speaker:	Transcript (paragraph number):	Emergent themes
Lawrence:	<p>) Okay, thank you for the question. If you have been prescribed antidepressants it means that you, you need rest and you need help.</p> <p>(2) In my circumstances I didn't ask about any side effects because that didn't enter my mind. All I wanted to do was get better, so I took the drugs</p> <p>(3) and in order to make sure that I took them and kept taking the right ones each day I went to a chemist and bought one of those, I call it a pill pot which has got Monday, Tuesday, Wednesday, Thursday, Friday on it. Some of them are am, pm, and then you can know if you have missed one. That will help you doing that.</p> <p>(4) I didn't suffer any side effects and in my experience, the side effects if there are any they will be minimal.</p>	<p>Projection.</p> <p>View medication as core to recovery. Projection.</p>
Pharmacist:	<p>) At the end of the day you need to get better, so you need to get the drugs into your system as soon as possible so they can start having an effect and then get back to normal. That is my experience.</p> <p>(6) I can't remember the other questions the man asked.</p> <p>(7) That's fine, we can go back. Towards the end?</p>	<p>View medication as core to recovery</p>
Lawrence:	<p>(8) Yes he asked something but I can't remember.</p> <p>[replayed end of the video]</p>	

(9) Yes he wants to know one thing that I would tell him.

My advice to you is to listen to your doctor, and take their advice and take the medication as prescribed because that the only way you are going to get better.

(10) So, listen to the doctor, tell them the truth, be honest with them, that's the only way they can make a proper diagnosis and then take the pills

(11) Try not to forget them, and if they aren't having any effect tell the doctor.

(12) That would be my advice to you. You have already been through the... you have already got half way, well not half, a third of the way there by actually going to the doctor and getting advice. That's the major battle, now listen to them, take the medication and report back to them the effects they are having to them.

View medication as core to recovery
Projecting.

Championing

Discussion.

Three themes have been termed following the interpretative phenomenological analysis of the case study media transcript. These are, Projecting, View medication as core to recovery, and Championing.

In the transcript from Laurence, in paragraph 1, Lawrence articulates an assumption about James. Triangulating with Lawrence's phase 3 interview it seems Lawrence believes his peer James to be in a crisis situation and references concern about suicide.

Lawrence: "This could be life, or death. So yeah, I would be interested."
(Phase 3 interview retrospective).

Yet depression can mean a large spectrum of symptoms, and contextual circumstances

(NICE 2009). Lawrence has not been given information on James's circumstances. He has been told James is a male about to start antidepressants (from the pharmacist) and that he has just come from the doctors, has been given a prescription for some antidepressants, and is a little nervous about starting them (from James). Possibly Lawrence is drawing on his own experience and projecting that onto his understanding of James's situation. This links to well established theory on schema, where one draws upon their previous experience to understand a situation (Hawke, Provencher 2011).

In this interaction, Lawrence by definition of being a peer will be drawing on his experience and construct his own subjective understanding of depression and healthcare to answer questions or share his insights. This theme, which has been termed 'projection' is an example of how bias has been introduced into the situation; Lawrence has made a judgment on James based on a characteristic that links to his own personal experience.

This is not necessarily problematic but it does link into a concern raised by some participants in the acceptability interviews about the characteristics of communication in this intervention. Lawrence has a relatively limited interaction with James, and no opportunity to get clarification on how James perceives either his situation, or how James interprets his message.

The next theme linking to the subject of introducing bias was: 'View medication as core to recovery'. This theme links to 'Projection' and has similar characteristics in that Lawrence is drawing on his past experiences. From his qualitative interview he discusses how he initially felt cynical about antidepressants and did not believe that they would work. However, he recovered and attributed this to the antidepressants. The reason this theme has been termed differently to 'projection', despite having similar characteristics, is because of the potential consequences of this theme. Expressing the view that medication is core to recovery could potentially be problematic, and merges lines between peers giving personal and clinical advice.

Lawrence: "...take the medication as prescribed because that's the only way you are going to get better." [Paragraph 11]

There is the risk that this view does not align with James's beliefs and risks alienating him. Again as previously discussed in this interaction Lawrence will not have the option to qualify his comments, and he is speaking his truth, however it could introduce bias. While this case does show that this is a potential risk, when considering peer support overall systematic reviews have not shown evidence of peer support worsening clinical or recovery outcomes in patients (Fuhr, Salisbury et al. 2014). Additionally, the acceptability interviews found that no peer participants reported worse wellbeing due to this service.

The final theme is 'Championing', and similarly, it shares core characteristics with the first theme of 'Projection', but unlike 'View medication as core to recovery' theme, where

negative consequences are considered, this is a theme potentially leading to positive outcomes because Lawrence draws on his own negative experiences to champion and support James.

There is the potential for peer interactions within this proposed pilot intervention to introduce bias. The case study from Lawrence is an example of this. The impact of this could be minimal, for example in the acceptability interviews no participants reported reduced wellbeing from taking part in this service, however as a concept it is important to be aware of, and highlights aspects that may need to be covered in the pharmacists debriefing.

In the next section overall considerations based on findings about acceptability, content analysis and the case study will be used to discuss core learnings about program theory and overall conclusions.

7.10. Program theory and overall conclusion.

Overall, this intervention was acceptable to both service users and community pharmacists. The work on affective attitude highlighted that there was a range of overall views around the intervention's acceptability. When exploring the six other aspects of acceptability it becomes apparent that some differences of opinions of acceptability were underpinned by different views held on the purpose of the intervention. The work comparing prospective and retrospective views also supported this, with participants reflecting that their views of the acceptability of the intervention changed (to more positive views) because their understanding of the purpose of the intervention changed.

Clarity on the purpose of the intervention is therefore an important part of the program theory. Based on suggestions from the acceptability interviews, and the content analysis, the purpose of this intervention could be as an 'initial step' or 'initial confidence' to support one in taking an informed decision on taking antidepressants, or as an initial step into accessing peer support.

This intervention was acceptable to participants because it enabled information exchange, both in relation to specific questions asked, and sharing of personal insights, and can potentially support patients in self-care management. From the work in chapter 4, it was identified that men, possibly due to their reduced cognitive functioning in depression, tended to not consider their information needs, or reflect at the point of initiation on their support needs in relation to treatment. This was particularly within a community pharmacy context, but men also spoke about these behaviours within their wider care (e.g. at the GPs, hospitals etc.). In the interviews men did recall questions that they wished they had asked, or spoke about assumptions that negatively affected their treatment (e.g. belief it was short term treatment, self-stigmatizing etc). The content analysis shows how the

replies focused on answering the questions, and sharing personal insights using experiential knowledge, and offering supportive advice, either by validating the questions as important questions to ask, or by offering hope and positive role modelling examples. There were examples where community pharmacists facilitated the comprehension and application of such knowledge, and facilitated the creation of a therapeutic relationship between the peer participants and pharmacists.

Another part of the program theory relates specifically to the peer participants who were providing the peer support (panel members). Altruistic benefits were reported, and suggestions of increased self-esteem and empowerment. The feedback mechanism, (where peer 1 participants acknowledged the panel members responses) was considered a key component that facilitated these benefits. Partaking could also promote a reflective practice, which helped some panel members consider their current situation, and where they were in their recovery journey.

The opportunity this service provides is an important part of its program theory. Participants felt they had limited opportunities for conversations around their mental health and treatment with others, and particularly other males. Without this opportunity, some participants predicted they, or others, may not have asked questions or struggled to find answers to specific questions, or read misleading information when using other sources such as the internet.

This suggest that a core part of this intervention's program theory is within the opportunity it provides, allowing this population to better access support sooner, and delivered in a way that is acceptable, and less threatening than other ways to access peer support.

There are still some uncertainties and future refinements. This is discussed in chapter 8, under further work.

In summary this intervention provided an opportunity for information exchange of lived experience, and the opportunity to combine this with expert scientific knowledge when needed. It also provided emotional support for peers through supportive content, positive role modelling and upward social comparison. The mechanisms for information exchange also facilitated discussions between pharmacists and the male patients, and could lead to a more recovery orientated discussion, and a greater therapeutic relationship. Participation as a panel member also had altruistic benefits and the feedback mechanism maybe a core component enabling this. The asynchronous delivery enabled logistical barriers such as time to be easier managed, and potentially means a larger pool of participants can be involved in the intervention.

7.11. Strengths and limitations of study

The work in chapter 7 has taken the intervention that was designed and developed in chapter 6 and applied it to its real-life setting. There are strengths and limitations to the research presented in this chapter and these will be discussed and structured by bullet points.

Strengths:

- Methods.

These were a strength, in that participants were able to model out the intervention in its real-life setting and give views of acceptability. Another strength was the capturing of both prospective and retrospective acceptability. In particular by comparing the two perspectives enabled important insights of the intervention program theory to be shared, such the purpose of the intervention. Another strength of this study was the analysis of both the qualitative interviews and content analysis, as this allowed triangulation, strengthening the studies credibility.

- Using thematic framework of acceptability

Using this theory-based categorisation in the data analysis enabled acceptability to be considered as a multi-stage construct. This was particularly important in this study because some participants had both negative and positive views about acceptability and these complex views were able to be organised and extensively explored. If acceptability was measured or analysed as a singular construct e.g., using quantitative methods, or not fully explored in depth, then it could have limited understanding. The theoretical framework has been systematically developed using expert opinion on acceptability of healthcare interventions and has been used in pharmacy disciplines (Murphy and Gardner 2019, Chew-Graham, 2022), therefore the author believes it to be an appropriate framework, and therefore its use strengthens this studies ability to explore views of acceptability and present them in a useful and meaningful way.

- Researcher / thesis author did all transcriptions

This helped her become familiar with the data. It is important in qualitative research that the researcher is familiar with the data. In this study one participant had a particular pattern of speech which could have led to his transcribed words being ambiguous because he would often use the word 'no' before articulating a phrase with a positive inclination.

Below are two illustrative examples:

- Kevin: "You know? So no, yeah definitely it's helped me."
- Kevin: "Yeah it was nice not knowing the person really."
- Researcher: "That's interesting. Did not knowing the person help?"
- Kevin: "No. It was alright. It was a lot better."

Due to this pattern of speech the author had to interpret meaning. Being familiar with the data facilitated this. Qualitative data analysis involves a process of decontextualizing data, and then re-contextualising data (Starks and Brown Trinidad 2007). In this study if a researcher worked only with Kevin's transcripts (de-contextualised data) and produced this into themes (re-contextualising) there is a higher potential for this ambiguous pattern of speech to be linked to another meaning. As the author was familiar with the raw data this potential confusion was able to be minimalised, because the researcher used a working knowledge of the raw data as a resource. Therefore, the author's familiarity with the raw data was a strength of this study.

Limitations:

- Limited views of those newly starting (or to start) antidepressants.

Due to recruitment issues only one participant involved in the study had newly started antidepressants. Two other participants who had just newly started antidepressants had initially been recruited for the modelling stage (phase 2 and 3) but later declined, one saying they didn't feel they could be involved in research now due to their circumstance, and another could not be contacted. Other peer participants who had taken antidepressants for longer were able to express views on their perceived view of how acceptable the intervention would have been to them when they were newly starting antidepressants, however these findings could be subject to recall bias and therefore were taken with caution when doing the data analysis. It may be that having only one participant who had just started taking antidepressants may limit the credibility of findings, yet qualitative research does not have to be statistically representative, and for the purposes of this chapter (exploring interventions' acceptability, understanding program theory, and deciding if development work could move to a next stage as per MRC guidance), it was felt that for these purposes the findings were credible, however having more participants who had newly started antidepressants would have strengthened this chapter's research.

- Pharmacist participants recruitment and stakeholder

This research involved working with a pharmacy stakeholder to enable the research to be carried out in its real context. This stakeholder pharmacy company was a small independent pharmacy, with five branches. A range of pharmacy companies operate in community pharmacy, and it can be that the organisational culture and policy in another company, such as a large multiple pharmacy company, is different to the stakeholder company engaged for this study. Therefore, only views of how the intervention may work in a small independent pharmacy were meaningfully captured, and this could be a limitation.

Both strengths and weaknesses:

- Peer participant recruitment

Peer participants were recruited from a pool of the chapter 4 participants (NB participants could join just for phase 2 and 3, but none did). The weakness was that there was an over-representation of middle-aged white ethnicity males due to the convenience sampling used in chapter 4. However, as a strength, this recruitment method did provide some benefit; it possibly meant that some participants took part who may not have taken part otherwise. One participant commented initially that he would not be interested in a peer support scheme, and it was likely that he would not have participated had he seen a recruitment just for the phase 2/3 work. It was because he had prior involvement that he also wanted to participate in sharing his views on acceptability of the intervention. It also meant that there was already an established rapport between interviewer (the thesis author) and participant, which the thesis author though helped.

- Researcher was a pharmacist

There is also the impact that the researcher being a pharmacist had on the data to consider. As the researcher is a key research instrument in qualitative research its likely this would have had an impact. It may be neither a strength nor a weakness of the study, but rather an important consideration to be aware of as it could have influenced the study.

Chapter 8 expands on this and presents an overall reflexive discussion of all research in this thesis. Chapter 8 also discusses future work and provides an overall conclusion to the thesis.

Chapter 8: Reflexivity, overall discussion, and conclusion.

8.1. Introduction and reflexivity

Figure 25: Introduction to chapter 8; highlighting the purpose, and situating it within the thesis schematic

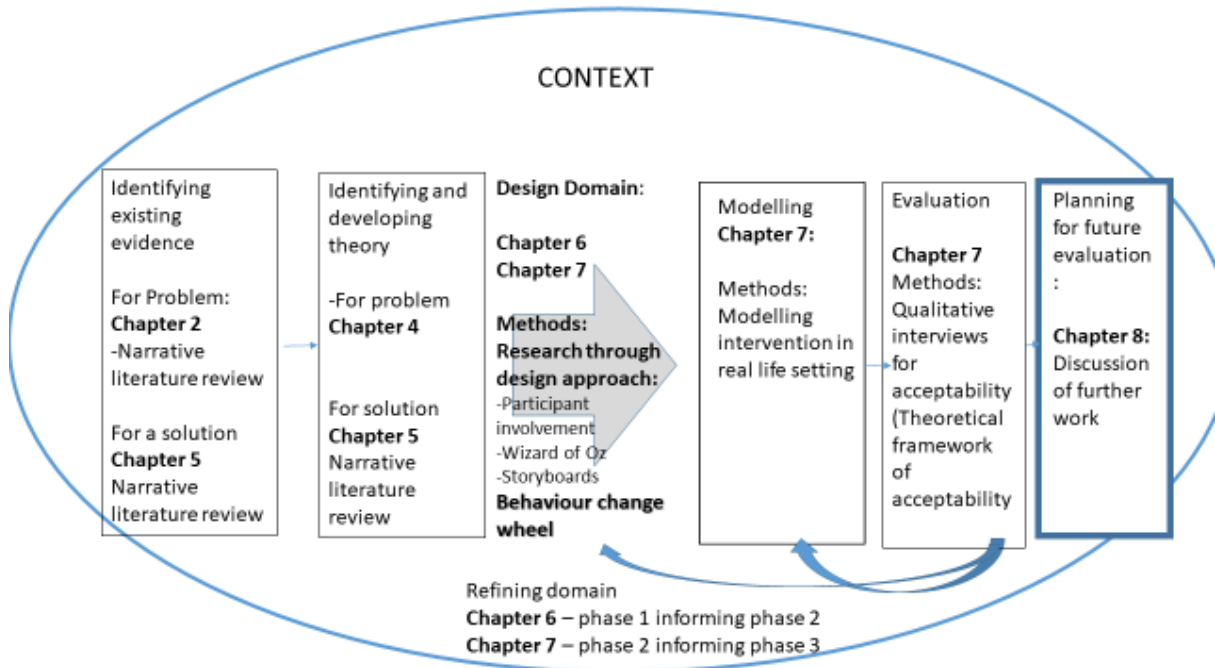


Figure 25 highlights where chapter 8 fits within the overall thesis schematic. In this section of the thesis the author takes a reflexive stance on the overall research, which leads onto a discussion about further work, and then a conclusion.

Based on the research paradigm taken in this thesis, and the belief that reality is multiple and subjective, it is important to be reflexive and be self-aware of judgments and influences (O'Brien, 2014, Ormston, 2014, Cypress, 2017, Amin, 2020, Peditto 2018).

There were various aspects of the data collection and analysis that involved interpretations and decisions that could have influenced the research.

The author of this thesis conducted all the interviews. For clarity the term 'researcher' will now be used to describe the thesis author. The researcher is a female and a practising

community pharmacist, and all interviews took place either in a room in a community pharmacy, or in the University of Nottingham School of Pharmacy. This is likely to have influenced the findings. Interview data is socially and contextually constrained (Murphy, 2017), and participants may seek to provide answers considered socially acceptable (Murphy, 2017). It may be that participants gave more positive accounts of pharmacy interactions, or potential roles for community pharmacy because of the context and knowing this was community pharmacy research. The researcher did however take steps to try and ensure that participants were not unduly influenced by context, and that the researcher had self-awareness in relation to the research.

One important step the researcher took is she became a research participant herself in unrelated qualitative studies so that she could experience what it was like to be asked questions on a topic of the researcher's choice and respond to that. At times she noticed a desire to give socially accepted answers, and this underpinned her replies. For example, two interviews were around pharmacy research projects, and at times she noticed giving positive responses in relation to pharmacy. These were her genuine views held, but she also felt a desire to express these views. Another reflection was the pressure she felt to respond coherently to all the questions asked. There were times when she lost her train of thought and favoured giving answers that were easier to articulate rather than express views that weren't fully formed. These were quite important insights and have helped her with interviews and made her more reflexive when analysing.

During the interviews a technique used was to get participants to further elaborate on their answers by repeating back words or phrases they had used, and asking them to elaborate further. This helped keep the language in the participants own words and avoided the researcher adding in her own words or interpretations. If these participants also had lost their train of thought or forgotten the research question while answering then this could help them refocus on the question, or link back to their train of thought. Similarly, the researcher would summarise her understanding of what had been said at various points during the interview and this was to give participant an opportunity to readdress anything, and give them time to express ideas that may be harder to articulate.

As mentioned in the methods it was important to build rapport and trust with participants. To do this the researcher balanced empathy with purpose and showed respect for participants information. Despite these being sensitive interviews there were many examples of humour during the interviews. Humour is a part of everyday social interactions and was considered by the researcher as a way that she helped develop rapport with participants.

Another technique the researcher used was to let participants finish their responses and encourage them to speak with 'umms' and 'ahhs'. Interview interactions can be dynamic, and if an interviewee has an experience of talking in depth, it can make it more likely for them to continue giving in-depth responses to subsequent questions as they learn this dynamic of dialogue is accepted and encouraged (Kvale and Brinkmann 2009).

There were some challenging aspects of interviewing. There were times during interviewing that neutral responses were deliberately expressed by the researcher. This was due to an awareness of how positive or negative responses may influence the participant, both in terms of their response, and the extent of the response they give.

This however created dynamics different to normal conversation. For example, one participant made a rhetorical response, which in normal conversation the researcher would have responded more empathetically. In this case a neutral 'uh-huh' response was deliberately chosen, which did not feel natural. The researcher had to balance being a neutral researcher aiming to gather research data whilst still responding sensitively and compassionately to the information shared. There were occasions during the interviews when participants revealed sensitive information about themselves.

Lawrence recalls a previous suicide attempt and reveals that he had never told anyone about it, other than during this interview.

Lawrence: "I decided that I'd had enough. It was no good. I thought 'gas just helps you go to sleep and well it doesn't matter then does it'. So I started sticking my head in the oven, and it would light. So I started. I had a beard then, I started going in and trying to blow the flame out. I burnt all my beard and bits of, you know, I didn't burn badly and then we had a cat. I love animals. He came up and was sort of purring beside me. And I'm saying 'Hello [name of cat]' you know. 'I'd better put him out.' And I remember picking him up and bawling my eyes out. And then I sort of stroked him and said 'yeah maybe it ain't so bad'. So I didn't. I don't think anybody knows that, apart from you and I. So yeah I did."

At these times the researcher tried to favour a sensitive response, and to also show respect for the information that was being shared with her. Nunkoosing (Nunkoosing, 2005) states 'the interview makes public what is often considered private thoughts' and therefore responding appropriately to the participant's responses was considered particularly important, as was ensuring participants knew that their confidentiality was respected. This could also link back into a pressure to give socially desirable answers. It may have been Lawrence disclosed this information for the first time in this setting because he was in a situation where he viewed the socially desirable interaction was to

talk about his experiences with depression. This is important for the researcher to be aware of because a power imbalance can exist in qualitative interviews (Kvale and Brinkmann 2009, Nunkoosing, 2005) and it is important to be sensitive to this and appreciate qualitative research gives privileged access to people's real lives and the real world (May 2022).

The researcher also had difficulty due to her dual identity as researcher and pharmacist. It was originally the intention that the researcher would present themselves as a researcher rather than a pharmacist. Unfortunately, during the first interview it became obvious to a participant that the researcher was a pharmacist. As consistency in this area may help with data analysis, it was decided following this interview to emphasise that the researcher was a researcher, but to mention she was a pharmacist. In some interviews it was clear that this knowledge influenced the content. One participant even asked during the interview a clinical question about their antidepressants. There was another situation where a participant expressed a belief that the antidepressant sertraline 50mg was twice as strong as another antidepressant citalopram 20mg, as the value 50 was over double the value of 20. This is not correct, and as a pharmacist the researcher knew this, and felt a responsibility to address this. Both of these are examples where clinical care and research purposes conflicted. In both these situations the researcher was able to manage the situation by asking the participants to discuss this with her after the interview. This meant that the interviews could remain focused and purposeful, yet the issues were not ignored.

On a similar topic there are differences between clinical care and research outcomes. In a clinical setting an individual's therapeutic situation and concern is used to make decisions about their treatment. In contrast research seeks to obtain information that can contribute to future advances in knowledge that provide benefit to the specific population under study. It is possible patients can get confused by these different goals. This concept has been termed therapeutic misconception (Lidz, 2002). It may be that the participant who was asking information may have expected a clinical outcome from the interviews as well as a research outcome.

Another issue that came up is one participant wanted to discuss a different topic relating to depression that was not the focus of this study; specifically, the participant wanted to highlight the lack of support available for his teenage daughter in relation to depression. Again, his motivations could have been underpinned by therapeutic misconceptions, or maybe the participant wanting to focus on a different agenda that was important to him. This is another example where the researcher should be aware and sensitive to power imbalances as it is the researcher who sets the research questions.

In research there needs to be consideration of when a research relationship ends. Once an interview ends, the relationship does not end. Participants may still be affected by the study and need information or support. In this study there was an example of this. About a week after completing the interview the researcher had a message from one of the participating pharmacies asking if the researcher could contact one of the participants who

had returned to the pharmacy he had been interviewed in (his regular pharmacy). The researcher contacted the participant. He was worried if any information he had said may be passed onto the HMRC Inland Revenue.

All aspects of the ethically approved study protocol had been correctly followed; prior to the interview this participant had been informed all information was confidential, and this information had been supplied to him in written form. He also had a debriefing after the interview and had the researchers email address. This concern had developed after the due research protocols had been completed. Therefore, this is an example of a need for continuing support, even after a situation where the information supplied to the participant had been deemed ethically appropriate. The participant was contacted, his concerns listened to, and reassured that all his information was kept confidential. It is also an example where the participant contacted the participating pharmacy first, before the research team (participant had study email address). This was possibly due to his poor internet access, which is discussed further below, however it is also an example of where the research relationship may also not end with participating stakeholders after the study. Therefore, there is a need to maintain communication links and support as required.

On reflection, there was not enough contingency in place for participants who did not have internet access. Three out of fourteen male participants that took part in the main study had either no household internet access (including mobile phone access), or limited internet access.

Inability to communicate via email (or delayed email communication) did cause some logistical issues. There was a study phone line available, however due to the part time nature of the project there were only limited times when this phone line was manned, and it was in a shared office. As a positive reflection, this also shows that the multiple recruitment options offered did enable participants to be recruited if they did not have internet access.

The part time nature of this project influenced this study. This meant the study took place over a longer period, and additionally the researcher took a year's maternity leave. The research field was moving faster than what would be occurring in a full time PhD. This particularly influenced this study as the MRC updated their guidance on developing and evaluating complex interventions. The study design and data collection occurred up to 2018. In 2021 the MRC updated their guidance. Therefore, it was too late to influence the study design, data collection, and analysis. The thesis however was still being written at this point. This resulted in slight mismatches as the design matched the 2008 guidance, yet the discussions and written content were influenced by the current version. Another significant issue was this study took place during the global pandemic due to COVID-19. One significant cultural change was that remote communications became normalised, whereas at the time the interviews were conducted this was not considered a normal method of communication.

Over the period of data analysis, the thesis author had two stressful life events, both involved personal decisions of a medical nature. The author reflected on how experiencing stress and emotions significantly affected her ability to hold thoughts in her head, take in information, and particularly impacted her decision-making ability. It was going through this (and reflecting) that made the researcher particularly attentive to the data and themes around cognitive functioning in depression.

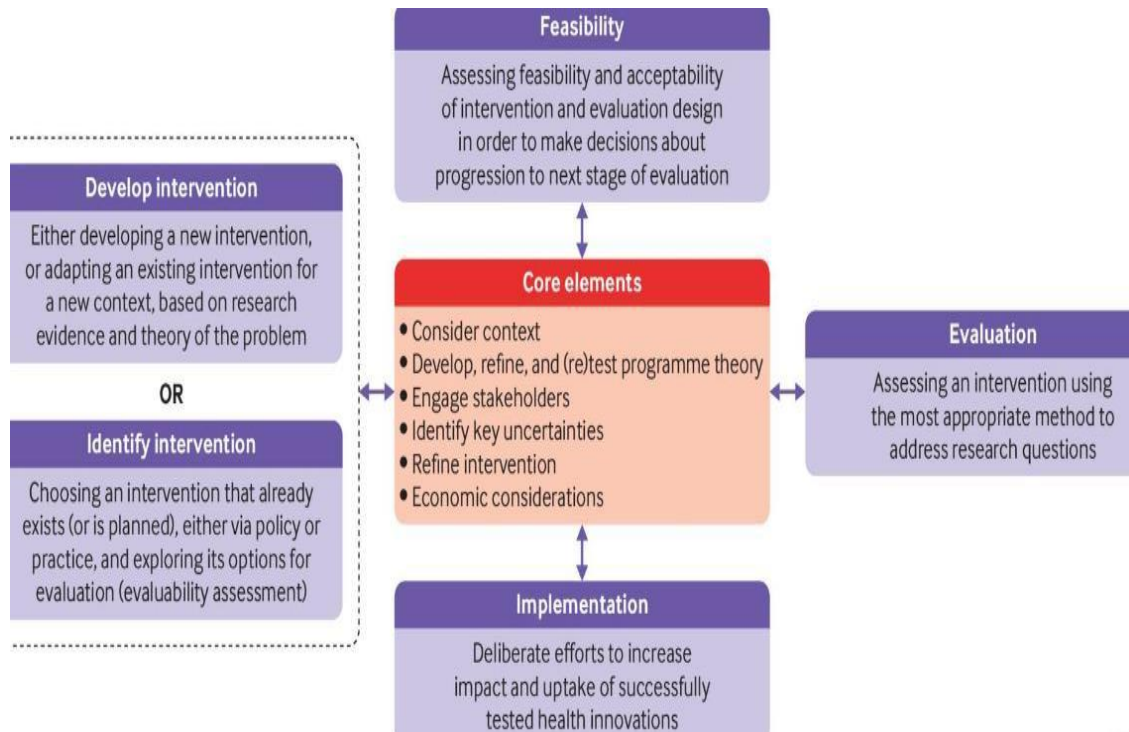
This theme was in the data the whole time; however, it had become accentuated through the researcher's experiences, and subsequently became an important part of the data analysis and discussion. Meaning is constructed through experiences and perceptions (Charmaz 2006). It is likely that if the researcher had not had these life experiences, then the meaning interpretation from the data could have been different, even if that difference is as subtle as a different weighting of importance for the theme.

This is in line with the constructivism epistemology this research takes, and the researcher sees this as a strength of her work.

8.2. Further work

Future work for developing a complex intervention would look to address any key uncertainties in the current development stage. Then further work will address the other 3 phases in intervention development. These are feasibility, evaluation, and implementation while revisiting any phases as appropriate. Future work should cover all core elements for each phase as highlighted in Figure 26 taken from Skivington et al. in the MRC updated guidance.

Figure 26: MRC updated guidelines for complex development and evaluation.



In terms of the development stage, there are still uncertainties. One uncertainty is who does this intervention work best for? The intervention design has been underpinned by theory on concepts such as masculinity and behavioural change. Further work investigating how the effect of the intervention is mediated or moderated by certain attitudinal characteristics such as self-stigma and adherence to hegemonic masculinity would be useful to help understand more about who this intervention is best suited for, and acceptable to. This is important knowledge for implementation work, and cost effectiveness studies.

Another uncertainty is what number of panel members responses should be shown to the peer 1 participant. The content analysis shows that while all responses provide information exchange, positive role modelling, and supportive content, there were differences in responses; with different responses adding different dimensions. A refinement could be to have 2-3 panel member responses per peer 1. This would on average add 3-6 minutes onto the consultation, and potentially is still acceptable.

How this intervention can fit into wider healthcare needs to be considered. Addressing this uncertainty was highlighted as important by the participants, and the wider literature. There were some ideas suggested by the participants, such as involving GPs in referring potential participants to the service, having the debriefing with panel members linking to a GP follow-up consultation, and transfer of relevant information between this service and

appropriate healthcare systems. It would be important to continue to involve stakeholders in the development research to address these issues. Medical prescribers such as GPs, psychiatrists, and relevant organisation policy stakeholders should ideally be included in this work.

As mentioned in the limitations of chapter 4 and 7, it would be beneficial to recruit more participants who have newly started antidepressants and gather more data on their views, similarly views from men of different ethnicities would be beneficial.

Purposeful sampling could be a beneficial approach used in future studies. Also, future studies should engage with a variety of different pharmacy stakeholder companies. Organisational and culture can be impactful on context, and subsequently affect implementation. Therefore, to address these uncertainties it could be beneficial to engage with diverse types of pharmacy company stakeholders.

The program theory produced in this thesis can be used for future work to promote a shared understanding among the diverse stakeholders, and therefore facilitates this refinement work and the progression to subsequent stages (Skivington, Matthews et al. 2021).

Another development uncertainty in this model is the administration and IT systems that may need to be implemented to support this service. The development and implementation of this system is likely to have a significant cost relative to the minimal costs involved in running the service thus far, and it therefore would be appropriate to understand further on the interventions effectiveness first before deciding if investing in such costs is justified.

The intended outcome of this intervention is to improve recovery orientated outcomes. Leamy et al (Leamy et al. 2011) have built a conceptual framework of recovery outcomes, and this CHIME model (Connectedness, Hope, Identity, Meaning, and Empowerment) can be used to consider outcomes. There is a body of work in the field about intermediate outputs for successful recovery as a final output (Winsper, Crawford-Docherty et al. 2020). Since a next step would be to take an effectiveness perspective in this study, such a study can look at outputs such as existential recovery outcomes. Self-esteem, empowerment, reduction in self-stigma, and quality of life are outcomes that a future effectiveness study could measure. These outcomes have been successfully used in effectiveness studies that have focused on mental health interventions (Winsper, Crawford-Docherty et al. 2020). In the past a large majority of community pharmacy intervention evaluations have overly reported adherence as the primary outcome. Many of these intervention studies that did show improvements in adherence could not show clinical improvements (Rubio-Valera et al. 2011; Bunchuailua et al. 2021). This arguably has led to evidence of limited use for real-world decision making. The work in this thesis suggests possibly it may be important to focus on multiple outcomes, particularly recovery-oriented ones. Feasibility work should further explore outcomes of interest for evaluation, how to measure them, and the

program theory that underpins these outcomes. It is likely that future evaluation work on this complex intervention would benefit from a mixed methods approach in line with MRC guidance. For an evaluation study key uncertainties should be firstly addressed using a feasibility of a future evaluation study, and cost effectiveness evaluation, and this could then lead onto an evaluation study.

In terms of cost, it would be important to address this at each stage, as per MRC guidance (Skivington, Matthews et al. 2021). Economic modelling at the feasibility stage can assess the likelihood that the expected benefit of the intervention justifies the costs of delivery, and the cost of further research (Skivington, Matthews et al. 2021). This can further guide whether it is worthwhile proceeding to a full-scale evaluation, and therefore is recommended as future work.

In the development stage, implementation should still be considered and having a community pharmacy as part of the research team facilitated this. It meant that implementation considerations could influence the design domain. Early consideration of implementation can increase the success of the implementation phase. Considerations were made early on how to design the service so that it could realistically operate in a community pharmacy setting, have minimal disruption of resources, and link to those that already operate in community pharmacy. For example, the community pharmacist researcher knew pharmacists can identify patients who are new to medications or have had medications for a certain period with existing resources.

A strength of the research approach used in this thesis is how stakeholders were involved in the design and development throughout. The research design also had different PPI strategies, such as PPIs as part of the research team offering prolonged engagement, and specific PPI sessions offering shorter involvements which had the advantage of enabling more patients and public involvement. Future work in all stages should continue to involve relevant stakeholders, and PPI.

8.3. Does RtD integrate with the MRC guidelines on developing and evaluating complex interventions?

This closing section focuses on methodological considerations. This thesis has made a methodological contribution to research knowledge by being (to the best of author's knowledge) the first research study to incorporate a RtD approach with MRC guidance on developing a complex intervention and applying this in pharmacy research. This part of the thesis discusses benefits and challenges of this methodological decision, and if RtD integrates with the MRC guidance.

Overall incorporating the RtD approach in this thesis and interpreting it into the MRC

guidance on developing and evaluating complex interventions provided benefit in the work of developing a complex intervention, and helped guide the development stage.

The MRC guidance on the development stage is brief (O'Cathain, Croot et al. 2019). The 2008 guidance contained three paragraphs discussing identifying the evidence base, developing theory, and modelling the complex intervention. Since 2021 a new revised version exists [see (Skivington, Matthews et al. 2021), and further publication exists specifically on the development stage (O'Cathain, Croot et al. 2019, Duncan, 2020)]. This updated guidance is welcomed, but overall, there is a need to increase knowledge about best practices in how to develop complex interventions. At current there is insufficient research and evidence on what actions and methods are most appropriate to use in the development stage (O'Cathain, Croot et al. 2019, Turner, 2019). The design activities of the development stage have been a neglected area (Rousseau, Turner et al. 2019). In the 2008 MRC guidance, design was not highlighted as a stage, and no methodological considerations were discussed. The 2008 guidance has also been criticized by experts in the field for having a research perspective overly focused on effectiveness (Raine, Fitzpatrick et al. 2016, Skivington, Matthews et al. 2021). This may have inadvertently curtailed development research, where there may have been an over focus on it being a step to an evaluation study. There therefore is a knowledge gap for methodological considerations in the development stage, particularly for design, and at the time this study was being conducted, this knowledge gap was even more so.

RtD is a flexible approach, but in doing so has little prescribed methods. Therefore, the benefits of using this methodology are more about its approach, rather than its specific methods. This could be problematic however, as methods as well as approaches could be useful, particularly as there has been a lack of attention to design and best methods.

A benefit of RtD is that it gets researchers to consider the design stage as a platform for knowledge generation, and that important knowledge can be produced through the act of designing. RtD also guides the researcher to consider the problem, and if the problem is a wicked problem. This is because RtD as an approach is best suited to address wicked problems. The problem to be solved in this thesis was considered by the researcher as a wicked problem (see chapter 3). While the term wicked problem has been used in health care research, there is little discussion around if complex interventions should be considered a wicked problem. Yet it is likely most complex interventions will be seeking to solve an unsolvable problem; for example, different stakeholders may see the problem in different ways. Having a better articulation and understanding of the problem type could benefit those involved in development work. It was felt by the author of this thesis that having an understanding that the problem was unsolvable was beneficial. It meant the research question was about seeking preferred states.

This helped in the overall conceptual understanding of this research and helped the thesis author in the design of this study, and how the aims of the study aligned with the research paradigm. For example, understanding that there were multiple realities or multiple ways

to see the problem, and that methods would therefore need to capture depth and meaning within context, led the researcher to choose qualitative methods.

Through applying RtD, researchers are continuously reframing the problem, and problem framing, and articulation of the preferred state becomes a research output (Zimmerman, Forlizzi et al. 2007). Problem framing helps identify important gaps in behavioural theory and models (Zimmerman, Stolterman et al. 2010). In this thesis there were examples where empirical work in chapter 4, helped link into behavioural theory work for chapter 6, specifically the behaviour change wheel.

The behavioural change wheel is not prescribed by MRC guidance, however publications focusing on the development stage have advocated its use. The benefit of the behaviour change wheel in this thesis is that it supported the incorporation of theory into the RtD approach. In this thesis it worked well because the behavioural change wheel work supported the findings from chapter 5 on evidence identification and could be used to help underpin the design. It is not clear however what to do if findings from the evidence, and conclusions from the behaviour change wheel contradict each other. It was also not clear what to do when changes were more cognitive rather than behavioural, however overall, it was felt the RtD approach, the MRC guidance, and the behavioural change wheel could all be successfully integrated.

Another benefit of the RtD in this thesis was the use of the 'wizard of Oz' approach. In chapter 7's modelling of the intervention, the researcher did some functions of the intervention such as sending panel members responses to the correct peer 1's pharmacy using WhatsApp. For implementation it is likely an IT program may need to be designed to support this intervention, yet at current this programming work was deliberately not done as it kept costs down at a stage prior to an effectiveness study. The underlying benefit of this approach is that it can reduce costs and time delays, while not compromising any core functions of the intervention. Similarly in the design work in chapter 6, different iterations could be mocked up and discussed with participants without the need to create working prototypes.

Where the RtD approach caused significant difficulties was during the ethics application. RtD, despite being well established, is not well recognised in healthcare and this caused difficulties during the NHS ethics process, both in its explanation as a method, and its implementation as an approach. The ethics application required detailed accounts of what was going to occur in the study, yet this conflicts with the RtD approach which advocates for design led processes, and iterative developments. Decisions of designs to be tested had to be made to satisfy ethics, and this could have compromised the RtD approach. Other studies have mentioned similar dilemmas, where knowledge generated during a design was not used due to pre-specifications agreed with ethics boards or funders (Turner, 2019). Creative thinking required for design needs a divergent approach and this can conflict with ethics applications which require convergent thinking and outcomes (O'Cathain, Croot et al. 2019, Gaver, 2012). RtD, by its exploratory nature risks being seen

as less methodologically rigorous (Rousseau, 2019, Gave, 2012). This does not necessarily make the RtD approach incompatible with MRC guidance, but it does suggest that more discussions are needed on how divergent, exploratory approaches, such as RtD, can be integrated into complex intervention development work, and be compatible with MRC guidance and ethics applications.

Specifically in relation to pharmacy practice, the use of RtD as an approach could be beneficial. Pharmacy practice has had a call to be more innovative, and to increase focus on clinical services (Hermansyah, 2017), and while significant transitions have occurred the change has been slow (Hattingh, Sim et al. 2020). Academic pharmacy similarly has faced similar challenges with the need to redesign courses to match the changing field of pharmacy practice (Wright, 2018). It may be that increasing knowledge on a research approach that positions design contribution as a knowledge, and at its core supports the involvement of stakeholders in the process could be beneficial for pharmacy research.

In conclusion RtD lends itself to forward focused nuanced research that is not suited to reductionist enquiry; it is beneficial for problems that cannot be solved. Embedded in a social context, this thesis's research question is not seeking to solve, but rather explore issues with men's depression and interactions with their community pharmacist, and potentially improve them through a complex intervention. Therefore, RtD was a useful approach. It is likely complex interventions, or the problems that complex interventions are designed for could also benefit from a RtD approach.

8.4. Conclusion

This study set out to develop a complex intervention that could be used in a community pharmacy setting to support men who are using antidepressants to treat depression and facilitate the community pharmacists in providing better care to these patients.

Men with depression are unlikely to engage with community pharmacists for support within the current interactions that are offered. This is due to a combination of factors. The men in this study did not have established therapeutic relations with the pharmacist and were not used to engaging with the pharmacist in this way. Many men spoke of unmet information needs, or holding conflicting, stigmatizing views on antidepressants, but they did not discuss these with the community pharmacist. Due to their cognitive state in initial stages of depression there was a focus on obtaining antidepressants, rather than reflecting on any underlying concerns, or unmet information needs. Men who were established on antidepressants and in remission also had support needs, particularly those who were considering when to stop medication. They could feel lost in the system.

A key finding for pharmacy practice is that pharmacy may need to find and offer other ways for men to interact with discussions around mental health treatment, rather than

wait for these patients to ask questions, or share their underlying attitudes to treatments. If community pharmacists are to proactively provide support to male patients experiencing depression, then this needs to be done in a way that is acceptable to men.

A peer support intervention using asynchronous technology delivered via smart phone has been developed. This work has built on the theories, evidence, and empirical studies presented within the previous chapters to gain a deeper understanding of an issue and to guide choice of intervention components.

This intervention provides an opportunity for men to interact with peers and the community pharmacist in a way that is more acceptable to men. This is particularly for those who do not have access to male networks, those that may find accessing other peer support options more threatening, or those that sought a tailored response to specific information needs, that would not be met through traditional peer support options.

For men established on antidepressants, the involvement of being a peer also provides benefits, such as feeling valued, listened to, and can help them reflect on where they are in their depression journey.

This intervention increased access and opportunity to both expert pharmacist knowledge and experiential peer knowledge. It is also through encouraging men to consider their underlying attitudes and norms, as well as their support and information needs, that this proposed intervention meets its objectives. It is acceptable to men and may allow this population to better access treatment and support sooner. The interactions can also facilitate the creation of a therapeutic relationship between the pharmacist and male patients and support recovery-orientated consultations.

Community pharmacists involved found the logistics of the intervention acceptable and valued the opportunity to incorporate lived experience into their consultations. Further work will be required before this intervention can be recommended for implementation.

The final contribution to knowledge that this thesis has made is a methodological one. It has explored the benefits and challenges of integrating a RtD approach into the MRC guidance on developing a complex intervention. There was value in doing this and future studies developing complex interventions could consider incorporating this approach.

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Appendices

Appendix 1: GUIDED 14 point checklist.

Adapted from <http://dx.doi.org/10.1136/bmjopen-2019-033516>

1	Report the context for which the intervention was developed.
	Community Pharmacy Setting
2	Report the purpose of the intervention development process.
	To develop an intervention that can support community pharmacy consultations with the target population and to support recovery orientated care.
3	Report the target population for the intervention development process.
	Men with unipolar depression who have been prescribed an antidepressant to treat their depression.
4	Report how any published intervention development approach contributed to the development process
	The behaviour change wheel. The MRC guidance on developing and evaluating complex interventions RtD approach
5	Report how evidence from different sources informed the intervention development process.
	Existing evidence base reviewed to identify relevant interventions. Guidance from experts in relevant fields. Primary research qualitative study focusing on the population and setting of interest. Stakeholders involved in design using a RtD approach.
6	Report how/if existing published theory informed the intervention development process.
	Behavioural change theory – COM-B model.
7	Report any use of components from an existing intervention in the current intervention development process.
	Peer support interactions

8	Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.
For intervention to be gender sensitive and acceptable to those who may adhere to hegemonic masculinity.	
9	Report how stakeholders contributed to the intervention development process.
Patient public involvement events were held prior to research studies. Stakeholders were involved in the design of the intervention, and reviewing the intervention, and suggesting refinements.	
10	Report how the intervention changed in content and format from the start of the intervention development process.
Adapted to ensure that the intervention did not cause negative revisiting of past events – instead a focus on answering or asking questions. Some of the terminology used changed e.g. 'feedback' Greater clarity on the purpose of the intervention was Briefings post intervention became a feature Removal of pharmacist video as not required.	
11.	Report any changes to interventions required or likely to be required for subgroups.
To link to more traditional peer support for those who desired a 'deeper' peer support relationship.	
12.	Report important uncertainties at the end of the intervention development process.
How to link to wider healthcare services. What characteristics of persons may find this intervention particularly beneficial. How to successfully implement service sustainably.	
13.	Follow TIDieR guidance when describing the developed intervention.
Yes – followed.	
14.	Report the intervention development process in an open access format.
Yes (funding required)	

Appendix 2 Standards for Reporting Qualitative Research (SRQR), and where covered in this thesis.

(Adapted from <http://www.equator-network.org/reporting-guidelines/srqr/>)

Title and abstract Chapter address in:

Title	Title page
Abstract	/

Introduction

Problem formulation	Chapter 2, 4 and 5.
Purpose or research question	Chapter 1, and specific aims for chapters 4-7.

Methods

Qualitative approach and research paradigm	Chapter 3.
Researcher characteristics and reflexivity	Chapter 3 and 8
Context	Chapter 2, 4, 5, 7 and 8
Sampling strategy	Chapter 3, 4, 6 and 7
Ethical issues pertaining to human subjects	Chapter 3, 4, 6 and 7.
Data collection methods	Chapter 3, 4 and 7.
Data collection instruments and technologies	Chapter 3, 4 and 7
Units of study	Chapter 4 and 7
Data processing	Chapter 3, 4 and 7
Data analysis	Chapter 3, 4 and 7

Techniques to enhance trustworthiness -	Chapter 3,4 , 7 and 8
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Results/findings

Synthesis and interpretation	Chapter 4,7 and 8
Links to empirical data	Chapter 4 and 7

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field	Chapter 4,7 and 8
Limitations	Chapter 4,7 and 8

Other

Conflicts of interest	N/A
Funding	Acknowledgments

Appendix 3 Interview Schedules for chapter 4 study

Purpose of question	Question	
Opening/ Introductory question:	How long ago have you been taking your (current) antidepressant?	
Second:	Was this the first time you used antidepressant medication?	
<u>General questions:</u>	When you had your new prescription, did you remember having any concerns?	
Follow up/Probe:	What were they, can you describe further? What specifically concerned you? Etc. Or if 'no' – ask about did they remember having a need for further information?	
<u>General questions:</u>	Did you ask any questions, or speak about these concerns?	(If relevant)
Follow up/Probe:	Who did you ask/speak to? What influenced your decision to ask this person?	If 'yes'
<u>General questions:</u>	Did you have any concerns that could be easily asked as a question?	
Follow up/Probe:	Can you give examples/What were they, can you describe further? What specifically makes them easy to ask? Etc.	
<u>General questions:</u>	Did you have any concerns that could be not easily be asked as a question?	If 'yes'
<u>General questions:</u>	Can you describe further? What are the challenges to ask these in a question form? What makes them not easily asked as a question?	
<u>General questions:</u>	A similar questions to before – but I'm going to ask about 'support'. When you had your new prescription, did you remember having any need for further support?	
Follow up/Probe:	Can you give example? Etc.	

<u>General questions:</u>	So you have taken your antidepressant medication for xxx long. Knowing what you know now, what would be the most important question you think someone should ask about when they are newly starting antidepressant medication?	
Follow up:	Can you explain further?	
<u>General questions:</u>	Again, knowing what you know now, what would be important advice you think someone should be given when they are newly starting antidepressant medication?	
	And finally, knowing what you know now, what would be important support someone should be given when they are newly starting antidepressant medication?	
<u>Clarification/Expanding question</u>	Is there anything you want to add or expand upon before I move onto new topic?	
Blurb: A focus of this research is understanding how community pharmacy can improve the support they offer to patients. In this study I'm focusing upon men with depression.		

NB: Check if participant is alright for time or needs a break.

Introductory Question:	You mentioned xxx support needed. Can community pharmacy help with providing this support?	(If relevant)
Follow up:	How might pharmacy help to provide this for support men treating depression?	
Direct Question:	What services could pharmacy deliver to better support men treating depression?	
Follow up:	Can you give further detail on that? Can you explain further?	(If relevant)
Direct Question:	Previously we spoke about concerns, information needs and support. What current needs in relation to your condition, and treating your condition are not being met?	(If relevant)
Direct Question:	Can pharmacy help meet these needs?	(If relevant)

Member checking process: If relevant confirm participant is still happy to do member checking process and give an estimate of the date when you will provide them with data to check.

Appendix 4 Interview Schedule for Chapter 7 study (Peer/Pharmacist participants)

Intro: Thank you for partaking in the modelling stage. To recap you took part in the service that involved two consultations in the pharmacy. I am going to ask for your views upon this service. To start I'll ask you upon your feedback on the service, then I'll ask you about specifically refining the design.

Purpose of question	Question	
Opening question for peer participant:		
Opening/ Introductory question:	Which pharmacy did you complete your consultations at?	
Second:	Would you consider this your regular pharmacy/pharmacist?	
Follow up/Probe:	Did that impact upon you modelling this service in any way?	
Opening question for pharmacist participant:		
Opening/ Introductory question:	How many consultations did you complete?	
Second:	Approx. how long did consultations last?	
<u>General questions:</u>	-What, if any of the characteristics of this service do you think were beneficial to your patient?	
<u>General questions:</u>	-What, if any of the characteristics of this service do you think were beneficial to you? / to your patient?	
Follow up/Probe:	Can you explain further? Tell me more... Why was this? Any other points?	If 'yes'
<u>General questions:</u>	-What, if any of the characteristics of this service were unappealing/barriers to you? / to your patient?	
Follow up/Probe:	Can you explain further? Tell me more... Why was this? Any other points?	(If relevant)

<u>Direct questions:</u>	-Specific features to discuss if not already mentioned: <ol style="list-style-type: none"> 1. Peer to Peer 2. Male only Peer – Peer 3. Use of pharmacy (as a location) 4. Use of pharmacist as a facilitator 5. Use of video messaging 6. Feedback aspect to service 7. Time commitments of consultation – ‘was there/ what if there was a delay between consultations’ etc etc. 8. Any aspects relevant to enablement 	
<u>Clarification/Expanding question</u>	Link back to key points participant said for clarification. Is there anything you want to add or expand upon?	

NB: Ask participant(s) if needs a break.

Direct Question:	If this design was being re-designed from scratch, what, if any, of the features would you keep?	
Follow up/Probe:	Can you explain further? Why is this?	If relevant
General question.	If you could improve this design, what would you suggest?	
Link back to comments:	When I first asked you initially about You said..... Do you still feel the same?	
<u>Clarification/Expanding question</u>	I’ve asked all my questions. Is there anything you want to add or expand upon?	

Debriefing:

Blurb: Thank you very much for your views. Really have appreciated your time and you talking to me. Before finish this interview just take a moment to reflect. Is there anything you want to ask about this study before we end this interview?

[For Peer Participants]: I also have a useful resources sheet. It contains useful websites that support mental wellbeing.

Member checking process: If relevant confirm participant is still happy to do member checking process and give an estimate of the date when you will provide them with data to check.

Appendix 5 Patient Information Sheet for Peer participants research

Peer Participant Information Sheet

Working Backwards: An Exploratory study on the effect(s) of a complex intervention using peer mentoring support to help men suffering from unipolar depression involving a community pharmacist in facilitator role.

Short title: Working Backwards.

Name of Researcher(s): [Sarah Brydges](#)

We would like to invite you to take part in our research study run by The University of Nottingham and Manor Pharmacy. Before you decide to partake we would like you to understand why the research is being done and what it would involve for you. You can contact one of our team who will answer any questions you have.

What is the purpose of the study?

The purpose of this study is to look at setting up a peer support service targeted to men taking antidepressants. Particularly this study looks at producing short video clips (featuring yourself) that can be used to aid another male with depression who takes antidepressants.

Why have I been invited?

You are being invited to take part because you are a MALE aged 18-65 years whom has been taking antidepressants for unipolar depression for 5 months or longer. We are interested in your views on a potential pharmacy service.

Do I have to take part?

No. It is up to you to decide whether to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason, although we may ask if you want to give a reason to aid our research. Withdrawing would not affect your legal rights nor any care given to you.

What will happen to me if I take part?

There will be two stages to this research. If you do decide to take part you will be asked to sign a consent form before participating. Typically it will take 1- 2months to complete stage 1-2 and take 3-4hours of your time.

Stage 1: Interview.

This will take place at a convenient time and location and will last about an hour.

In this interview we will ask you about what questions you wanted to ask when you first started antidepressants. We will also show you an outline of the proposed peer service and ask for you to comment upon it.

With your permission, we will audio record this interview.

Stage 2: Modelling service Step a:

Modelling the service will involve you having 2x20min visits to the community pharmacist. The focus of these visits will be on producing and watching video messages as part of the peer support scheme. This will occur in the pharmacy consultation room.

Step b:

This will involve an follow up interview with a researcher. The focus of this interview is how acceptable this service is to you, and how beneficial you feel it is. We are also interested in what you didn't feel was good/didn't like about the service and why that was. This will take place at a convenient time and location and will last about an hour. With your permission, we will audio record this interview.

Following the interview there will be a 5-10min debriefing session where you can ask any questions relating to the research.

Expenses and inconvenience allowance

Participants will receive 2x£10 (in amazon vouchers) to participate in the study as a gratitude for your time and participation. You will receive the first voucher after completing stage 1, and the second after completing stage 2.

What are the possible disadvantages and risks of taking part?

The research will involve talking and recording a video about your experiences relating to unipolar depression, and using antidepressants as treatment. Therefore you need to consider if discussions linked to your condition and treatment pose any emotional or other risks to yourself. Please note you only need to share information you are happy to share.

Consider also that you will be hearing others talk about their own depression and/or treatment. Therefore you need to consider if hearing

others talk on the topic of mental health is a risk or a disadvantage for yourself. Please note you will only hear information that that peer has decided that they want to share with you.

You will be recording videos where your face is shown. You need to consider if you are comfortable having yourself recorded. (see also **What will happen to any media/videos I produce?** for further details.)

What are the possible benefits of taking part?

The information we collect may help develop a service, or knowledge on how services could be delivered. This may help improve care and support provided in the future for men with depression.

You may personally benefit from taking part in research.

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 who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you should then contact the University of Nottingham Research Governance officer:
Research Governance Officer King's Meadow Campus University of
Nottingham Nottingham NG7 2NR Sponsor@nottingham.ac.uk

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. You will use a pseudonym throughout the study and only the authorised research team will have access to your personal data. Please be aware that other participants in the study will see and interact with you, however all research participants are asked to sign a confidentiality clause confirming they will not discuss any personal information obtained during the study outside of the study (see consent form).

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from The University of Nottingham who are involved in the research. They 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 research will be kept **strictly confidential**, stored in a secure and locked office if on hard copy, and on a password protected computer a backed up server if it is in

electronic. Only members of research team and systems administrator have access to the electronic folder. Only the research team have encryption keys.

Your personal data (address and telephone number) will be kept for 3 years after the end of the study so that we are able to contact you about the findings of the study *and 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 7 years. 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. The data produced will be in the form of media, audio and words. All data produced during the study becomes research data and is subject to Data Protection Act 1998.

In rare circumstances confidentiality may need to be breached to seek further medical or professional help if it is required during the study. In the consent form you must sign that you understand and accept that this breach may occur if your health, safety, or the safety/health of others is of a concern.

What will happen to any media/videos I produce?

You will be recording videos as part of this research.

Videos you make will only be shown to participants in the study and to those involved in the study (e.g. pharmacists, researcher team), unless you give additional consent otherwise (see consent form).

Any videos that you produce will be encrypted and stored securely on a password protected server. Only the pharmacists and research team have the password to decrypt the encrypted videos.

These videos will be watched by the research team for research purposes. Transcriptions of the videos will be made and may be used in publications and research thesis, and we ask for your permission that we can do this before the study (see consent form). All quotes are anonymous.

Audio and video media files produced from this experiment becomes research data. All research data is owned by the University of Nottingham and will be stored (encrypted) for 7years, then securely destroyed.

Do I have to record myself on a video?

With your permission, we would like to record your face as part of the peer support scheme (modelling stage). If you do not want to record your face you can still partake in the peer support messaging using audio only.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason. If you withdraw, the data and content you made prior to this point remains ownership of the researcher, and forms the research data. It is not possible for data from your prior participation to be extracted and destroyed. However any video media you produced for the study will not be shown to any further participants if you request this. The research team may contact you to ask for reasons on why you withdrew, as this knowledge may aid the research, however you do not need to give a reason if you do not wish to do so.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will receive a letter stating that 'one or more of their patients are involved in the study'. You will not be personally identified in this letter. It is not expected that your GP will routinely be involved in this research, unless however there is a medical need and we ask that you sign that we can breach confidentiality to seek medical assistance should such a circumstance occur.

The research team will not ask for details about your medical information, however if you have any medical conditions that you feel the research team should know about in the interest of health and safety, then you should let the research team know.

If the research team feels that in the interest of health and safety you should not participate then you may be excluded from the study, although we will involve you in this decision.

What will happen to the results of the research study?

The results of this study will form part of a PhD thesis, and study may be published in a paper. You will not be personally identified in any report/publication.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by PhD research account and school funding for MPharm project student.

Who has reviewed the study?

This research is approved by independent group of people, who authorise NHS ethics. This study has been reviewed and given favourable opinion.

I want to take part. What do I do?

Please contact either Sarah Brydges (Project Manager) at sarah.brydges@nottingham.ac.uk , or ask the pharmacist who gave you this leaflet to forward your email address to research team.

Following this a member of the research team will reply to discuss any questions, confirm that you meet the eligibility criteria, and discuss study details further.

Further information and contact details

Sarah Brydges = sarah.brydges@nottingham.ac.uk (Project Manager)

School of Pharmacy

University of Nottingham, Nottingham, NG7 2RD Tel: 0115 74
84556

Claire Anderson = Claire.anderson@nottingham.ac.uk

Professor of Social Pharmacy Head of Division of Pharmacy Policy and
Practice. University of Nottingham, Nottingham, NG7 2RD
Tel: 0115 951 5389

Appendix 6 Pharmacist Participation Information Sheet

Participant **Pharmacist** Information Sheet.

Working Backwards: An Exploratory study on the effect(s) of a complex intervention using peer mentoring support to help men suffering from unipolar depression involving a community pharmacist in facilitator role.

Short title: Working Backwards.

Name of Researcher(s): [Sarah Brydges](#)

We would like to invite you to take part in our research study run by The University of Nottingham and Manor Pharmacy. Before you decide to partake we would like you to understand why the research is being done and what it would involve for you. You can contact one of our team who will answer any questions you have.

What is the purpose of the study?

The purpose of this study is to look at setting up a peer support service targeted to men taking antidepressants. Particularly this study looks at producing short video clips (featuring yourself and patient) that can be used to aid another male with depression who takes antidepressants.

Why have I been invited?

You are being invited to take part because you are a Pharmacist employed within Manor Pharmacy Group, which has kindly agreed to pilot this service.

Do I have to take part?

It is up to you to decide whether to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason, although we may ask if you want to give a reason to aid our research. Withdrawing would not affect your legal rights nor your employment.

What will happen to me if I take part?

You will receive training on the pilot service and aspects of the study before partaking in the study. The study will involve you running a novel service

within the pharmacy targeted for men who are taking antidepressants (referred to as 'Peer participants'). There are 3 key steps outlined below. You will be asked to sign a consent form before partaking in the study.

Step a: Identifying potential peer participants who meet the eligibility criteria.

Step b: Run a pilot peer scheme involving participants. For each participant you will have 2x 15-20min consultations with them. The consultations involve you both producing and watching videos, and will occur in the pharmacy consultation room.

Step c: Following completion of step b, a focus group (or individual interview if requested) where the research team will ask about your views upon the piloted service. This focus group/interview will take place at a convenient time and location and will last about an hour. With your permission, we will audio record this interview.

Following the interview there will be a 5-10min debriefing session where you can ask any questions relating to the research.

Expenses and inconvenience allowance

Participants will individually receive £10 (in Amazon vouchers) for participating in the study as a gratitude for your time and participation. This will be paid after completing step c.

What are the possible disadvantages and risks of taking part?

The research focuses upon peer support with issues around depression and treatment. Sensitive issues may be discussed and this could affect you emotionally. Specific CPPE training packages will be completed prior to involvement in this service to ensure you are equipped with skills that may be required in this service.

It could be possible the peer participant discloses information that concerns you. Situations may result that require referral to further professional support

e.g. patient revealing suicidal intent. The study has been designed so that in appropriate circumstances you can break peer participant's confidentiality to seek further help.

You will be recording videos where your face is shown. You need to consider if you are comfortable having yourself recorded. (see also **What will happen to any media/videos I produce?** for further details.)

What are the possible benefits of taking part?

The information we collect may help develop a service, or knowledge on how services could be delivered. This may help improve care and support provided in the future for men with depression.

You may personally benefit from taking part in research.

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 who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you should then contact the University of Nottingham Research Governance officer:
Research Governance Officer King's Meadow Campus University of Nottingham Nottingham NG7 2NR Sponsor@nottingham.ac.uk

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. You will use a pseudonym throughout the study and only the authorised research team will have access to your personal data. This study may involve other participants hearing your views. All participants partaking in the study have consented that they treat information about other participants confidentially.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from The University of Nottingham who are involved in the research. They 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 research will be kept **strictly confidential**, stored in a secure and locked office if on hard copy, and on a password protected computer a backed-up server if it is in electronic. Only members of research team and systems administrator have access to the electronic folder. Only the research team have encryption keys.

Your personal data (address and telephone number) will be kept for 3 years after the end of the study so that we are able to contact you about the findings of the study *and 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 7 years. 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. The data produced will be in the form of media, audio and words. All data produced during the study becomes research data and is subject to Data Protection Act 1998.

What will happen to any media/videos I produce?

You will be recording videos as part of this research.

Videos you make will only be shown to those involved in the study (i.e participants and research team), unless you give additional consent otherwise (see consent form).

Any videos that you produce will be encrypted and stored securely on a password protected server.

These videos will be watched by the research team for research purposes. Transcriptions of the videos will be made and may be used in publications and research thesis, and we ask for your permission that we can do this before the study (see consent form). All quotes are anonymous.

Audio and video media files produced from this experiment becomes research data and will be stored (encrypted) for 7years, as per section above.

Do I have to record a video?

With your permission, we would like you to record a video featuring yourself as part of the peer support scheme (modelling stage). If you do not want to record your face you can still partake in the peer support messaging using audio only.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason. If you withdraw, the data and content you made prior to this point remains ownership of the researcher, and forms part of the research data. It is not possible for data from your prior participation to be extracted and destroyed. However any video media you produced for the study will not be shown to any further participants if you request this. The research team may contact you to ask for reasons on why you withdrew, as this knowledge may aid the research, however you do not need to give a reason if you do not wish to do so.

Involvement of the General Practitioner/Family doctor (GP)

The research team will not ask for details about your medical information, nor involve your GP. However, if you have any medical conditions that you feel the research team should know about in the interest of health and safety, then please let the research team know.

What will happen to the results of the research study?

The results of this study will form part of a PhD thesis, and study may be published in a paper. You will not be personally identified in any report/publication.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by PhD research account and school funding for MPharm project student.

Who has reviewed the study?

This research is approved by independent group of people, who authorise NHS ethics. This study has been reviewed and given favourable opinion.

I want to take part. What do I do?

Please contact Sarah Brydges (Project Manager) at sarah.brydges@nottingham.ac.uk to let the research team know if you are interested in taking part in the study, or would like to discuss the study further.

A member of the research team will reply to discuss any questions, confirm that you meet the eligibility criteria, and discuss study details further.

Further information and contact details

Sarah Brydges = sarah.brydges@nottingham.ac.uk (Lead researcher/project manager)

School of Pharmacy, University of Nottingham, Nottingham, NG7 2RD
Tel: 0115 74 84556

Claire Anderson = Claire.anderson@nottingham.ac.uk

Professor of Social Pharmacy Head of Division of Pharmacy Policy and Practice. University of Nottingham, Nottingham, NG7 2RD
Tel: 0115 951 5389

Appendix 7 Participation Information Sheet for chapter 6.

Working Backwards: An Exploratory study on the development of a complex intervention.

Short title: Working Backwards.

Name of Researcher(s): [Sarah Brydges](#)

We would like to invite you to take part in our research study run by The University of Nottingham. Before you decide to partake we would like you to understand why the research is being done and what it would involve for you. You can contact one of our team who will answer any questions you have.

What is the purpose of the study?

The purpose of this study is to gather your views on a potential service that can be delivered in a community pharmacy setting for men experiencing depression, and using antidepressants.

Why have I been invited?

You are being invited to take part because you are a MALE aged 18-65 years whom has identified with experiencing stress.

Do I have to take part?

No. It is up to you to decide whether to take part. If you decide to take part you are still free to withdraw at any time, and without giving a reason, although we may ask if you want to give a reason to aid our research.

What will happen to me if I take part?

You will be asked to share your views, we will ask you to help with the design of this intervention, and trial out various designs. You may be audio or video recorded during this time.

Expenses and inconvenience allowance

Participants will receive £5 (in Boots vouchers) to participate in the study as a gratitude for your time and participation.

What are the possible disadvantages and risks of taking part?

You will be asked questions about your experiences of stress, particularly in relation to being a male. You should reflect if discussions of this nature may cause any disadvantage to yourself.

What are the possible benefits of taking part?

The information we collect may help develop a service, or knowledge on how services could be delivered. This may help improve care and support provided in the future for men with depression.

You may personally benefit from taking part in research.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. You will use a pseudonym throughout the study and only the authorised research team will have access to your personal data.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from The University of Nottingham who are involved in the research. 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 research will be kept **strictly confidential**, stored in a secure and locked office if on hard copy, and on a password protected computer a backed-up server if it is in electronic. Only members of research team and systems administrator have access to the electronic folder. Only the research team have encryption keys.

Your personal data (address and telephone number) will be kept for 3 years after the end of the study so that we are able to contact you about the findings of the study *and 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 7 years. 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. The data produced will be in the form of media, audio and words. All data produced during the study becomes research data and is subject to Data Protection Act 1998.

What will happen to any media/videos I produce?

You may be recording videos as part of this research.

Videos you make will only be shown to participants in the study and to those involved in the study (e.g. pharmacists, researcher team), unless you give additional consent otherwise (see consent form).

Any videos that you produce will be encrypted and stored securely on a password protected server. Only the research team have the password to decrypt the encrypted videos. These videos will be watched by the research team for research purposes. Transcriptions of the videos will be made and may be used in publications and research thesis, and we ask for your permission that we can do this before the study (see consent form). All quotes are anonymous.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason. If you withdraw, the data and content you made prior to this point remains ownership of the researcher, and forms the research data.

What will happen to the results of the research study?

The results of this study will form part of a PhD thesis, and study may be published in a paper. You will not be personally identified in any report/publication.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by PhD research account and school funding for MPharm project student.

Who has reviewed the study?

This research is approved by the School of Pharmacy ethics department.

I want to take part. What do I do?

Please contact Sarah Brydges = sarah.brydges@nottingham.ac.uk
(Project Manager)

School of Pharmacy
University of Nottingham, Nottingham, NG7 2RD Tel: 0115 74
84556

Appendix 8 Consent Forms for all research studies.

CONSENT FORM

Title of Study: Working Backwards: An exploratory study on the effect(s) of a complex intervention for men suffering from unipolar depression, involving a community pharmacist.

IRAS Project ID: 212445 [Remove for chapter 6 study]

Name of Researcher: Sarah Brydges

Name of Participant:

There are 3 Sections to this form. Section 1 is required consent. Section 2 is optional consent. Please initial all that you consent to. Section 3 is contact details. There are 3 pages to this form.

Section 1: Required consent. All section 1 must be consented to for study involvement.

Please initial box

1. I confirm that I have read and understand the information sheet version number [XXX] dated [month/year] 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. I understand that my personal details will be kept confidential. **[Remove for chapter 6 study and Pharmacist Participants]**

4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports.

5. I understand that the information held and maintained by the Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact me. **[Remove for chapter 6 study and Pharmacist Participants]**

6. I agree that the research team, or pharmacist with a duty of care to me, may contact relevant professionals (e.g. my GP) if they feel they have a duty of care to do so (e.g. medical issues) and I understand, and agree, they may break my confidentiality to do this.

7. I understand this research may involve me producing a video of myself and watching videos of others. I understand and agree that these videos will be shown to others involved in the study. I understand I cannot record the videos that I watch, and I will respect the confidentiality of any other participants.


8. I shall receive an inconvenience allowance as stated in participant information sheet. If I withdraw from the study I understand this payment may not be made from the study, and shall be at the discretion of the supervising investigator.

9. I agree to take part in the above study.

Section 2: Optional consent. Consent points in section 2 are optional and consent is not a requirement to participate in study.

2.a Publication of video media:

Please read the sentences below relating consent to publication of the Video media produced during the experiment. **Do you consent to any of the following?** Please *initial* in the boxes that *apply*.

	Y E S	N O
Video featuring you used in events or publications relating to this research project (NB assume these to be publicly available):		
Video featuring you where your <u>face is blurred</u> , used in events or publications relating to this research project (NB assume these to be publicly available)		
Video stills featuring you used in events or publications relating to this research project (NB assume these to be publicly available):		
Video stills featuring you, where image is altered (see image below), in events or publications relating to this research project (NB assume these to be publicly available): 		
Audio of your voice from the video you produce in publications or events relating to this research project (NB assume these to be publicly available):		

2.b: Further involvement.

1) It is the intention that data from this experiment aids a further related experiment. If you are interested in being contacted about further studies please initial the box. We will securely destroy your contact details after 3years.

2) The reliability of research can be increased by a process called 'member checking'. This involves you reading back parts of your interview and confirming the findings are interpreted correctly. Please tick if you are happy for us to contact you about this.

Section 3: Contact details and signatures:

Please fill in box. We will store your details securely.

Name:	
Tel no:	
Email address:	
Date of birth or NHS number:	
Details of your GP	

Please sign below:

Name of Participant Date Signature

Name of Person taking consent Date Signature