Research Project Portfolio

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School of Medicine

Department of Clinical Psychology

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Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

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Submitted in part fulfilment of the requirements for the

Doctorate in Clinical Psychology

Acknowledgements

I would like to dedicate my thesis to my grandma Kathleen Mary Read (14/07/1927-20/01/2025). Though she did not know what a smartphone app was, she would have been immensely proud, nonetheless.

I would like to extend my sincerest gratitude to my research supervisors Dr Nima Moghaddam, Dr Jacob Andrews, Dr Sam Malins, and Dr David Dawson. They have been unrelentingly kind, helpful, enthusiastic, and patient throughout every part of this study. I have greatly appreciated their expertise, guidance, and support throughout this process. They have taught me invaluable lessons about research and being a clinical psychologist, which I will apply to the entirety of my career. I would also like to thank the app developer Elitsa Dermendzhiyska, who provided crucial information and technological support. Special thanks to Kinga Simko who kindly conducted the interviews for this study.

I would like to take this opportunity to highlight the invaluable role of the participants, as I am grateful for their time and effort whilst engaging in this study. I learnt a lot from the participants, and I hope that they were able to take something positive from their participation. I would also like to extend my thanks to the NHS staff at the participant identification centre, who identified and approached the participants on my behalf. Their support enabled this study to become a reality.

Finally, I would like to thank my fiancé, parents, sister, family, and friends for their ongoing support throughout this time. They have supported me with encouragement, empathy, humour, and care, when it was thoroughly required. Thank you to everyone who has supported me throughout this process.

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1. Thesis Abstract

Background: Mental health is central to overall wellbeing, and there is an increasing demand for mental health services, resulting in longer waiting times. A potential solution could be apps which support emotion regulation, as systematic reviews of such apps have found promising results. Emotion regulation can be defined as regulating positive and negative emotions, based upon personal goals. The smartphone application 'Betwixt' aims to improve emotion regulation, and it could offer interim support to those waiting, with an immediate and potentially effective intervention. Betwixt is a narrative gaming app, and it is purported to be based upon psychological theory, and the emotion regulation strategies of cognitive reappraisal, and self-compassion. Previous studies of Betwixt found positive results, though none had investigated individuals with mental health conditions. Numerous apps purport to improve mental health, though few are evaluated empirically, therefore this study evaluated an app with promise for clinical utility.

Aims: A) Evaluate the effectiveness of the Betwixt intervention in improving emotion regulation, cognitive reappraisal, and self-compassion in a clinical population. B) Investigate whether changes in processes targeted by Betwixt resulted in improvements in clinical outcomes. C) Explore the acceptability, and theoretical components of Betwixt within a clinical context.

Methods: A mixed-methods single-case experimental design was used to investigate the effectiveness and acceptability of Betwixt within an adult clinical population of individuals experiencing depression or anxiety disorders. Seven participants were recruited from the waiting list for an NHS Talking Therapies service within the UK. These are publicly funded mental health services, which support individuals experiencing depression or anxiety disorders (including generalised anxiety disorder and post-traumatic stress disorder) with talking therapies. The average age of participants was 44.6 years, and they were all female. They used Betwixt every other day for four weeks, and there were weekly check-in calls to troubleshoot technical issues and support app engagement. Participants also completed qualitative interviews or surveys,

which focused on acceptability and perceived changes associated with Betwixt use.

Results: Findings were mixed regarding improvements in emotion regulation, cognitive reappraisal, and self-compassion as three participants had significant improvements in emotion regulation, one had significant deteriorations, and one had a combination of improvements and deteriorations. Two participants had a significant improvement in cognitive reappraisal and two in self-compassion. However, there were positive indications that Betwixt may improve clinical outcomes as three participants had significant improvements in low mood (and one had a significant deterioration), four in anxiety, four in wellbeing and three (of four eligible participants) in functioning. Participants' views on acceptability ranged from positive to negative, with three of the participants having overall positive views of Betwixt, two having mixed views, and one having overall negative views. It is worth noting that the majority of individuals on waiting lists for talking therapies can experience a deterioration, hence, these significant improvements were deemed encouraging by comparison.

Discussion: This study indicates the feasibility, acceptability, and effectiveness of a narrative-based ER gaming app for individuals with depression or anxiety disorders. With further evaluation, Betwixt could be a promising intervention for individuals waiting for talking therapies. Future research should include randomised controlled trials, long-term studies, and assessments of feasibility in severe mental health conditions. Betwixt has promise for clinical applications; the design of this study could be replicated to assess other apps; check-in calls could be included in other interventions; and targeting ER in an intervention may indirectly improve low mood or anxiety. This research is an original contribution of knowledge as it was the first study to evaluate Betwixt within a clinical population; the design was innovative and could be replicated for other apps; and there was a novel finding that emotion regulation and psychological distress may be correlated across timepoints. The journal paper was appraised positively, with numerous strengths, though some limitations. A critical reflection on the study process and a conference poster have also been included.

2. Statement of Contribution

Project design: Victoria Harper, Dr Nima Moghaddam, Dr Jacob Andrews and Dr Sam Malins.

Application for ethical approval: Victoria Harper, with support from Dr Nima Moghaddam, Dr Jacob Andrews and Dr Sam Malins.

Writing the review of literature: Victoria Harper, supervised by Dr Nima Moghaddam, Dr Jacob Andrews, Dr David Dawson, and Dr Sam Malins.

Recruiting participants: Victoria Harper and members of Lincolnshire NHS Talking Therapies service.

Data collection: Victoria Harper, with support from Dr Nima Moghaddam, Dr Jacob Andrews, Dr David Dawson, and Dr Sam Malins.

Scoring questionnaires: Victoria Harper.

Conducting interviews: Kinga Simko.

Entering data: Victoria Harper.

Data analysis: Victoria Harper, supervised by Dr Nima Moghaddam, Dr David Dawson and Dr Sam Malins. Dr Nima Moghaddam analysed the Simulation Modelling Analysis data.

Writing the journal paper: Victoria Harper, and sections were derived from her protocol for this project.

3. Journal Paper

Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Short Title: Is Betwixt app effective and acceptable?

Formatted for submission to Psychology and Psychotherapy: Theory, Research and Practice. The maximum word limit for articles with a qualitative element is 8,000 words. Full submission guidelines: https://bpspsychub.onlinelibrary.wiley.com/hub/journal/20448341/homepage/forauthors.html.

Authorship

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Abstract:

Objectives: Mental health is central to overall wellbeing, and there is an increasing demand for mental health services, resulting in longer waiting times. The smartphone application 'Betwixt' could offer interim support to those waiting to access psychological therapies, with an immediate and potentially effective intervention. Betwixt is a narrative gaming app, aimed at improving emotion regulation and purported to be based upon psychological theory, cognitive reappraisal, and self-compassion. Previous studies of Betwixt found positive results, though none had investigated individuals with mental health conditions, specifically depression or anxiety disorders. Numerous apps purport to improve mental health, though few are evaluated empirically, therefore this study evaluated an app with promise for clinical utility.

Design: A mixed-methods single-case experimental design was used to investigate the effectiveness and acceptability of Betwixt within an adult clinical population of individuals experiencing depression or anxiety disorders in the UK. Participants also completed qualitative interviews or surveys, which focused on acceptability and perceived changes associated with Betwixt use.

Methods: Seven participants on the waiting list for NHS Talking Therapies and experiencing clinical depression or anxiety, used Betwixt every other day for four weeks. There were weekly check-in calls throughout the study to troubleshoot technical issues, and support app engagement.

Results: Findings were mixed regarding improvements in emotion regulation, cognitive reappraisal, and self-compassion. However, there were encouraging indications that Betwixt may improve clinical outcomes. Participant views on acceptability ranged from positive to mixed.

Conclusions: With further evaluation, Betwixt could be a promising intervention for individuals waiting for talking therapies. Future research should include randomised controlled trials, long-term studies, and assessments of feasibility in severe mental health conditions.

Practitioner Points

1. The Betwixt application may have promise for clinical applications, though further evaluation is required before it can be recommended as some participants experienced significant deteriorations.
2. The design of this study could be replicated to evaluate other smartphone applications for clinical use.
3. The use of check-in calls, and other human contact may be beneficial for individuals accessing a digital intervention.
4. Targeting emotion regulation in interventions may have the potential to indirectly support an individual's psychological distress, low mood, or anxiety, though further evaluation is required.

Keywords

Mental health, smartphone application, effectiveness, acceptability, emotion regulation, adult clinical population.

Data Availability Statement

At the point of submission, all study data will be made publicly available, via an active link in the final accepted manuscript.

Acknowledgements

This study partially fulfils the requirements for Victoria Harper's doctorate in clinical psychology, at the University of Nottingham. This course and study were funded by Health Education England. Regarding conflicts of interest, Elitsa Dermendzhiyska is an app developer and created 'Betwixt'. She was not involved in data collection or analysis.

3.1 Introduction

Global and National Impact of Mental Health

Mental health is central to overall wellbeing, and mental health conditions are among the most significant contributors to global disease burden, profoundly affecting personal functioning, social connections, and economic participation (Vos et al., 2020; Dattani et al., 2021). Globally, 792 million people (10.7%) have been estimated to experience mental health conditions, and anxiety is the most prevalent, followed by depression (284 and 264 million respectively; Dattani et al., 2021).

Nationally, one in six adults experience symptoms of depression or anxiety (one woman in five and one man in eight), and their reported prevalence has increased (McManus et al., 2016). The demand for support from NHS mental health services is increasing, which has led to longer waiting times (Al-Haboubi & Oladimeji, 2022). Waiting for treatment has been shown to intensify psychological distress, including heightened stress and uncertainty, and may result in worse treatment outcomes (Osuna, 1985; Van Dijk et al., 2023). These findings highlight the urgent need for innovative solutions to address the mental health needs of an increasing population.

Role of Mobile Health (mHealth) in Meeting Mental Health Needs

A potential solution to meet mental health needs and support individuals on waiting lists could be mHealth[1], which involves providing interventions via a mobile device. Digitally enabled mental healthcare is one of the NHS's mental health priorities, and during the COVID-19 pandemic, mHealth was suggested to increase the access and quality of mental health support (NHS England, 2019). The health secretary has also discussed the digital healthcare agenda and the impetus of the NHS "moving from analogue to digital" (Streeting, 2024). mHealth may increase access to interventions, decrease waiting times, and be an effective and acceptable method of delivering large-scale mental health support at a lower cost (Cuijpers et al., 2008; Teachman et al., 2022). The reach of mHealth is also crucial as an app that can be accessed by more

[1]Please refer to extended paper section 4.1.1 for additional information about mHealth.

people (even if it has a smaller effect size) has a larger impact on public health than an intervention that is available to fewer people (with a large effect size; Prochaska et al., 2019).

Over 10,000 mHealth applications ('apps') are available, with nearly 100 new mHealth companies started every year (Roland et al., 2020). Some mHealth appears to be effective, low cost, and supportive, however, limited systematic evaluation has been undertaken, and few apps have been rigorously tested in peer-reviewed literature (Roland et al., 2020). A review of the efficacy and research methodology of mental health apps found that only 5% of reviewed apps had been rigorously evaluated, and less than 4% were evidence-based (Marshall et al., 2019). In addition, it has been recommended that robust research is undertaken prior to an app being recommended clinically (Badesha et al., 2022). These gaps highlight the critical need for robust research to ensure that mHealth tools meet their promise of safe and effective support for mental health needs, including those of individuals on waiting lists.

Emotion Regulation (ER) as a Key Target for mHealth

Within mHealth, ER[2] has emerged as a promising focus area (Slovak et al., 2023). ER can be defined as: "shaping which emotions one has, when one has them, and how one experiences or expresses these emotions" (Gross, 1998). It entails regulating positive and negative emotions, dependent upon one's personal goals, and it has been proposed to be required for daily functioning (Gross & Muñoz, 1995). ER can be targeted within psychological interventions, such as, ER therapy, dialectical behaviour therapy for ER, and mindfulness (Gross, 2014). ER interventions aim to improve the management or modulation of ER, or to change an individual's emotional experiences, expression, and responses (Gross, 2014). There is also "encouraging evidence that digital technologies may be beneficial for enhancing ER skills and providing personalised care remotely" (Jadhakhan et al., 2022).

[2]Please refer to extended paper section 4.1.2 for additional information about emotion regulation.

ER appears to be an underlying meta-factor relevant to various psychological therapies, including psychodynamic therapy and cognitive-behavioural therapy (CBT; Palmieri et al., 2022). Deficits in ER also appear to be related to the development, maintenance, and treatment of mental health conditions (Berking & Wupperman, 2012). It has been further proposed that the recent increase in digital ER interventions may be due to recognition that ER difficulties are a transdiagnostic factor in mental health conditions (Slovak et al., 2023).

Previous studies have researched ER mHealth and emphasised the importance of such interventions being theory-driven and enabling timely interventions (Bettis et al., 2022). Further to this, a systematic review of ER apps in a general population concluded that they have "promising outcomes", however, few apps specifically promote ER (Eisenstadt et al., 2021). A systematic review in a clinical mental health population also deduced that such interventions may improve low mood, anxiety, and trauma symptoms, however, the evidence-base was found to be sparce (Harper et al., 2025). These findings highlight that few apps specifically target ER, and more theory-driven studies of ER apps are required.

Betwixt: A Theory-Driven ER mHealth App

Betwixt[3] is a narrative-based gaming app which aims to improve ER[4]. Unlike many digital interventions (Bucci et al., 2019), Betwixt is explicitly theory-driven, incorporating self-determination theory (autonomy, relatedness, and competence; Deci & Ryan, 2012) and social cognitive theory (learning within a social context; Bandura, 1989). It is also purported to be based upon the two ER skills of cognitive reappraisal[5] and self-compassion[6], prominent features of CBT and compassion-focused therapy (CFT) respectively (Harmon et al., 2025). Cognitive reappraisal entails reframing and reinterpreting situations

[3]It is worth noting that the research team are not affiliated with Betwixt.
[4]Please refer to extended paper section 4.1.3 for further information about Betwixt. Please refer to Appendices 5.1 and 5.2 for further information about Betwixt, including app imagery, QR codes, and a summary of the app's content from the app developer.
[5]Please refer to extended paper section 4.1.4 for additional information about cognitive reappraisal.
[6]Please refer to extended paper section 4.1.5 for additional information about self-compassion.

perceived to be stressful (Lazarus & Folkman, 1984), and self-compassion involves actively being kind and understanding toward oneself (Neff, 2003).

Previous research has mapped evidence-based psychological interventions onto Betwixt content, and the app was found to incorporate deep breathing, muscle relaxation, self-identification, self-compassion, self-distancing, reflection, and self-affirmation (Masselink & Scholten, 2025)[7]. An acceptability study of Betwixt found positive results in a general population sample (i.e., individuals not experiencing a mental health condition), such as, 73.1% of participants found that the app informed their way of thinking (Dermendzhiyska et al., 2025). It is worth noting that this study had a small sample size (n = 26), and the results may not be generalisable. A general population randomised controlled trial of Betwixt found significant and large improvements in depression, stress, and self-reflection (Masselink & Scholten, 2025). These studies indicate that Betwixt had not previously been evaluated in a clinical population of individuals experiencing depression or anxiety disorders, with those who may benefit most from targeted ER interventions.

Summary and Study Rationale

In conclusion, there is an urgent need for digitally enabled mental healthcare, which is accessible, evidence-based, and capable of supporting individuals awaiting treatment. ER is a transdiagnostic factor in various mental health conditions, and ER apps have “promising outcomes”, yet few apps specifically target this construct. In addition, few ER mHealth apps have been found to be based upon theory or systematically evaluated. To potentially overcome this, Betwixt is a theory-driven app with foundations in ER. It is purported to be evidence-based, and it has indications of acceptability and effectiveness in a general population. Hence, this research aimed to address whether Betwixt was effective and acceptable at improving ER in a clinical population[8].

[7]Please refer to extended paper section 4.1.6 for additional information about previous literature in the research area.
[8]Please refer to extended paper section 4.1.7 for additional information about the study rationale and aims.

Study Aims

A: Evaluate the effectiveness of the Betwixt intervention in improving ER, cognitive reappraisal, and self-compassion in a clinical population.

B: Investigate whether changes in processes targeted by Betwixt resulted in improvements in clinical outcomes.

C: Explore the acceptability and theoretical components of Betwixt within a clinical context.

3.2 Materials and Methods

This research was sponsored by the University of Nottingham, approved by the NHS Health Research Authority and a Research Ethics Committee[9] (IRAS project ID 334141), and adhered to the British Psychological Society Code of Human Research Ethics (Oates et al., 2021).

Design

This study involved a mixed-methods[10] design[11], to investigate the effectiveness and acceptability of Betwixt. To investigate effectiveness (aims A and B), a single-case experimental design (SCED) series was undertaken. This evaluates treatment effects on a case-by-case basis, whereby each participant acts as their own control condition. This entailed an AB design (comparing the baseline [A] and Betwixt treatment [B] phases), with multiple baselines staggered across participants to mitigate the influence of external events on results. Staggering the intervention for different participants is also more naturalistic to NHS service referrals. This SCED element involved the systematic and repeated measurement of dependent variables (measures of ER, low mood, and anxiety) against the independent variable (usage of Betwixt). In addition, pre- and post-

[9]Please refer to Appendices 5.3 to 5.6 for Research Ethics Committee favourable opinion letter, ethics approval letter, and ethics amendment letters. Please also refer to extended paper section 4.2.1 for additional information about ethical considerations and 4.2.2 for additional information about the ethical application process.
[10]Please refer to extended paper section 4.2.3 for additional information about epistemology.
[11]Please refer to extended paper section 4.2.4 for additional information about the study design.

intervention measures were completed to compare cognitive reappraisal, self-compassion, distress, and functioning before and after the Betwixt intervention.

Qualitative interviews and surveys were then undertaken with the dual purpose of understanding change (triangulating the findings from the quantitative studies, aims A and B) and exploring the acceptability of the intervention (aim C). The interviews and surveys had the same structure, with the interview being offered initially, and the survey being provided if the participant was not able to engage in an interview. To structure the interviews and surveys[12], the constructs of the Theoretical Framework of Acceptability (Sekhon et al., 2017) and Client Change Interview Schedule (Elliott, 2006) were amalgamated. This included questions about affective attitude, perceived effectiveness, ethicality, intervention coherence, opportunity costs, burden, and self-efficacy (Sekhon et al., 2017); and general questions, changes, helpful aspects, resources, problematic aspects, limitations, and suggestions (Elliott, 2006). Participants were also asked about the components underpinning Betwixt (cognitive reappraisal and self-compassion; study aim A).

Recruitment

Participants were recruited[13] from an NHS Talking Therapies service (supporting individuals with depression or anxiety disorders). Clinicians within the service offered eligible individuals the opportunity to participate during their assessment appointment. If they wanted to participate, they consented to their contact details being provided to the research team, who then provided further information and documentation[14]. If the individual decided to participate in the study, participation was discussed, and they completed consent virtually either via Microsoft Teams or using a Microsoft Form.

The eligibility criteria were the same as the criteria for accessing NHS Talking Therapies services (National Collaborating Centre for Mental Health, 2024):

[12]Please refer to Appendices 5.9 and 5.10 for the Interview Topic Guide and Exit Survey.
[13]Please refer to extended paper section 4.2.5 for additional information about recruitment.
[14]Please refer to Appendices 5.7 and 5.8 for the Participant Information Sheet and consent form.

Adults with an anxiety disorder and/or depression (defined by meeting the clinical cut-offs on the Patient Health Questionnaire-9 measure of depression, Kroenke et al., 2001; or the Generalised Anxiety Disorder-7 measure of generalised anxiety, Spitzer et al., 2006). Participants were required to own a smartphone to access Betwixt, which they were comfortable using for extended periods of time. Participants were also required to have a sufficient English reading ability to be able to engage with the intervention, due to the narrative nature of Betwixt. This study was delivered as a waiting list intervention, to prevent a delay in treatment for individuals in a clinical population. Hence, participants were required to be on the waiting list for the specific NHS Talking Therapies service, and available for up to seven weeks whilst waiting.

Participants

Ten participants were recruited and seven completed the study (demographics in Table 1). The three participants who did not finish the study withdrew[15] prior to initiating the treatment phase. The average age of participants was 44.6 years, which is in keeping with NHS Talking Therapies referral data (NHS Digital, 2018). All the participants who completed the study were female, though two of the withdrawing participants were male. NHS Talking Therapies data (e.g., NHS Digital, 2018) demonstrates that fewer males tend to access these services, however, they tend to represent 36% of referrals, as opposed to 20% in this sample.

Table 1

Demographics of Participants who Completed the Study

Participant	Pseudonym	Age	Gender	Diagnosis
1	Kirsty	42	Female	Depression
2	Christine	49	Female	Depression
3	Lynne	44	Female	Generalised anxiety disorder
4	Sarah	23	Female	Depression
5	Sharon	55	Female	Depression

[15]Please refer to extended paper section 4.2.6 for additional information about the withdrawing participants.

6	Lucy	53	Female	Post-traumatic stress disorder
7	Carol	46	Female	Post-traumatic stress disorder

Intervention

Participants were provided with the narrative gaming app Betwixt, which aims to improve ER, and is based on the two ER skills of cognitive reappraisal and self-compassion. They were invited to use this app every second day, during their treatment phase. Betwixt takes place in the imagined location of the 'In-Between', and contains 11 'dreams', which are separate chapters within the narrative. When engaging with the app, users interact with the story and hear background sounds which fit with the narrative. The story aims to support users to imagine the scene being described and users provide responses at certain time-points, which influence the direction of the narrative. The story uses a guiding voice and magical creatures, designed to support users to reflect on their ER. Users also collect 'powers' (skills) and there are additional resources which they can access after completing each dream.

Measures

The measures[16] for the SCED (Table 2) assessed psychological outcomes, including ER, as Betwixt aims to improve this construct. Psychological distress (low mood and anxiety) was also assessed to ascertain participant distress throughout the phases. The measures had sufficient psychometric properties, and shorter versions of questionnaires were chosen to decrease participant effort.

[16]Please refer to extended paper section 4.2.7 for additional information about selection of the measures.

Table 2

Measures for the SCED Series

Construct	Measure	Scoring	Example item	Reliability	Validity	Reference
Emotion regulation	Difficulties in Emotion Regulation Scale – Short Form (DERS-SF)	18 items, 5-point Likert scale. Higher scores indicate more difficulty in ER. Total score ranges from 18 to 90. Six subscales: strategies, non-acceptance, impulse, goals, awareness, and clarity.	"I pay attention to how I feel"	α=0.89	Construct =0.96	Kaufman et al. (2016)
Psychological distress	Patient Health Questionnaire-2 (PHQ-2)	Two items, 4-point Likert scale. Higher scores indicate more severe depression symptoms. Total score ranges from zero to six, where three or above indicates depression.	"Little interest or pleasure in doing things"	α=0.84	Criterion =0.93	Kroenke et al. (2003)
	Generalised Anxiety Disorder-2 (GAD-2)	Two items, 4-point Likert scale. Higher scores indicate more severe generalised anxiety symptoms. Total score ranges from zero to six, where three or above indicates anxiety.	"Feeling nervous, anxious, or on edge"	α=0.82	Construct =0.93	Kroenke et al. (2007)

The pre- and post-intervention measures (Table 3) assessed therapeutic processes and clinical outcomes. The measures included the ER skills underpinning Betwixt (cognitive reappraisal and self-compassion), psychological distress, and functioning (to ascertain the impact of Betwixt on daily life). All measures had appropriate psychometric properties, and the participants did not complete measures at the mid-point to decrease burdensomeness and attrition.

Table 3

Pre- and Post-Intervention Measures

Construct	Measure	Scoring	Example item	Reliability	Validity	Reference
Cognitive reappraisal	Cognitive Emotion Regulation Questionnaire – Short (CERQ-short)	18 items, 5-point Likert scale. Higher scores indicate greater use of cognitive reappraisal strategies. Total score ranges from 18 to 90. Nine subscales: self-blame, other-blame, rumination, catastrophising, putting into perspective, positive refocusing, positive reappraisal, acceptance, and refocus.	"I am preoccupied with what I think and feel about what I have experienced"	α=0.77	Construct =0.96	Garnefski et al. (2001)
Self-compassion	Self-Compassion Scale – Short Form (SCS-SF)	12 items, 5-point Likert scale. Higher scores indicate higher levels of self-compassion. Total score ranges from 12 to 60. Two subscales: self-disparagement, and self-care.	"I try to see my failings as part of the human condition"	α=0.87	Construct =0.90	Raes et al. (2011)
Psychological distress	Patient Health Questionnaire-9 (PHQ-9)	Nine items, 4-point Likert scale. Higher scores indicate more severe depression symptoms. Total score ranges from zero to 27, where ten or above indicates depression.	"Little interest or pleasure in doing things"	α=0.89	Criterion =0.93	Kroenke et al. (2001)
	Generalised Anxiety Disorder-7 (GAD-7)	Seven items, 4-point Likert scale. Higher scores indicate more severe generalised anxiety symptoms. Total score ranges from zero to 21, where eight or above indicates anxiety.	"Feeling nervous, anxious, or on edge"	α=0.92	Construct =0.97	Spitzer et al. (2006)

Construct	Measure	Scoring	Example item	Reliability	Validity	Reference
Psychological distress continued	Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS)	Seven items, 5-point Likert scale. Higher scores indicate better mental wellbeing. Total score ranges from seven to 35, where 20 indicates probable clinical depression.	“I’ve been feeling optimistic about the future”	α=0.84	Construct =0.95	Stewart-Brown et al. (2009)
Functioning	Work and Social Adjustment Scale (WSAS)	Five items, 9-point Likert scale. Higher scores indicate greater impairment in work and social adjustment. Total scores range from zero to 40, where 10 indicates impairment in functioning. Participants did not complete this measure if they did not have a job for reasons unrelated to their mental health.	“Because of my [problem] my ability to work is impaired”	α=0.82	Construct =0.97	Mundt et al. (2002)

Procedure[17]

Baseline Phase. Following recruitment, participants completed the pre-intervention measures (outlined in Table 3) via QuestionPro, an online survey and data collection platform. The baseline phase (A phase) duration was either two or three weeks, to decrease the threats to internal validity of participants having the same baseline phase duration (Barlow et al., 2009). Baseline phase duration was allocated based upon consent form completion, whereby odd-numbered participants were allocated to two weeks, and even-numbered participants were allocated to three weeks. During the baseline phase, participants were asked to complete the SCED series measures (outlined in Table 2) on every second day. This is in keeping with Kratochwill et al.'s (2010) recommendation that the minimum number of data points required for a baseline phase is three-to-twelve (modal number of three-to-four).

Treatment Phase. The treatment phase (B phase) duration was four weeks. During this phase, participants engaged in a chapter on Betwixt and completed SCED series measures every second day. Throughout the baseline and treatment phases, participants had weekly check-in phone calls with the researcher to troubleshoot technical issues, overcome obstacles, and as a cue to engage with Betwixt. Check-in calls can increase compliance (Patel et al., 2020); hence, it was acknowledged that these could influence Betwixt-specific change processes, as the participants were interacting with the researcher and the intervention was guided self-help, as opposed to self-directed. Hence, each call was documented to ensure that the support provided was practical (as opposed to psychotherapy), and the calls were discussed in the interviews to deduce their impact on the participants. The average length of the calls was three minutes. The research team requested app usage data from Betwixt, as an observation for understanding levels of engagement. When participants were not using Betwixt every other day, this was discussed in the weekly check-in calls, to support engagement. At the end of the treatment phase, participants completed the post-intervention measures.

[17]Please refer to extended paper section 4.2.8 for additional information about the study procedure.

Interview. At the end of the treatment phase, participants were invited to an interview with an independent interviewer. Five participants completed an interview, and the average length was 28 minutes. Participant three chose to complete a survey only, and participant one did not complete either. After completing the study, participants were emailed a debrief form[18] and a £15 Amazon voucher as appreciation for their participation. Each participant was then due to start their intervention with the NHS Talking Therapies team.

Analysis

To analyse[19] the effectiveness of Betwixt on ER, cognitive reappraisal, and self-compassion (aim A), structured visual analysis (Kratochwill et al., 2010) of the SCED time-series data was undertaken. This entailed analysing changes between the phases, and it included analysing stability, phase contrast, immediacy, and overlap of the data (Wolfe et al., 2019). Kendall's Tau-U, a non-parametric statistic suited to short data-series, was then calculated to quantify phase contrasts. To examine changes in pre- and post-intervention measures, Reliable and Clinically Significant Change (RCSC) analysis (Jacobson and Truax, 1991) was completed. These analyses enabled comparisons of pre- and post-intervention scores for each individual, regarding statistical robustness (whether there were changes beyond chance or error variability) and clinical meaningfulness (whether reliable changes represented improved functioning).

To analyse whether changes in processes targeted by Betwixt resulted in improvements in clinical outcomes (aim B), Simulation Modelling Analysis (SMA) was completed (Borckardt & Nash, 2014). SMA is a time-series analysis programme which enables analysis of temporal relationships between pairs of variables over the course of the SCED (for example, whether changes in ER scores precede changes in psychological distress). SMA accounts for autocorrelation over time and can identify the temporal precedence within paired process and outcome variables using cross-lagged correlations.

[18]Please refer to Appendix 5.11 for the participant debrief form.
[19]Please refer to extended paper sections 4.2.9 and 4.2.10 for additional information about the analysis rationale.

To analyse the acceptability and theoretical components of Betwixt within a clinical context (aim C), and to further explore effects and change processes (aims A and B), Gale et al.'s (2013) Framework Method (FM) was used. FM was chosen to analyse the interview and survey data as it was designed to analyse qualitative data in multi-disciplinary health research. FM includes the stages of transcription, familiarisation, coding, developing a framework, charting data into the matrix, and interpretation (Gale et al., 2013), which were used to analyse this data. FM can be deductive (using existing theory), inductive (creating a new theory), or in combination (Trochim, 1999). In this research, FM was in combination, as existing ER (e.g., Gross, 1998) and acceptability theory (Sekhon et al., 2017) were used, and the participants brought new inductive aspects. No themes were chosen in advance of the analysis.

3.3 Results

Attrition and Adherence

Ten participants were recruited to the study, with seven completing all phases (70%). Of the three who withdrew, none entered the treatment phase. Among the seven completers, adherence varied. Participant one did not complete the post-intervention measures, interview, or survey; however, she had used Betwixt consistently according to app data, and she had provided seven data points for her treatment phase. Participant three only engaged with the app twice during her treatment phase, though she completed her measures on every second day, hence, her data was considered a comparison for an individual on a waiting list. She also chose to complete a survey, as opposed to an interview. Participant four only used Betwixt and completed surveys on three occasions in her treatment phase, though this was deemed sufficient. Participants two, five, six, and seven overall completed the treatment phase as directed. All seven completers provided sufficient data for SCED analysis, meeting the recommended minimum number of datapoints (Kratochwill et al., 2010).

Quantitative Results (SCED, RCSC, and SMA): Aims A and B

For the SCED analysis[20], Table 4 outlines the Tau-U data comparing the baseline and treatment phases for each participant on the SCED measures. Overall, there were seven significant differences between phases, for five of the participants. This included five improvements and two deteriorations (for participants three and six). Graphs (Figures 1, 2, 3, 4, and 5) have been provided when significant SCED results were found, to support interpretation of the results.

Table 4

Tau-U Analysis Comparing Baseline and Treatment Phases for the SCED Series Measures

Participant	DERS-SF (ER)		PHQ-2 (low mood)		GAD-2 (anxiety)	
	Tau-U	*p* value	Tau-U	*p* value	Tau-U	*p* value
1	-0.143	0.655	0.000	1.000	0.020	0.949
2	-0.625	0.013*	0.358	0.156	0.292	0.249
3	0.364	0.205	0.584	0.042*	0.143	0.618
4	-0.222	0.606	0.111	0.796	-0.333	0.439
5	-0.213	0.450	-0.938	0.001*	-1.000	0.000*
6	0.604	0.029*	0.000	1.000	0.000	1.000
7	0.702†	0.000*	-0.871	0.000*	-0.286	0.242

*p<0.05

†The baseline was not stable, and a baseline correction was required

For the RCSC analysis[21], participant one did not complete the post-intervention measures, hence, her RCSC could not be calculated. Table 5 outlines the RCSC scores, and all participants had at least one significant reliable or clinical change. There were 27 reliable improvements: eight in ER subscales (DERS-SF), three in cognitive reappraisal subscales (CERQ-short), two in self-compassion (SCS-SF), three in low mood (PHQ-9), four in anxiety (GAD-7), four in mental wellbeing (SWEMWBS), and three in functioning (WSAS). There

[20]Please refer to extended paper section 4.3.1 for additional SCED data.
[21]Please refer to extended paper section 4.3.2 for additional RCSC data.

were nine clinical improvements: two in low mood (PHQ-9), four in anxiety (GAD-7), and three in mental wellbeing (SWEMWBS). There were two reliable deteriorations in ER subscales (DERS-SF).

Table 5

Reliable and Clinically Significant Change Analysis of Pre- and Post-Intervention Measures

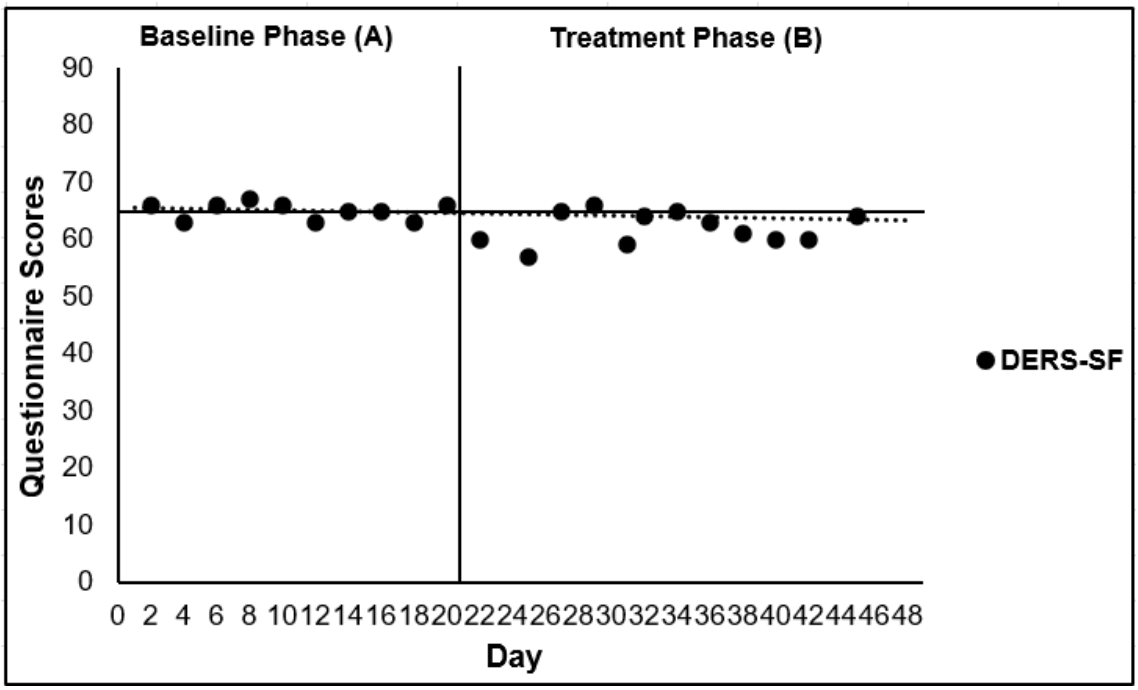
Measure	Reliable improvement (%)	Clinically significant improvement (%)	Reliable deterioration (%)
DERS-SF (ER)	22	N/A	6
CERQ-short (cognitive reappraisal)	13	N/A	0
SCS-SF (self-compassion)	33	N/A	0
PHQ-9 (low mood)	50	33	0
GAD-7 (anxiety)	67	67	0
SWEMWBS (mental wellbeing)	67	50	0
WSAS (functioning)	75	0	0

Participant One (Kirsty). Kirsty's scores on the Tau-U (Table 4) and her structured visual analysis indicated that she did not have any significant differences between her baseline and treatment scores of ER (DERS-SF), depression (PHQ-2), or anxiety (GAD-2). It is worth noting that her PHQ-2 Tau-U statistic was not estimable, due to a constant in her treatment phase data. Kirsty did not complete the post-intervention measures, hence, RCSC could not be completed. Kirsty's overall profile indicates no benefit or detriment of Betwixt.

Participant Two (Christine). Christine's scores on the Tau-U (Table 4) indicated a significant improvement in ER (DERS-SF), but non-significant results in low mood (PHQ-2) and anxiety (GAD-2). Her structured visual analysis of ER (Figure 1) indicated limited differences on stability, phase contrast, immediacy, and overlap of data. Her RCSC analysis had one significant reliable improvement in functioning (WSAS). Christine's overall profile indicates benefits of Betwixt for improving ER and functioning.

Figure 1

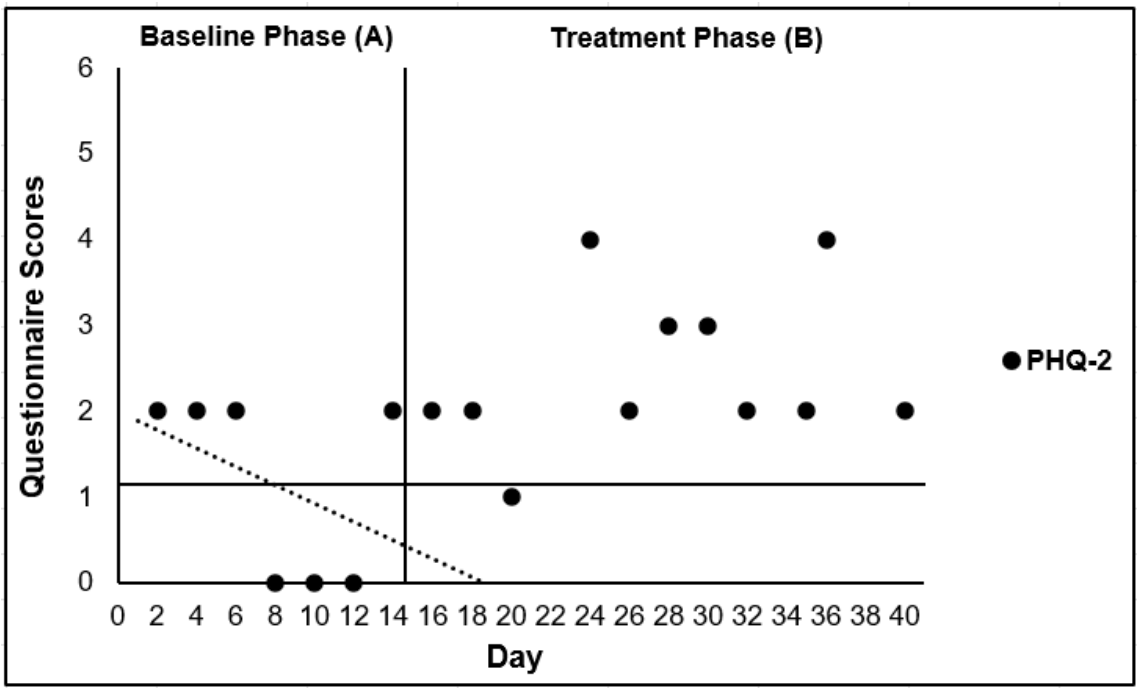
SCED Graph for Participant Two's PHQ-2 Measure



Participant Three (Lynne). Lynne only used Betwixt on two occasions; hence, she was deemed a comparison for an individual on a waiting list. Her Tau-U scores (Table 4) indicated non-significant results in ER (DERS-SF) and anxiety (GAD-2). Her Tau-U score in low mood (PHQ-2) indicated a significant deterioration between her baseline and treatment phases. The structured visual analysis (Figure 2) demonstrated stability, phase contrast, some immediacy, and limited overlap of data. In the RCSC, Lynne had seven significant improvements, including reliable improvement in five ER (DERS-SF) strategies and a reliable and clinically significant improvement in anxiety (GAD-7). Lynne's overall profile highlights enhancing ER, though variability in psychological distress (PHQ-2 and GAD-7), with two doses of Betwixt.

Figure 2

SCED Graph for Participant Three's PHQ-2 Measure



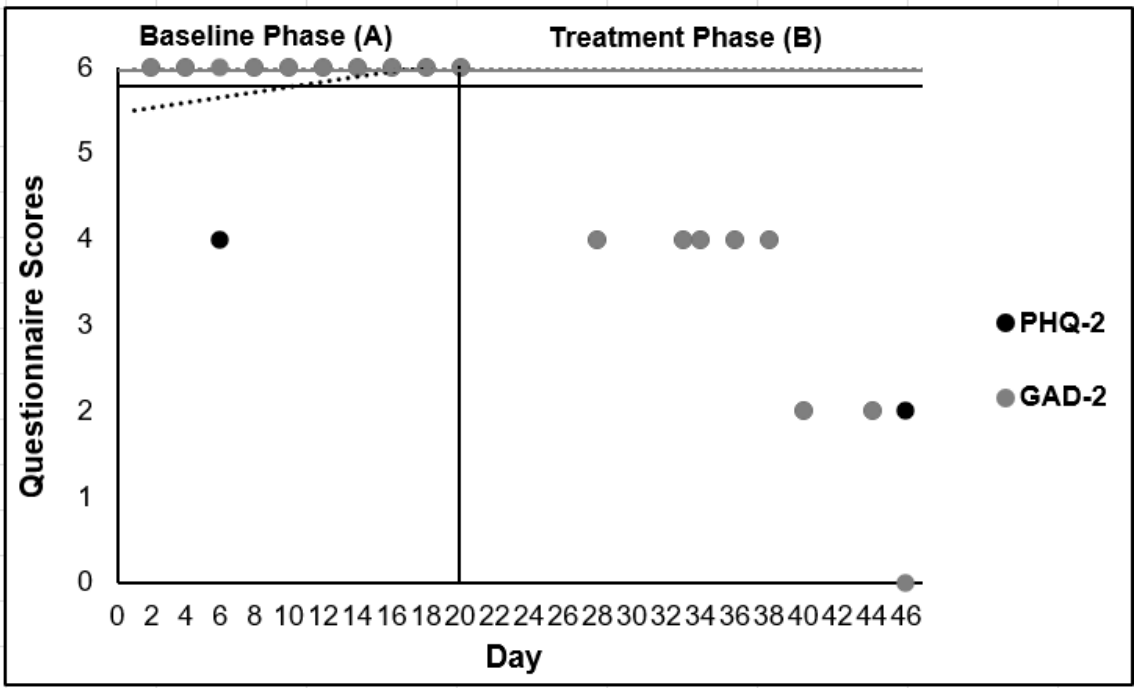
Participant Four (Sarah). Sarah's scores on the Tau-U (Table 4) and her structured visual analysis indicated non-significant results in ER (DERS-SF), low mood (PHQ-2) and anxiety (GAD-2). The RCSC analysis demonstrated that she had seven improvements, including reliable improvements in self-compassion (SCS-SF), low mood (PHQ-9), anxiety (GAD-7), mental wellbeing (SWEMWBS), and functioning (WSAS), as well as clinical improvements in anxiety (GAD-7) and mental wellbeing (SWEMWBS). Sarah's overall profile indicates substantial benefits of Betwixt for reducing distress, and enhancing self-compassion, and functioning.

Participant Five (Sharon). Sharon's scores on the Tau-U (Table 4) indicated significant improvements in low mood (PHQ-2) and anxiety (GAD-2), though no significant change in ER (DERS-SF). The structured visual analysis (Figure 3) on the PHQ-2 and GAD-2 demonstrated stability, phase contrast, immediacy, and limited overlap of data. In the RCSC analysis, Sharon had thirteen significant changes, including nine reliable improvements: in ER strategies (DERS-SF), cognitive reappraisal strategies (CERQ-short), low mood

(PHQ-9), anxiety (GAD-7), mental wellbeing (SWEMWBS), and functioning (WSAS). She also had three clinically significant improvements in low mood (PHQ-9), anxiety (GAD-7), and mental wellbeing (SWEMWBS), as well as one reliable deterioration in an ER strategy (DERS-SF). Sharon's overall profile highlights substantial benefits of Betwixt for reducing distress and enhancing cognitive reappraisal and functioning, despite some variability in ER outcomes.

Figure 3

SCED Graph for Participant Five's PHQ-2 and GAD-2 Measures

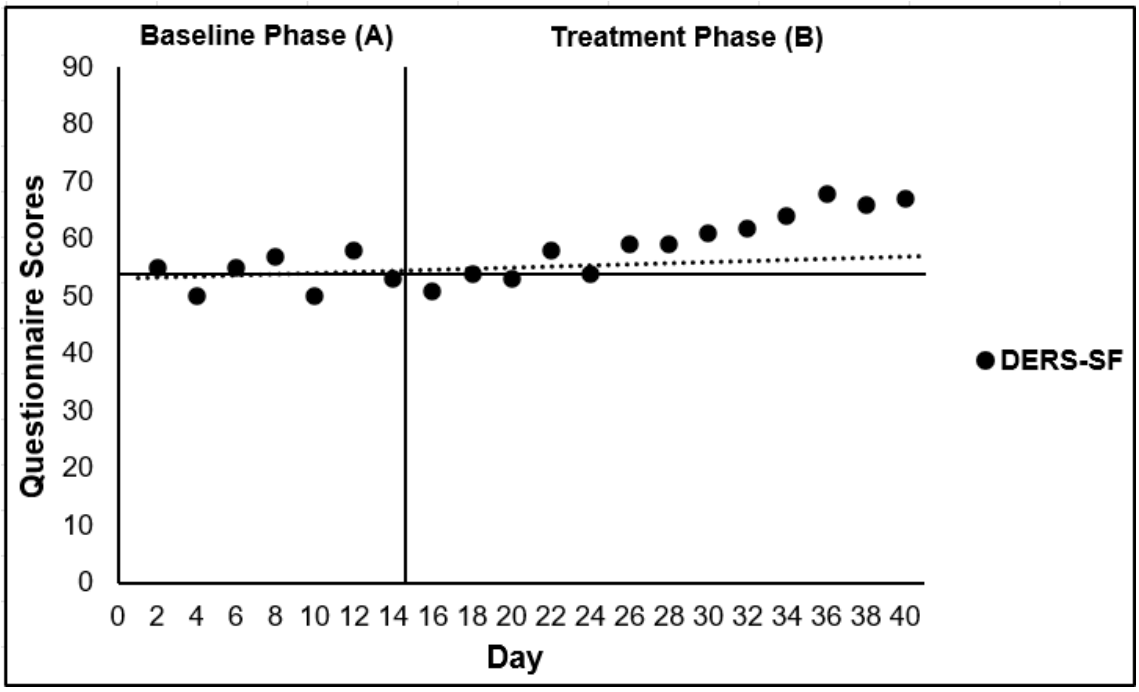


Participant Six (Lucy). Lucy's scores on the Tau-U (Table 4) indicated a significant deterioration in ER (DERS-SF), though her low mood (PHQ-2) and anxiety (GAD-2) scores were not estimable, due to a constant in her data. The structured visual analysis of ER (Figure 4) demonstrated stability, limited phase contrast, some immediacy, and limited overlap of data. Her RCSC analysis demonstrated three significant changes, including reliable improvements in self-compassion (SCS-SF) and mental wellbeing (SWEMWBS), and one reliable deterioration in an ER strategy (DERS-SF). Lucy's overall profile indicates

substantial benefits of Betwixt for enhancing self-compassion, and reductions in distress, but worse ER outcomes.

Figure 4

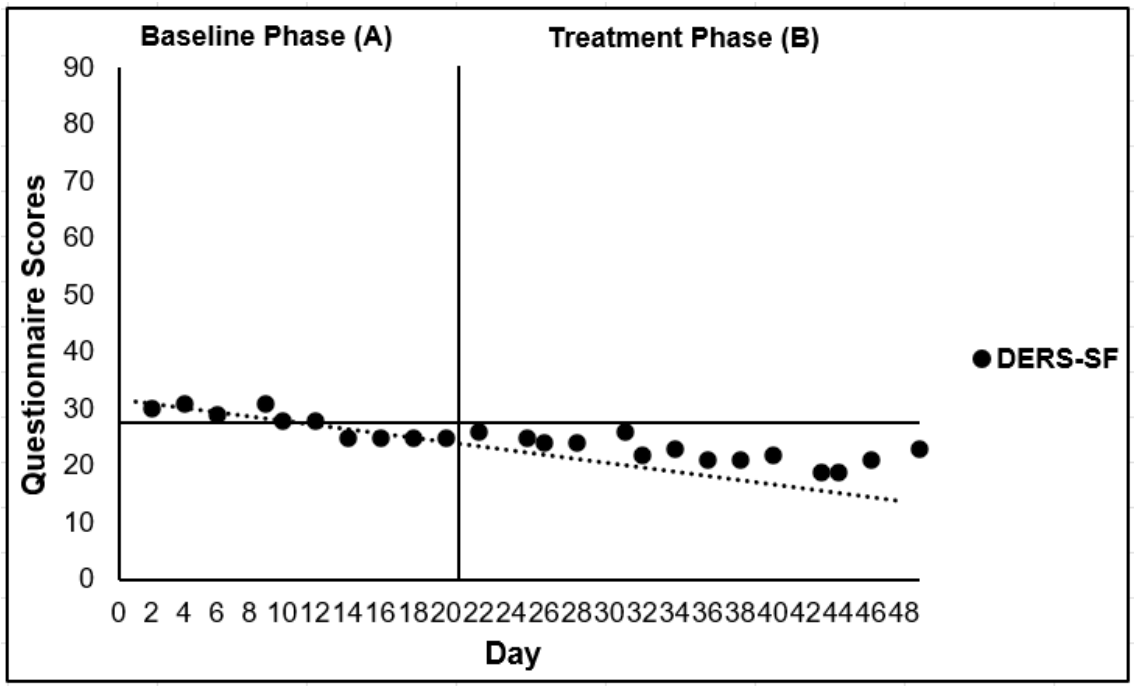
SCED Graph for Participant Six's DERS-SF Measure

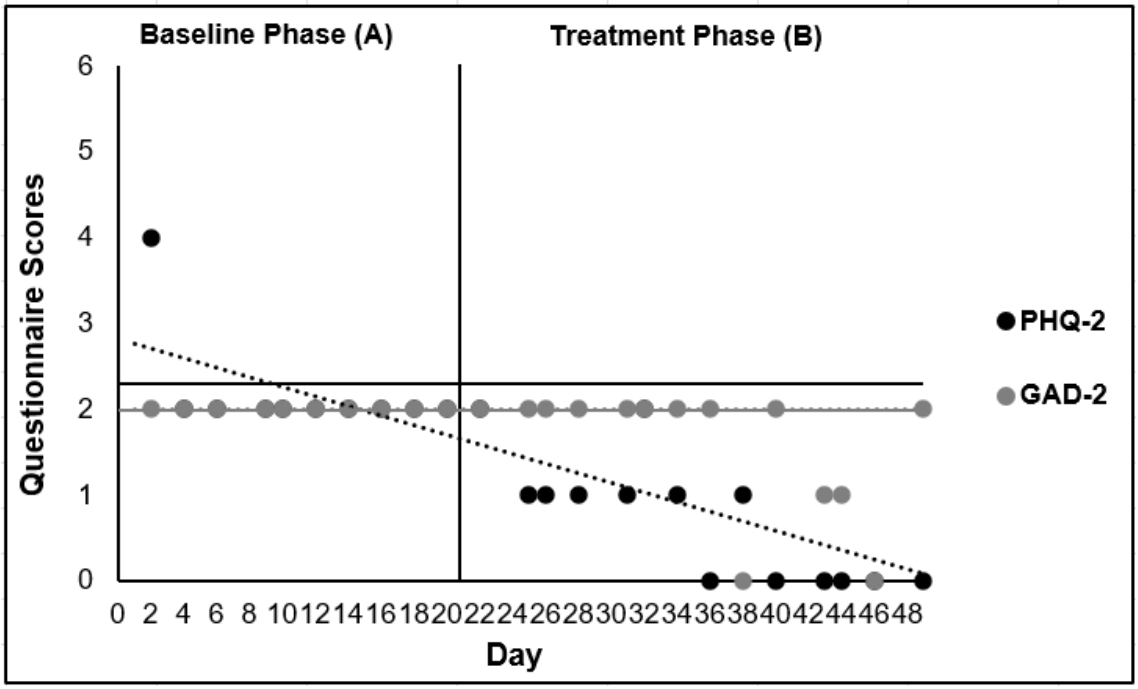


Participant Seven (Carol). Carol's scores on the Tau-U (Table 4) indicated a significant improvement between the baseline and treatment phases in ER (DERS-SF) and low mood (PHQ-2). It is worth noting that a baseline correction was required on the DERS-SF, as her baseline scores were not stable. The structured visual analysis (Figure 5) of ER and low mood demonstrated some stability, phase contrast, some immediacy, and limited overlap of data. Her RCSC analysis had seven significant improvements, including a reliable improvement on a cognitive reappraisal strategy (CERQ-short), as well as reliable and clinically significant improvements in low mood (PHQ-9), anxiety (GAD-7), and mental wellbeing (SWEMWBS). Carol's overall profile highlights substantial benefits of Betwixt for reducing distress and enhancing ER, and cognitive reappraisal.

Figure 5

SCED Graphs for Participant Seven's Measures





SMA. SMA was completed on the SCED data to ascertain the cross-correlations within participants between their ER (DERS-SF) and psychological

distress (PHQ-2 and GAD-2) scores[22]. Of the participants, three demonstrated significant levels of cross-correlations in their process and outcome measures, when adjusted using the Bonferroni correction. Participant three had significant high correlations for the PHQ-2 (r=0.69, p=0.001) and GAD-2 (r=0.61, p=0.006), indicating that her ER, low mood, and anxiety scores were predictive of each other, at the same time-point. Participant five had significant moderate correlations for the PHQ-2 (r=0.59, p=0.008) at Lag+1 and GAD-2 (r=0.59, p=0.005) at Lag-1, indicating that low mood predicted ER in the subsequent time-point and that ER predicted anxiety in the subsequent time-point. Participant seven had significant high correlations for the PHQ-2 at Lag-1 (r=0.67, p=0.01), Lag0 (r=0.77, p=0.002), and Lag+1 (r=0.74, p=0.003), indicating that ER and low mood were predictive of each other across time-points. Overall, these results were mixed, with some variables predicting others within participants, and no correlations for other participants. On average across all participants, the ER-low mood (DERSSF-PHQ2) correlation at Lag0 was 0.41 and the ER-anxiety (DERSSF-GAD2) correlation was 0.42. This demonstrated that although the individual-level significance varied, ER difficulties were generally moderately correlated with distress.

Qualitative Results (Interviews and Survey): Aims A, B, and C

Table 6 outlines the framework matrix[23], from the five interviews and one survey. The matrix includes eight themes and their associated codes, and it is worth noting that the matrix does not reference the frequency of each code. For example, one code may have been referenced by multiple participants on multiple occasions, however, another code may have been mentioned once by few participants.

Overall, the participants seemed to have mixed views of Betwixt[24]. All participants reported some positive aspects of the app, including perceived benefits, app features, and effectiveness, and all reported code 3.1: Betwixt

[22]Please refer to extended paper section 4.3.3 for additional Simulation Modelling Analysis data.
[23]Please refer to extended paper section 4.3.4 for information about reflexivity.
[24]Please refer to extended paper section 4.3.5 for additional qualitative data.

enabled them to learn and reflect on themselves. However, the participants also felt that Betwixt had opportunity costs, burdens, and disadvantages, and there were also mixed views of the study design. There were individual differences on views of Betwixt, for example, participants four, five, and six seemed to have a more positive perspective, participants two and seven had a mixed view, and participant three had a more negative opinion (it is worth noting that she used Betwixt on two occasions).

Table 6

Framework Matrix (Gale et al., 2013) from the Interviews and Survey

Code	Description	Example
Theme 1: Betwixt use has positive benefits.		
1.1 Positive and helpful	Betwixt is positive, helpful, and useful.	“As I say, if it isn't broke, don't fix it. I think it's brilliant…I don't understand why nobody thought of it before.” – Lucy
1.2 Enjoyable	Betwixt is enjoyable, interesting, and compelling.	“Well, I very much enjoyed the app.” – Sharon
1.3 Normalises difficulties	Betwixt normalises difficulties, enables one to feel understood, and instils hope for recovery.	“It helped me to see that I'm not just one person that's going through it. There are other people, and the app sort of highlights that.” – Sarah
1.4 Supports day-to-day coping	Betwixt supports with day-to-day coping and provides a foundation of support.	“For the shorter term, coping with the day-to-day, I think it'd be very useful.” – Christine
1.5 Different to other interventions	Betwixt is different to other interventions.	“I've never used anything like that before, I've normally had talking therapy, CBT, things like that.” – Sarah
1.6 Recommend to a friend	One would recommend Betwixt to a friend.	“If anybody ever says to me ‘can you recommend something?’, I would definitely recommend Betwixt.” – Lucy
Theme 2: Betwixt features enhance the experience.		
2.1 Interactive and customisable	Valuing Betwixt's interactive and customisable features.	“It gives you the option to wake up from the dream or carry on. And…I woke up, but it was still very helpful.” – Sharon
2.2 Immersive elements	Appreciating the immersive visual and audio elements of Betwixt.	“Some of the…descriptions of the way things were and so it is very descriptive, so you could picture it.” – Christine
2.3 Encourages engagement	Betwixt encourages engagement.	“It checked that you was engaging in it… so it kind of throw these questions in to know that you were using it.” – Carol
Theme 3: Perceived effectiveness of Betwixt.		
3.1 Learning and reflecting on oneself	Betwixt enables learning and reflecting on oneself.	“It made me look at what I was feeling and take stock.” – Lynne

3.2 Gaining new and more positive perspectives	Betwixt enables gaining new and more positive perspectives on oneself.	“It did help with sort of seeing things in a more positive light, and the world isn't that bad. In…the dream world, things can seem a lot worse than they are. And it relates to like day-to-day life, things can seem a lot worse than they are.” – Sarah
3.3 Prompts use of coping skills	Using Betwixt reminds one to use coping skills, such as, relaxation, grounding, and self-care.	“It's sort of like some of it was in there already…it was good as a reminder of things that I had done in the past as well in like previous CBT sessions and things like that.” – Christine
3.4 Support whilst waiting	Betwixt enables support to be accessed whilst waiting for an intervention.	“While I'm waiting for some more support but using an app rather than just sitting and waiting and not being able to do anything.” – Sarah
3.5 Escapism	Betwixt enables escapism from difficulties and relieves pressure.	“At night, when I've gone through my day, this works best to sort of bring everything together and sort of…relax you, bring you back down.” – Sharon
3.6 Love oneself	Betwixt enables loving oneself again.	“I am learning to love myself again.” – Lucy
3.7 Improve conditions	Using Betwixt improves conditions (for example, anxiety and chronic pain).	“But I can deal with anxiety a lot better, it still happens, but it's…I have these mechanisms in place now.” – Lucy
3.8 Challenging yet helpful	Some dreams in Betwixt are challenging, yet helpful.	“You know, even the bits that were difficult, were still positive.” – Lucy
3.9 Not effective	Betwixt is not effective.	“I’m afraid it didn’t help me much.” – Lynne
3.10 Other factors impacted	Other factors outside of Betwixt have also impacted upon changes in life.	“There's a lot of aspects of my life that have improved… which includes using the app. So, the app’s helped me, but then other things have probably contributed.” – Sharon
Theme 4: Ethicality, self-efficacy, and Betwixt use.		
4.1 Aligns with values	Betwixt aligns with what is important and values.	“So yeah, in that way, it does align with the way that I think.” – Lucy
4.2 Does not align with values	Betwixt does not align with what is important and values.	“Not really [aligns with values].” – Carol
4.3 Compassion value	Betwixt has a value of compassion.	“I don't have a lot of compassion for myself, I don't like myself very much. And so, it did make me think, ‘well, why don't you? These other people do, you should too’.” – Lucy
4.4 Caring value	Betwixt has a value of caring.	“The caring…bit, I keep bringing it up, but the caring bit is a very important bit to me.” – Sharon

4.5 Continue use	One can or will continue to use Betwixt.	“Oh yes, yeah I will carry on using it.” – Sarah
4.6 Not continue use	One will not continue to use Betwixt.	“No, I won’t continue to use it.” – Lynne
Theme 5: Opportunity costs and effort of Betwixt.		
5.1 Time can be made	Time can be made to use Betwixt.	“It's fitted in really well…it's always fitted in really well.” – Lucy
5.2 Requires time	Using Betwixt requires substantial time.	“You do need to make sure you have time away; you are in a position where you can engage fully with it for the amount of time, because it is very in-depth to be reading all that information.” – Christine
5.3 Priorities can impede	Other priorities can impede Betwixt use.	“I don't know if it is because, you know, I am older and I have got like family issues, I've got like work issues, things like that.” – Christine
5.4 Requires motivation and concentration	Betwixt requires motivation and concentration.	“I don't really have that motivation to do it.” – Sarah
5.5 Requires minimal effort	Betwixt requires minimal effort.	“But I would say on the whole, not a huge effort.” – Lucy
5.6 Requires some effort	Betwixt requires some effort.	“But…it does need…some effort.” – Christine
5.7 Effort is worthwhile	The effort required for Betwixt is worthwhile.	“And it's definitely been worth it, definitely.” – Lucy
5.8 Effort is not worthwhile	The effort required for Betwixt is not worthwhile.	“No, it wasn’t worthwhile.” – Lynne
Theme 6: Burdens, disadvantages, and improvements of Betwixt.		
6.1 Reading and complex language	Betwixt entails a significant amount of reading and the language can be complex.	“And it was a lot of reading to take in.” – Christine
6.2 Accessibility	The accessibility of Betwixt could be improved, for example, the font and visual appeal.	“My only issue was maybe the…way it was set. I didn't mind the sort of colours, but you know, just…the continuous sort of text thing…yeah, that broken up a bit.” – Sharon

6.3 Not for everyone	Betwixt is not suited to everyone.	“It is for like maybe more of an anxiety issue maybe…not huge issues, just like smaller.” – Christine
6.4 Technology of Betwixt	One was not keen on the technology of Betwixt.	“I'm not into AI, I'm not into technology, but that's me and my generation, that's where I am in my life.” – Carol
Theme 7: Impact of Betwixt on its theoretical components.		
7.1 Improves cognitive reappraisal	Betwixt use somewhat improves cognitive reappraisal.	“The app has definitely helped [ability to respond to stressful situations]; the app has definitely helped.” – Sharon
7.2 Cognitive reappraisal is still difficult	Cognitive reappraisal is still somewhat difficult following Betwixt use.	“But also, that [responding to stressful situations] is still something that I really struggle with.” – Sarah
7.3 Increases self-compassion	Betwixt use somewhat improves self-compassion.	“I was very down on myself before, very focused on my sort of negative feelings. Whereas…as it stands today, I don't feel negative about myself at all.” – Sharon
7.4 Self-compassion is still difficult	Self-compassion is still somewhat difficult following Betwixt use.	“It didn’t make me kinder to myself.” – Lynne
Theme 8: Views of study design and check-in calls[25].		
8.1 Study helpful and enjoyable	Engaging in the study and surveys was helpful and enjoyable.	“I found the surveys helped me more as I was taking stock of how I felt.” – Lynne
8.2 Study design improvements	There were improvements to the study design, for example, using Betwixt less frequently or a follow-up condition.	“More research…a follow-up. If I was to engage in that again and do like another part of it, how I would feel on the other side.” – Carol
8.3 Measures repetitive	Completing the measures was repetitive and they were close together.	“Because it was the same questions every couple of days, that was being repetitive.” – Christine
8.4 Check-in calls positive	The weekly check-in calls were positive and prompted Betwixt use.	“I really liked them, because it just made you like know that there was someone else there.” – Sarah
8.5 Check-in call difficulties	There were difficulties with the check-in calls, for example, being available and not having anything to discuss.	“If I'm out and about, because of the time-frame of the call that would come in, it's not known if it was [researcher] or if you're getting a spam call or something.” – Carol

[25]Please refer to extended paper section 4.3.6 for check-in call data.

Theme 1: Positive Benefits. Theme one was a deductive theme about the perceived benefits of Betwixt, such as, it being positive, enjoyable, and normalising. Five of the six participants had codes about Betwixt being positive (code 1.1), and overall, five of the six participants reported any positive benefits to using Betwixt.

Theme 2: Features Enhance Experience. Theme two was an inductive theme about app features, which the participants perceived positively. This was not asked about specifically in the interview topic guide, and these codes tended to occur when the participants were asked about affective attitude and perceived effectiveness. The codes referred to interactivity, immersion, and engagement.

Theme 3: Perceived Effectiveness. Theme three was a deductive theme about the participants' views on the effectiveness of Betwixt. Code 3.1 was the only code in the matrix which all participants reported, and this referred to Betwixt enabling them to reflect on themselves. Most of theme three was positive, as participants discussed Betwixt enabling them to gain perspective and use coping skills, for example. Some positive and unexpected outcomes of using the app were reported, such as, loving oneself (3.6), and improving anxiety or decreasing chronic pain (3.7). There were codes about some aspects of Betwixt being challenging though helpful (3.8), not feeling effective (3.9), and other factors impacting the changes observed (3.10). It is worth noting that these latter codes were reported by either one or two participants each.

Theme 4: Ethicality and Self-efficacy. Theme four was a deductive theme about ethicality and self-efficacy with Betwixt. The results were somewhat mixed and dialectical as three participants felt that Betwixt aligned with what was important to them, however, one did not. One participant had codes about Betwixt having a compassion value and another participant had a code about Betwixt having a caring value. Five of the six participants reported feeling able to continue to use Betwixt, though two participants discussed not wanting to continue to use Betwixt.

Theme 5: Opportunity Costs. Theme five was a deductive theme about the opportunity costs and effort of Betwixt. There were mixed and dialectical

views, for example, some participants felt that time could be made to use Betwixt (code 5.1), others felt it required substantial time to use (5.2), and some felt that other priorities impeded its use (5.3). In addition, some of the participants felt that Betwixt required minimal effort (5.5), whereas some felt that it required some effort (5.6). Three of the participants felt that this effort was worthwhile (5.7), however, one felt that it was not (5.8). Five of the participants reported that using Betwixt requires motivation and concentration (5.4).

Theme 6: Burdens, Disadvantages, and Improvements. Theme six was a deductive theme referring to the burdens, disadvantages, and improvements of Betwixt. It is worth noting that some of the codes were reported by one participant each. There were codes about the reading required, accessibility, Betwixt not being appropriate for everyone, and technology.

Theme 7: Theoretical Components. Theme seven was deductive and referred to the impact of Betwixt on the participants' cognitive reappraisal and self-compassion. The results were mixed and dialectical as some participants felt that Betwixt had improved their cognitive reappraisal or self-compassion, and some reported that these were still difficult.

Theme 8: Study Design. Theme eight was a deductive theme and referred to the study design. Codes about the study design were mixed as three participants reported that the study was helpful, and two participants felt that improvements may have been useful. Regarding the measures, some felt that they helped them, however, others felt that they were repetitive or too frequent. Participants appeared to have positive views about the check-in calls as five of the participants reported that they were positive (code 8.4). Participants also reported that the check-in calls were reassuring, prompted app use, and troubleshooted issues. Some felt that it was difficult to be available for the calls, there was little to discuss, and they had difficulties with the calls being from a private number.

Integration of Quantitative and Qualitative Results

Overall, the participants had differing views of Betwixt, though they all had at least one improvement on the quantitative measures. Participant two (Christine) appeared to hold mixed views about Betwixt, and she had improvements in ER and functioning, following Betwixt use. Participant three (Lynne) held a more negative view of Betwixt (and only used it twice), and she had improvements in ER, though variability in psychological distress. It is worth noting that she only accessed Betwixt twice, and her results can be used as a comparison for an individual on a waiting list. Participant four (Sarah) had a more positive view of Betwixt and she had improvements in distress, cognitive reappraisal, self-compassion, and functioning. Participant five (Sharon) appeared to hold a positive view of Betwixt and she had improvements in distress and functioning, though she also had variability in her ER outcomes (including a significant deterioration). Participant six (Lucy) provided positive feedback and had improvements in self-compassion, though she had deteriorations in ER. Participant seven (Carol) provided mixed feedback on Betwixt, yet she had improvements in distress, ER, and cognitive reappraisal. Hence, there were differing views of Betwixt between participants, and differing effectiveness.

3.4 Discussion

Summary of Findings and Relationship to Existing Literature

This study investigated the effectiveness, acceptability, and clinical utility of Betwixt, a narrative-based ER gaming app, for individuals with depression and anxiety disorders. Findings provide preliminary evidence[26] supporting its feasibility as a digital intervention, though results also highlight variability in outcomes and user experience. In this section, the findings are considered in relation to the study aims, previous literature, potential clinical implications, and future research.

Aim A was to evaluate the effectiveness of Betwixt on ER, cognitive reappraisal, and self-compassion. While the results showed that Betwixt can lead to reliable

[26]Please refer to extended paper section 4.4.1 for information about the original contribution to knowledge.

improvements in ER, cognitive reappraisal, and self-compassion for some participants, others demonstrated a deterioration or no change in ER. This variability may reflect differences in baseline ER skills, engagement with the app, adaptability of the narrative structure to individual needs, or perhaps other factors. The mixed findings were consistent with previous studies[27] indicating that app-based interventions may show differential effectiveness across populations (Rowland et al., 2020). Future refinements in app design could explore scope for greater personalisation, tailoring features to individual profiles to optimise outcomes (Jadhakhan et al., 2022).

Aim B was to investigate whether changes in processes targeted by Betwixt resulted in improvements in clinical outcomes. There were encouraging results from the SMA, RCSC, and interviews that Betwixt improved clinical outcomes. These results were consistent with previous findings that ER apps having "promising outcomes", and may improve psychological distress (Eisenstadt et al., 2021; Harper et al., 2025). They were also consistent with previous research on Betwixt, that the app is perceived to be acceptable and improves clinical outcomes, though in a clinical population (Dermendzhiyska et al., 2025; Masselink & Scholten, 2025). Hence, upon further evaluation, individuals could be directed to Betwixt. This could be invaluable as an intervention as it could be accessed by many people, potentially resulting in a larger impact on public health than an intervention with a large effect size that is only available to few people (Prochaska et al., 2019).

Aim C was to explore the acceptability, and theoretical components of Betwixt (cognitive reappraisal and self-compassion). The participants appeared to have mixed views of Betwixt overall and the theoretical components of the app. The participants did not appear to find Betwixt unacceptable, which is in keeping with the findings that mHealth is an acceptable method of delivering mental health support (Teachman et al., 2022), and most individuals had positive views of Betwixt (Dermendzhiyska et al., 2025). However, Betwixt was not deemed to be acceptable by all participants, which is consistent with the finding that mHealth apps are generally viewed positively, though various factors can affect

[27]Please refer to extended paper section 4.4.2 for additional information about the relationship to existing literature.

perceptions (Chan & Honey, 2022). Hence, once Betwixt has been further evaluated, it could be offered to patients alongside other apps, to enable them to choose the type of app best suited to their specific needs.

This research was also consistent with initiatives within the NHS toward digital interventions and preventing worsening outcomes whilst waiting (Streeting, 2024; Van Dijk et al., 2023). One of the participants only used Betwixt twice and had worsening of some symptoms, hence, providing waiting list interventions may support the prevention of deterioration. Though two other participants who used Betwixt consistently also had worsening of some symptoms. Previous research has demonstrated that numerous apps purport to be theory-based and to improve mental health, though few are evaluated (Marshall et al., 2019). Betwixt has now been evaluated in this study and others (Dermendzhiyska et al., 2025; Masselink & Scholten, 2025), and it has demonstrated promise for clinical utility.

Clinical Practice Implications

The results of this study demonstrate that Betwixt has promise for clinical applications[28], and it was not deemed to be unsafe or iatrogenic, as the participants did not report any harmful or dangerous aspects to the app in their check-in calls or interviews. They reported some aspects that they did not like, however, they did not designate these as unsafe. Though it is worth noting that information on adverse events was not routinely collected as part of the SCED design. The majority of individuals on waiting lists for talking therapies can experience a deterioration (Rethink Mental Illness, 2024), hence, the significant improvements were deemed encouraging. Hence, upon further evaluation patients could be directed to this app. The design of this study could also be replicated to undertake initial research of apps which have not previously been evaluated, to obtain quality information about the impact of such interventions.

Another application may be in the use of check-in calls, as it has previously been found that any human contact during an intervention can increase

[28]Please refer to extended paper section 4.4.3 for additional information about clinical practice implications.

engagement (Patel et al., 2020). Most of the participants in the current study had a positive view of the check-in calls, hence, the scaffolding of these calls could be implemented in an NHS service, as guided self-help. This could support engagement and troubleshoot technical difficulties, and there could also be a protocol whereby if an individual does not engage with an app for a certain period, a clinician could contact them to support engagement.

The SMA results suggest that ER and psychological distress are correlated, which reinforces the assumptions of this study (ER is transdiagnostic). It also provides a promising direction for future interventions as individuals could use strategies to train their ER, given that it would be difficult to train low mood or anxiety in this manner. Hence, targeting ER in an intervention could be an indirect route of improving low mood or anxiety.

Future Research

As previous research has found that robust research is required before apps can be clinically recommended (Badesha et al., 2022), future research[29] may include a large-scale study. This may involve a randomised controlled trial into the effectiveness of Betwixt in a clinical population, as the current study indicates the feasibility of such a study. Also, few studies of apps include long-term follow-up (Badesha et al., 2022), and one of the participants of this study discussed the potential value of a follow-up condition (code 8.2). Hence, a longer-term study of Betwixt or a follow-up condition could provide further information about the impact of the intervention on individuals beyond this study time-frame. An alternative may be to evaluate whether engaging with Betwixt whilst on a waiting list supports later therapy, or if the app and individual therapy could be integrated. This study focused upon individuals with depression and anxiety disorders and future research may involve a study into the effectiveness and acceptability of Betwixt for individuals with more severe mental health conditions.

[29]Please refer to extended paper section 4.4.4 for additional information about future research.

Study Limitations

The current study had a few limitations, for example, all the final participants were female, hence, the results may not be representative of NHS Talking Therapies patients, or generalisable to individuals who are not female. In addition, the design of the study could have perhaps been improved (for example, including a phase with a different intervention as a comparator), though there were no specific concerns about statistical robustness, and doing so would likely have required more time and resources. Also, the questionnaires were dependent upon self-report, which can be subjective and susceptible to bias (Tarescavage, 2022). It may have been beneficial to have included observer-rated data, to compare to the self-rated data.

Some participants reported that other factors had also impacted the changes observed during the study. Hence, the participants may have been affected by a variety of factors including demand characteristics or social norms, which could have impacted their responses to the questions, though this would likely also be true of alternative designs. When the study was designed, it was acknowledged that check-in calls could have complicated understanding of Betwixt-specific change processes, as the participants were interacting with the researcher. Hence, check-in calls were documented, participants were asked about their experiences of them during interviews, and the calls were brief (average length of three minutes).

3.5 Conclusion

This study indicates the feasibility, acceptability, and effectiveness of a narrative-based ER gaming app for individuals with depression or anxiety disorders. Upon further evaluation, Betwixt could be a promising form of intervention for individuals awaiting psychological therapies.[30] [31]

Word count for journal paper (excluding abstract, reference list, tables, and figures): 6,552/8,000

[30]Please refer to extended paper section 4.4.5 for appraisal and evaluation of this study.
[31]Please refer to extended paper section 4.4.6 for a critical reflection on the study process.

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4. Extended Paper

4.1 Extended Background

4.1.1 History of mHealth and NHS Recommended Apps

mHealth is an abbreviation of ‘mobile health’ and it is a sub-section of the field of eHealth (‘electronic health’), which uses digital technology, such as, computers, mobile phones, and satellite communications, in healthcare services (Vital Wave Consulting, 2011). Istepanian and Lacal (2003) coined the term ‘mHealth’ and proposed using mobile technology to improve access to healthcare. Since its inception, the field and research interest of mHealth has grown exponentially (Fiordelli et al., 2013). 117 articles on mHealth were published between 2002 and 2012, most of which were published in the second half of this period, with a significant increase between 2007 and 2008 (Fiordelli et al., 2013). Most of these studies involved delivering interventions via text messaging, and few used the medium of apps (Fiordelli et al., 2013). A systematic review of systematic reviews of mHealth found 23 review articles, covering 10,689 articles, and 79,665 patients (Marcolino et al., 2018). Though a variety of interventions were found, most of the articles investigated text messaging interventions. Numerous conditions were targeted by the interventions, including chronic diseases, asthma, cardio-pulmonary disease, heart failure, diabetes, hypertension, obesity, tuberculosis, and human immunodeficiency virus. They concluded that there was increased interest in the field of mHealth, however, the evidence for its efficacy was limited and the quality of studies reviewed was low.

Within the field of mHealth, some interventions are delivered via smartphone apps, utilising the ubiquity of smartphone ownership. A systematic review of mHealth apps identified that the advancement of mobile technologies has had a significant impact on healthcare systems (Jusoh, 2017). They identified a plethora of mHealth apps available; however, few had been rigorously evaluated, and they found more published software available than scientific research investigating them. They also identified that many mHealth apps lack grounded theory, and that involving healthcare stakeholders is crucial. A

systematic review of mHealth app quality found disparity between how the quality of different apps was assessed (Rowland et al., 2020).

Badesha et al. (2022) undertook an umbrella review of mHealth apps aimed at improving psychological difficulties. They reviewed 24 articles and deduced that the most compelling support was for apps that targeted anxiety symptoms, followed by depression symptoms, with little evidence in other mental health conditions. They found limited evidence about adverse effects, change mechanisms, or quality reporting. As discussed in the journal paper, they concluded that robust research is required prior to recommending mHealth apps in a clinical setting.

The NHS previously had a library of approved apps which closed in 2021 and now their only recommended apps are the NHS app and COVID-19 app (NHS Apps Library, 2021). As a result, NHS England created the Digital Technology Assessment Criteria for Health and Social Care (NHS England, 2021), an assessment tool for ensuring digital health technologies meet standards of legislation and good practice. This contains five components: clinical safety; data protection; technical security; interoperability criteria; and usability and accessibility. In addition, the National Institute for Health Research (2019) emphasised in their Industry Strategy the importance of private companies creating their own innovations to improve the health and care system. This initiative aimed to be cost-saving and to improve quality within the NHS. As Betwixt was privately funded, its creation did not require public funding, though if it is deemed to be effective and acceptable, it could be offered to NHS patients. In conclusion, mHealth and mHealth apps are a growing area of healthcare intervention, though there is currently no database of recommended apps within the NHS and there is an onus on healthcare organisations to assess each app at the point of procurement.

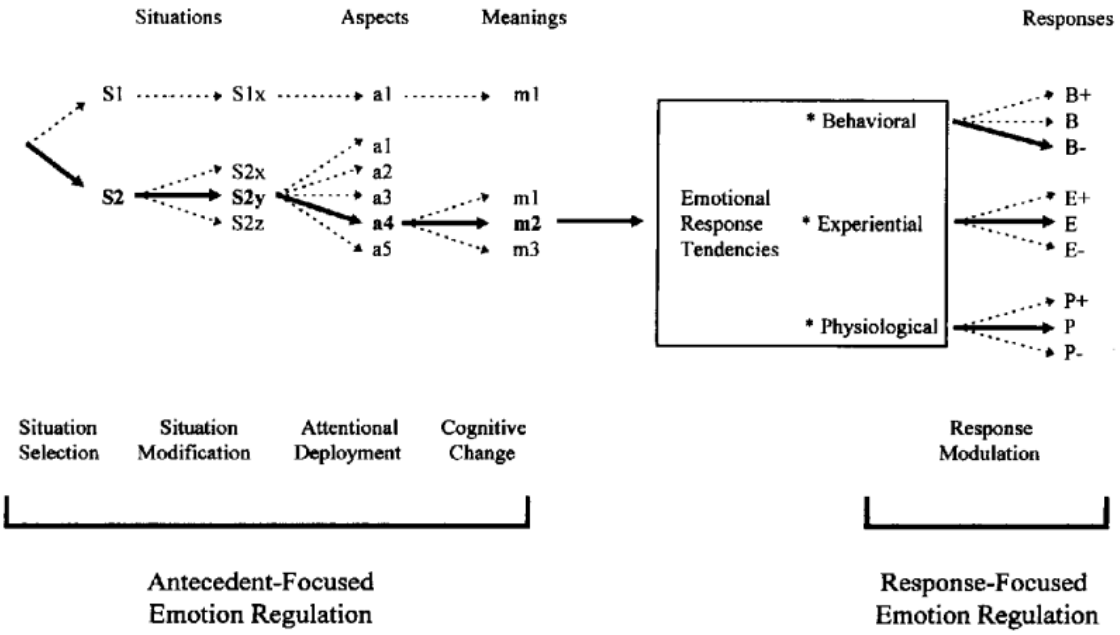
4.1.2 History of ER and its Clinical Applications

Gross (1998b) pioneered ER and undertook a review of the preceding two decades of the “emerging field of ER”. He outlined the differing terminology within the field (affect, emotion, moods etcetera); that emotions are evolutionary

and adaptive; and that ER can be considered in relation to different fields of psychology (clinical, cognitive, developmental, social etcetera). Gross argued that due to being evolutionary, emotions are dependent upon situation-response connections, though emotional responses that were appropriate to situations thousands of years ago, may no longer be appropriate. Hence, Gross proposed a process model of ER, to conceptualise ER processes (outlined in Figure 6). In this model, he proposed that stimuli are evaluated, and those that are deemed important lead to an emotional response tendency. These are then modulated via an increase, decrease or no change in behavioural, experiential, and physiological responses. Hence, stimuli are evaluated based upon the selection of the situation, modification of the situation, deployment of attention, and changes in cognition. If evaluated as important, there is a behavioural, emotional, and physiological response. Gross reviewed the evidence-base to create his conceptual framework, though he also discussed further challenges: Differentiating between ER and emotion generation; the importance of individual ER goals; and the connection between ER and other forms of self-regulation. Gross identified that previous research investigated specific ER strategies in isolation, without considering the definition of ER. He also identified that there were theoretical and empirical uncertainties within the evidence-base, though he remained optimistic about the future of the field. Since its publication, this review has been widely cited (in over 15,100 articles as of January 2025).

Figure 6

Gross' (1998b) Process Model of ER



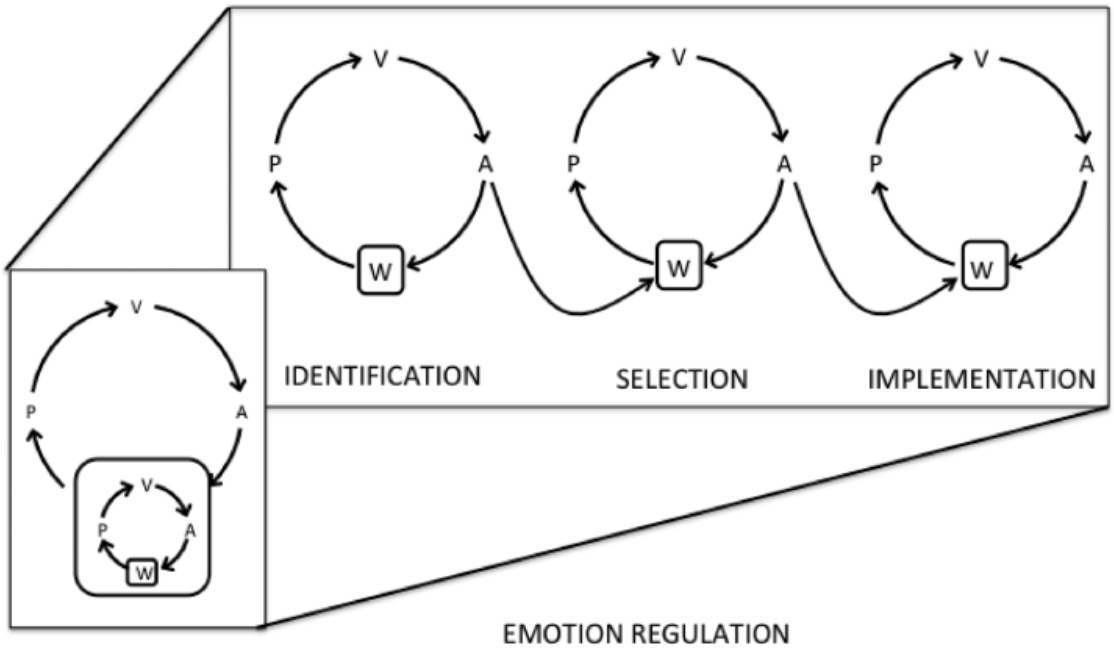
Thirteen years later, Tamir (2011) undertook a further review of the field of ER and argued that it was "maturing", and no longer 'emerging'. She stated that the field had grown exponentially, as evidenced by the increase in publications on the topic. Since Gross' (1998b) review, Tamir (2011) identified two implications of the emerging evidence-base: The definition and assumptions of emotions impacts research in the area; and research into ER can inform conceptualisations of emotions. She found that most of the research on ER focused on how ER occurs, as opposed to why it occurs. Tamir (2011) stated that since Gross' (1998b) article, there had been mixed opinions on whether ER and emotion generation were different, though there was consensus that ER should be studied, nonetheless. In addition, research also investigated the impact of interpersonal processes on ER, and studies took place within numerous different fields of psychology. Finally, it was stated that future ER research should consider the internal and external validity of the construct.

Similar to Tamir (2011), Gross (2015) undertook a follow-up review of the ER evidence-base and found an exponential increase in the number of articles published on the topic. He found comparable results to his previous research

regarding areas of psychology, and studies had also been undertaken within the area of industrial organisational psychology. He again discussed the differing terminology used, related processes, and how ER was conceptualised. Using the recent evidence within the field, Gross attempted to expand his ER model (outlined in Figure 7). This entailed cycles of situation (“world”), attention (“perception”), appraisal (“value”), and response (“action”) repeated over time. These cycles occur in stages of identification, selection, and implementation: First, an emotion is evaluated, then an appropriate ER strategy is chosen, and finally the ER strategy is initiated. As this model entails repeating cycles, different ER strategies can be implemented dynamically, when previous ones are deemed to be ineffective. Following on from this, Gross proposed five areas for future research: Flexibility of ER strategies, the neural basis of ER, ER across the lifespan, individual differences in ER, and ER interventions. Gross concluded that there had been vast amounts of research conducted since his initial review.

Figure 7

Gross’ (2015) Updated Process Model of ER



In reference to the clinical applications of ER, an umbrella review of the effectiveness, safety, and potential mechanisms of ER interventions was undertaken (Saccaro et al., 2024). They identified 21 quantitative and qualitative systematic reviews, and it was deduced that CBT and dialectical behaviour therapy may be effective at reducing emotion dysregulation in adults with transdiagnostic mental health conditions, from a general population. However, there was less evidence for adolescents and children. They concluded that there are potentially transdiagnostic advantages of ER interventions, and that they could be used proactively to prevent a further deterioration in mental health, which is in keeping with the rationale for the current study. In addition to this finding, Wucherpfennig et al. (2024) deduced that ER is a proposed core mechanism of psychotherapy and a common factor which influences the outcome of therapy. In conclusion, vast amounts of research have been undertaken within the field of ER, particularly within the past three decades, models of ER have been proposed, and applied to ER interventions. There are still many areas within the field whereby further research has been recommended.

It is worth noting that the majority of this research has focused on individual and intrapsychic concepts, such as attentional deployment, cognitive change, behavioural responses, physiological responses, attention, and appraisals (Gross 1998b; Gross, 2015). Relational and interpersonal processes have rarely been discussed within the literature, and the onus of regulating emotions appears to have been placed on individuals (Zaki & Williams, 2013). Some of the research has included relational considerations, for example Tamir (2011) referenced the impact of social processes on ER (Kappas, 2011); the impact of social construction and social interactions on ER (Barbalet, 2011); and the relational approach to ER, including the social context (Campos et al., 2011). In addition, Gross (2014) discussed the cultural perspective of ER: He theorised that ER is not an individual process as cultural practices, social situations and social interactions impinge upon ER and hence, it is culturally regulated. This was based upon Kappas' (2011) and Mesquita and Frijda's (2011) work which focused upon the importance of intrapersonal, interpersonal and cultural

processes within ER. Nonetheless, it is worth acknowledging that the majority of Gross (2014) appears to focus on individual processes in ER.

Some research within the field of ER has focused on interpersonal ER and the impact of relational processes on ER. For example, it has been proposed that individuals seek the support of others to regulate their emotions (Zaki & Williams, 2013); individuals attempt to change others' emotions (Niven, 2017); and difficulties in interpersonal ER may impact upon mental health (Dixon-Gordon et al., 2015). Other researchers have theorised that intrapersonal and interpersonal processes are required for ER, for example Marroquín et al. (2017) and Li et al. (2025). Though it is worth noting that the majority of the field of ER emphasises intrapersonal processes (Zaki & Williams, 2013).

The Betwixt app arguably focuses on intrapsychic ER as it is based upon cognitive reappraisal and self-compassion, and discusses values, drives, self-distancing, self-destructive behaviour, meditation, responses, strengths, negative self-talking, and reframing difficulties, which tend to be individual processes (further detail in the next section and Appendix 5.2). The app does not focus on interpersonal processes, though it does include a voice that the player interacts with, a monster who is the player's foe, and chimera (mythical creatures) which provide players with comfort. It is worth noting that the monster symbolises the player's inner world, hence arguably is intrapersonal. Overall, ER theory and research mostly focuses upon intrapsychic processes, which is reflected by the design and development of Betwixt. There are also some references to interpersonal ER within the evidence-base and Betwixt, though the primary focus of both is on intrapsychic ER.

4.1.3 History and Content of Betwixt

Betwixt was invented by UK-based Mind Monsters Games Limited. The two app developers are Elitsa Dermendzhiyska (entrepreneur and former science writer) and Hazel Gale (former talking therapist and published author). Elitsa explained that they designed Betwixt due to dissatisfaction with existing apps and desiring to utilise visualisation and gaming as a mechanism for change. She explained that they chose ER, cognitive reappraisal, and self-compassion, due to feeling

that they were evidence-based, yet overlooked within mHealth apps. They aimed to integrate ER, cognitive reappraisal, and self-compassion, to attempt to increase engagement and results. Elitsa stated that she approached the University of Nottingham for independent evaluation of Betwixt, due to their MindTech department ("a national centre focusing on the development, adoption and evaluation of new technologies for mental healthcare and dementia"; MindTech, 2025).

The content of Betwixt includes identifying values; noticing drives; self-distancing; connecting self-destructive behaviour and unmet needs; meditating on fear; reacting to threat; identifying strengths and skills; reflecting on negative self-talking; reframing difficulties; and a reflection on the process (further information in Appendix 5.2). This Appendix contains a synopsis of Betwixt content from the app developers, outlining the 11 dreams from the app, their content, additional information, primary focus, and resources. In addition, Appendix 5.1 contains Betwixt app imagery, including the app icon, advertisement, app content, and QR codes.

4.1.4 Cognitive Reappraisal

Cognitive appraisal was defined by Lazarus and Alfert (1964), who theorised that stress is as an imbalance between the demands placed on an individual and their resources to cope. They hypothesised that the experience of stress differs between individuals due to their interpretation of the event and the outcome of their thinking patterns ("appraisals"). In contrast to cognitive appraisal, cognitive reappraisal can be defined as "a widely utilised ER strategy that involves altering the personal meaning of an emotional event to enhance attention to emotional responses" (Wang & Yin, 2023). Effective cognitive reappraisal has been found to have numerous potential benefits, such as, improving negative emotions (Gross, 1998a). However, there is no consensus on how individuals utilise cognitive reappraisal; either by increasing the regulation of positive emotions, or by decreasing regulation of negative emotions (McCrae et al., 2012).

A central premise of CBT is that changes in negative thoughts and beliefs lead to a reduction in mental health symptoms (Beck et al., 1979), hence, cognitive reappraisal has been used within CBT (Clark, 2022). In addition, cognitive restructuring is a change method within CBT, which targets cognitive reappraisal and aims to improve mental health symptoms (Beck et al., 1985; Clark, 2022). In a review of meta-analyses of the processes of CBT, one of the constructs they identified was 'modifying cognitive processes', such as, reappraisal and restructuring (Kazantis et al., 2018). They deduced that eight meta-analyses investigated these processes in CBT for anxiety, with small to large effect sizes. They also found small to medium effect sizes for CBT for depression with this technique. In addition, a systematic review and meta-analysis of cognitive reappraisal in mHealth interventions found that most of the reviewed interventions were CBT-based, with a small to medium effect size for cognitive reappraisal interventions over comparators (Morello et al., 2023). Though cognitive reappraisal is ubiquitous with CBT, it has also been applied to other psychological therapies, such as, schema therapy, and mindfulness therapy (Wang & Yin, 2023; Garland et al., 2015).

Cognitive reappraisal is also ubiquitous within ER literature as it is perceived to be a strategy for improving ER (Gross & Thompson, 2007). A review of the evidence-base of ER strategies found that cognitive reappraisal is "more adaptive" than other strategies, but that other techniques, such as, distraction, can be more adaptive in certain situations (McCrae, 2016). McCrae and Gross (2020) outlined the importance of cognitive reappraisal by identifying that most ER research has focused upon this ER strategy, and it has promise of being "effective and adaptive". In conclusion, cognitive reappraisal shows promise as an intervention within CBT and for improving ER.

4.1.5 Self-Compassion

Self-compassion can be defined as:

> Being touched by and open to one's own suffering, not avoiding or disconnecting from it, generating the desire to alleviate one's suffering and to heal oneself with kindness. Self-compassion also involves offering non-

> judgmental understanding to one's pain, inadequacies, and failures, so that one's experience is seen as part of the larger human experience. (Neff, 2003)

Neff argued the importance of self-compassion for psychological health, particularly as the predominant measure of the construct at this time was self-esteem, which she deemed to be flawed. Self-compassion is a fundamental tenet of Buddhist philosophy (Hanh, 1997); however, it had not been widely applied to the field of clinical psychology at this time (Neff, 2003). Neff theorised that self-compassion contains three components: Self-kindness (being kind and understanding to oneself in the face of adversity), common humanity (seeing one's experiences as a normal part of human experiences), and mindfulness (paying attention to the present moment in a non-judgemental manner). Neff concluded that targeting self-compassion may improve psychological health.

Self-compassion is one of the active ingredients of contemporary therapies, such as, CFT, mindfulness-based cognitive therapy, and acceptance and commitment therapy (Wilson et al., 2018). A meta-analysis of the association between such therapies and mental health found a relationship with a large effect size (r=-0.54) between self-compassion and mental health conditions (MacBeth & Gumley, 2012). They deduced that compassion is an explanatory variable for understanding mental health and resilience. A further systematic review and meta-analysis of therapies aimed at self-compassion found them to produce greater improvements in anxiety, depression, and self-compassion, when compared to control conditions (Wilson et al., 2018). However, when comparing such therapies to active control conditions, there were limited differences. Wilson concluded that these therapies improve self-compassion and mental health symptoms, though not significantly more than therapies that were not explicitly targeting self-compassion. A further review of self-compassion therapies proposed that they may support individuals to cope with mistakes, failure, or rejection (Stutts, 2022).

Neff (2003) also outlined the utility of self-compassion as an ER strategy, and that self-compassion can be used to improve ER. A systematic review of mechanisms of change between self-compassion, ER, and mental health

deduced that the relationship between self-compassion and mental health was significantly mediated by ER (Inwood & Ferrari, 2018). They argued that self-compassion may have promise as a treatment target for improving ER. It is worth noting that the studies in this review were all cross-sectional, hence, it is not possible to discern causation. In conclusion, self-compassion has shown some promise for improving mental health and being correlated with ER.

4.1.6 Previous Literature in the Research Area

Two systematic reviews of ER apps were found upon reviewing literature, in a general population (Eisenstadt et al., 2021) and a clinical population (Harper et al., 2025b). Eisenstadt et al. (2021) undertook a systematic review and meta-analysis of the effectiveness of ER, positive mental health, and wellbeing apps, within an adult general population (18–45-year-olds). They reviewed 3,156 abstracts and identified 52 publications which met their inclusion criteria, and these evaluated 48 unique apps. They found a small effect for reducing mental health symptoms, a small effect for improving wellbeing, and a medium effect for improving ER. They also identified that the studies were from 15 countries and the apps used a variety of different techniques. It was concluded that such apps have “promising outcomes”, though few promote ER specifically. They also suggested that ER may be an important mechanism for future apps, and that further robust research is required to develop and evaluate evidence-based interventions. Eisenstadt et al. also discussed the potential benefit of future studies incorporating a mixed-methods design to deduce the potential limitations of technology or app features in psychological support.

Harper et al. (2025) replicated Eisenstadt et al.’s (2021) design within a clinical population. 604 studies were extracted from databases, though only ten studies met the inclusion criteria. A narrative synthesis found that ER apps may improve symptoms of depression (negligible-to-small effect size), anxiety symptoms (small-to-medium effect size), and post-traumatic stress disorder symptoms (negligible-to-large effect size). These effects sizes were quite varied and evidence certainty of the reviewed studies was low. Hence, future research was recommended including evaluating the effectiveness and acceptability of

such interventions. It is worth noting that Harper et al. (2025) was completed by the current researcher, and it has not yet been published in peer-reviewed literature.

Previous studies of Betwixt have included an acceptability study (Dermendzhiyska et al., 2025) and a randomised controlled trial (Masselink & Scholten, 2025) within a general population. In addition, Harmon et al. (2025) outlined the features of Betwixt and proposed future progress, though this article did not include research. It is worth noting that none of these three studies have yet been published in peer-reviewed literature. Dermendzhiyska et al. (2025) was undertaken in the UK by students at the University of Bournemouth and the University of Southampton. This was a mixed-methods design which investigated the acceptability of Betwixt in a general population and included 26 participants. All the participants completed a survey on Betwixt and 11 of the participants also engaged in an exit interview. Twenty-two of the participants reported that they enjoyed the experience of using Betwixt and four reported that they did not. They also found that those who did not enjoy using the app, used it less frequently than those who enjoyed using it. Overall, most participants had a positive opinion of Betwixt and reported that the app felt different to other mental health apps. They also found that participants reported positively on interactivity, control over the experience, and wanting to continue with the app to find out how the narrative progressed. It is worth noting that there were some methodological limitations with this design, such as, no test statistic was used for the quantitative analysis, and the qualitative analysis method was unclear. In addition, the study had a small sample size (n = 26) and, hence, the results may not be generalisable to other populations.

Masselink and Scholten (2025) undertook a randomised controlled trial of the effectiveness of Betwixt on psychological and affective wellbeing, within a general population. This study was undertaken by a student and staff member at the University of Twente in the Netherlands. Five-hundred-and-five participants completed the study, including an experimental condition whereby participants engaged with Betwixt for two weeks, and a control condition. At the start and end of the study, participants completed measures of depression, anxiety, stress, self-awareness, self-reflection, self-compassion, affirmation of

self-aspects, and value-awareness. The results indicated that using Betwixt for two weeks significantly decreased depression, stress, and also self-reflection levels. In addition, the participants reported a positive experience of app design, game experience, and overall experience. They concluded that Betwixt had "helped enlighten wellbeing difficulties", and they suggested future research in longer-term studies and follow-up conditions. This study appeared to have a more robust design, and it investigated the app within a large sample.

In conclusion, a paucity of evidence was found on systematic reviews of ER apps and evaluating Betwixt, especially within a clinical population of individuals experiencing mental health conditions. Hence, there was a need for research evaluating Betwixt within a clinical population. Please refer to the subsequent section for more information about the study rationale.

4.1.7 Study Rationale and Aims

The introduction section in the journal paper identified that there is a need for evidence-based and theory-driven mHealth interventions for individuals on waiting lists. ER could be the focus of such interventions and Betwixt focuses on ER, and the two ER strategies of cognitive reappraisal, and self-compassion. Previous research on Betwixt (Dermendzhiyska et al., 2025; Masselink & Scholten, 2025) had indicated that the app may be effective and acceptable for individuals from a general population, however, it had not been evaluated within a clinical population.

In order to evaluate Betwixt within a clinical population, and in keeping with previous research, the constructs of effectiveness and acceptability were chosen. Effectiveness refers to how effective an intervention is, and it is referenced throughout NHS literature, such as, in the NHS constitution where it is stated: "We earn the trust placed in us by insisting on quality and striving to get the basics of quality of care – safety, effectiveness and patient experience – right every time" (Department of Health and Social Care, 2023). Effectiveness is also recognised as a Standard by the Care Quality Commission (2024), and throughout the National Institute for Health and Care Excellence (NICE, 2025) guidelines.

Acceptability is defined by how appropriate patients and clinicians find an intervention, including cognitive and emotional responses (Sekhon et al., 2017). Acceptability was chosen because an intervention that is deemed to be acceptable, is more likely to be adhered to, and to lead to improved outcomes (Hommel et al., 2013). In addition, acceptability has been deemed to be necessary for deducing the effectiveness of an intervention, though acceptability alone is not sufficient for assessing this (Sekhon et al., 2017). Hence, effectiveness is of utmost importance to the NHS, and to supplement this information and provide further information about effectiveness, the construct of acceptability was also chosen. In order to evaluate the effectiveness and acceptability of Betwixt, the three aims were chosen.

Aim A referred to the effectiveness of Betwixt on ER, cognitive reappraisal, and self-compassion. This was chosen in order to deduce whether Betwixt may have been effective in a clinical population, and if it effectively improved measures of ER, cognitive reappraisal, and self-compassion. As this was the first study of Betwixt within a clinical population, this aim was chosen to provide information about its feasibility and whether effectiveness of the app should be further evaluated. It was also chosen to ascertain whether Betwixt was affecting the constructs it aimed to improve.

Aim B pertained to whether changes in processes targeted by Betwixt led to improvements in clinical outcomes. This aim was chosen to further supplement aim A and evaluating the effectiveness of Betwixt. It was identified to assess whether Betwixt impacted other clinical outcomes (psychological distress and functioning), other than ER, cognitive reappraisal, and self-compassion.

Aim C referred to the acceptability and theoretical components of Betwixt. This was chosen to supplement the effectiveness aims, and to deduce whether Betwixt was acceptable or not, to individuals within this population. This was of utmost importance as if an intervention is deemed to be not acceptable (even if it is highly effective), it may not be adhered to and there may not be positive outcomes (Hommel et al., 2013). In addition, some of the information about acceptability also informed the effectiveness research.

4.2 Extended Methods

4.2.1 Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013), and the UK Policy Framework for Health and Social Care (Health Research Authority, 2017). The British Psychological Society Code of Human Research Ethics (Oates et al., 2021) highlights the importance of informed consent, protection from harm, confidentiality, debriefing, the right to withdraw, and ethics reviews in research. Regarding informed consent, the participants provided consent for their contact details to be shared with the researchers, who then provided information to enable informed consent. During the consent process, it was reinforced to participants that participation was their choice and voluntary, and they did not initiate the study until they had provided informed consent (Appendix 5.8).

In reference to confidentiality and data protection, the researchers did not have access to the participants' medical records. The only information they had access to was from the participants and from the NHS Talking Therapies service (demographic information and contact details). The demographic information (age, gender, and diagnosis) was collected to facilitate contextualised understanding of the research findings. This data was stored in a password protected Microsoft Excel form, on an encrypted drive. At the end of participation in the study, the participants received a debrief form (Appendix 5.11), which included the contact details of the researchers to enable further support, if required.

Throughout the process of the study, participants were able to withdraw, and it was outlined in the participant information sheet (Appendix 5.7) that participating in, or withdrawing from the study would not affect their treatment with the NHS Talking Therapies service. The participants who completed the study were also remunerated with a £15 Amazon voucher as appreciation for their engagement in the study and to recognise their contribution. This study was also subject to an ethics review, which is outlined in the subsequent section.

4.2.2 Ethical Application Process

In September 2023, the University of Nottingham Sponsor department was contacted to initiate the ethical application process, and they provided advice. The application was submitted via the Integrated Research Application System (IRAS), due to the participants being NHS patients. On the application, Jacob Andrews was documented as the chief investigator, due to him being an employee of the university. The sponsor supported with the application and asked about certain aspects to prevent delays during the research ethics committee (REC). There were particularly discussions about whether Betwixt constituted as a medical device, which it was deemed not to be. Another discussion entailed whether the NHS site would be considered a participant identification centre (PIC), which it was. During this time, the researcher also completed Good Clinical Practice e-learning to update their knowledge on research processes.

The application was submitted through IRAS on 21st December 2023 (IRAS project ID: 334141). Supporting documentation was also submitted, including the participant information sheet (Appendix 5.7), consent form (Appendix 5.8), interview topic guide (Appendix 5.9), exit survey (Appendix 5.10), and debrief form (Appendix 5.11). The REC requested further information, such as, the questionnaires and content of Betwixt, which were provided. On 24th January 2024, the London Bridge REC took place via Zoom (video conferencing platform) and the researcher answered questions about the proposed study. Jacob Andrews was also asked to attend as the chief investigator, though the researcher answered the questions. Overall, they appeared to be content with the application, and they asked four questions. They asked about patient and public involvement, and it was explained that experts by experience had been involved in university panels and in assessing the readability of participant forms for the project (further detail in section 4.2.4; forms in Appendices 5.7-5.11). The panel also asked about Elitsa's role in the study, to which it was explained that she provided information and app access, but that she would not be involved in data collection or analysis. They asked about the app and its team having access to personal participant information. It was explained that the participants would only need to provide an email address to the app team to

enable access to Betwixt and that the app developers would have no other information about the participants. Finally, the REC asked about the sample size. The rationale for the sample size was explained, including the published average, and minimum requirement from the literature, to which they seemed satisfied.

On 30th January, the favourable opinion letter (Appendix 5.3) was received from the REC with four conditions to be met before full approval could be granted. All the conditions referred to the participant information sheet (Appendix 5.7), which was updated and re-submitted. On 8th February, full Health Research Authority approval was granted (Appendix 5.4), and permission was given to start recruitment. Following the approval, the questionnaires were attempted to be inputted into Qualtrics (online survey and data collection platform), however, there were access issues, hence, QuestionPro was chosen as an alternative. An ethics amendment (Appendix 5.5) was completed on 13th February to change from Qualtrics to QuestionPro. This was deemed to be a 'non-substantial' change, hence, this only required inputting data into a spreadsheet, requesting the sponsor to authorise it, and submitting it to the IRAS system.

On 15th February, Lincolnshire Partnership NHS Foundation Trust confirmed capability and capacity for the PIC site (Stamford and Boston NHS Talking Therapies service), and they later sent a letter to provide a right of access to conduct the research within the trust. Subsequently, the trust completed the PIC agreement, authorising the start of recruitment. On 1st March, the researchers met with the senior manager of the team to discuss how the study would be operationalised, and later met with the team manager to discuss how the staff members (psychological wellbeing practitioners) would recruit participants. Staff training was provided on 28th March (presentation in Appendix 5.12), and this included information about Betwixt, the study design, eligibility criteria, recruitment process, and a discussion. Recruitment started on 8th April.

There was a subsequent ethical amendment (Appendix 5.6) on 6th August, to change the sample size to up to eight participants, with replacement participants for withdrawals who did not provide sufficient data. This was required as three consecutive participants had withdrawn prior to providing any

treatment phase data, and the data from the remaining participants may not have been sufficient to provide meaningful conclusions. Like the first amendment, this was deemed a 'non-substantial' change, only requiring inputting data into a spreadsheet, requesting the sponsor to authorise it, and submitting it to the IRAS system.

Participant recruitment continued until 11th October, when it was closed due to sufficient participants being recruited and recruitment being open for six months. Hence, the PIC site was informed to cease recruitment, and the trust research and development department was also informed. The University of Nottingham sponsor was contacted, and the end of study declaration was completed, and submitted to London Bridge REC. In the 12 months following this date, the final report to IRAS will be submitted.

4.2.3 Epistemology

This study was approached from the epistemological position of pragmatism, which emphasises the importance of using practicality, judgement, and experience. Pragmatism developed in the 1990s due to dissatisfaction with the polarised paradigms of positivism and interpretivism, and a desire for combining them (Tashakkori & Treddlie, 1998). The positivist paradigm purports the importance of scientific knowledge, rationality, and objectivity and this underlies quantitative methods (Howe, 1998). The interpretivist paradigm refutes claims of objectivity and emphasises construction of reality, and this underlies qualitative research (Howe, 1998). Pragmatism enables knowledge to be pragmatically gained, using judgement and experience, including the use of mixed-methods designs (Tashakkori & Treddlie, 1998).

4.2.4 Study Design

As a result of the aims pertaining to effectiveness and acceptability, and the epistemological position of pragmatism, a mixed-methods design was chosen. Mixed-methods designs have various strengths, such as, they increase validity

due to “methodological triangulation”, as combining quantitative and qualitative elements reduces threats to internal and external validity (Denzin, 1978).

A SCED series was chosen as these evaluate treatment effects on a case-by-case basis, with each participant acting as their own control condition. SCEDs provide valuable information about the mechanisms of therapeutic change, the effectiveness of interventions (via systematic manipulation of the independent variable), and enable empirical approaches to be translated into naturalistic clinical settings (Nash et al., 2011). ABA designs (baseline, intervention, baseline) are more statistically robust; however, they entail forgetting all learning from an intervention and there are ethical considerations when withdrawing an intervention (Rassafiani & Sahaf, 2010). Hence, an AB design was chosen.

A limitation of this design is that prolonged baseline phases can delay participants receiving an intervention (Barger-Anderson et al., 2004), however, the baseline phases in this study were short in duration (two or three weeks) and receiving Betwixt whilst waiting was supplemental to their NHS Talking Therapies intervention. In addition, a potential weakness of this design is in establishing causation due to limited samples, however, this was an initial feasibility study, and this was deemed appropriate for this stage of research. In future, there would be value in further evaluation, such as, with multi-site SCED studies or replication with larger and more diverse cohorts, to improve the precision of estimates and strengthen external validity. Section 4.4.4 provides detail about proposed areas of future research.

In the interviews and survey, the Theoretical Framework of Acceptability (Sekhon et al., 2017) and Client Change Interview Schedule (Elliott, 2006) were amalgamated. The rationale was that collecting information about acceptability and change was hoped to contextualise the findings beyond only researching acceptability. This amalgamation of constructs was also used by the authors in Harper et al. (2025a) and found to be a promising method for ascertaining information about acceptability and changes related to an intervention. The interviews were semi-structured to allow additional questions to be asked of participants, with examples in the topic guide. For all the interviews and survey,

the questions were asked in the same order to increase consistency and decrease threats to validity.

When designing the study, a member of the University of Nottingham Service User and Carer Group provided consultancy support, to potentially improve the experience for participants. This entailed providing feedback on the readability and visual appeal of the materials provided to participants (the participant information sheet, consent form, exit survey, and participant debrief form). The individual provided specific suggestions about the participant information sheet and survey questions which were discussed and implemented. The individual was also remunerated to acknowledge their contribution.

4.2.5 Recruitment

This study was the first to research Betwixt within a clinical population, hence, participants were recruited from an NHS Talking Therapies service, as these support individuals with “depression and anxiety disorders that can be managed effectively in a uni-professional context” (National Collaborating Centre for Mental Health, 2024). In other services, individuals may have more severe mental health conditions and multiple professionals providing support, which may increase the risk of extraneous factors affecting the outcome. In addition, in an acceptability study of Betwixt (Dermendzhiyska et al., 2025), the participants reported that the app had the potential to positively influence those that have “mild mental health concerns”. As outlined in the journal paper, depression and anxiety disorders are also the most prevalent mental health conditions globally (Dattani et al., 2021).

The eligibility criteria for this study were the same as the criteria for accessing NHS Talking Therapies services (National Collaborating Centre for Mental Health, 2024): Adults with an anxiety disorder and/or depression (defined by meeting the clinical cut-offs on the Patient Health Questionnaire-9 measure of depression, Kroenke et al., 2001; or the Generalised Anxiety Disorder-7 measure of generalised anxiety, Spitzer et al., 2006). Participants were also required to own a smartphone to access Betwixt, which they were comfortable using for extended periods of time, and to have a sufficient English reading

ability to be able to engage with the intervention (due to the narrative nature of Betwixt). This study was delivered as a waiting list intervention, to prevent a delay in treatment for individuals in a clinical population. Hence, participants were required to be on the waiting list for the specific NHS Talking Therapies service, and available for up to seven weeks whilst waiting. At the time of the study, the waiting list was 10-weeks, hence, there was sufficient time for participants to engage in the study before their NHS Talking Therapies intervention.

The published guidance recommends a minimum sample size of three participants for SCED series to achieve sufficient data (Kratochwill et al., 2010) and the published average is six (Smith, 2012). Therefore, recruitment was open for six months to enable sufficient participants to be recruited, and more participants were recruited than the published average to allow for attrition. As a result of the small sample size in SCEDs, replication with the same subject, and across multiple subjects improves the external validity of such studies (Morgan & Morgan, 2008). This sample size also aimed to enable data sufficiency in the interview element of the study.

4.2.6 Withdrawing Participants

In total, 20 individuals expressed interest in participating in the study and were invited to participate. Of these individuals, ten participants provided informed consent, equating to 50%. No data was collected from the 10 individuals who expressed interest in the study but did not consent to participate. Three of the participants who consented withdrew prior to finishing the study, and their demographics are outlined in Table 7. Participants eight and nine withdrew at the end of their baseline phases (three- and two-week durations respectively) and, hence, they did not use Betwixt. Participant ten consented to engage in the study, however, she did not complete any surveys or start the baseline phase before withdrawing. Participant eight did not discuss withdrawing, they merely ceased communication. Participants nine and ten reported that they withdrew due to not having sufficient time to dedicate to the study. The participants who withdrew were varying ages (24-46 years) and were different genders. They

were all diagnosed with depression; however, it is unlikely that this is related to their withdrawal as 57% of the participants who completed the study also had this diagnosis. The prevalence of this diagnosis within the sample is likely a reflection of NHS Talking Therapies services demographics (NHS Digital, 2018).

Table 7

Demographics of Participants who Withdrew

Participant	Age	Gender	Diagnosis	Withdrawal
8	33	Male	Depression	Withdrew at end of baseline phase
9	24	Male	Depression	Withdrew at end of baseline phase
10	46	Female	Depression	Withdrew following consent

4.2.7 Selection of Measures

The measures used in the study were selected due to their psychometric properties, being short versions (to decrease participant effort), mapping onto the targets of Betwixt, and being consistent with the measures used in NHS Talking Therapies services. The PHQ-2 (Kroenke et al., 2003), PHQ-9 (Kroenke et al., 2001), GAD-2 (Kroenke et al., 2007), GAD-7 (Spitzer et al., 2006), and WSAS (Mundt et al., 2002) were chosen due to their sufficient psychometric properties (outlined in Tables 2 and 3) and their use within NHS Talking Therapies services (National Collaborating Centre for Mental Health, 2024), to enable continuity of care for the participants. The PHQ-2 and GAD-2 were chosen for the SCED series as they are brief versions, in order to reduce participant effort. The SWEMWBS (Stewart-Brown et al., 2009) was chosen as it has appropriate psychometric properties, is comprehensive, and it measures mental wellbeing which was not directly assessed by other measures. The DERS-SF (Kaufman et al., 2016), CERQ-short (Garnefski et al., 2001), and SCS-SF (Raes et al., 2011) were chosen due to their psychometric properties and mapping onto the targets of Betwixt (ER, cognitive reappraisal, and self-

compassion). The abridged version of each measure was used to decrease participant effort.

4.2.8 Changes to Procedure

Overall, the procedure of the study took place as planned in the study protocol, however, there were some changes to the recruitment strategy. Initially, it was planned that there would be two weeks of recruitment, followed by a period without recruitment, and then further recruitment, if required. This was planned due to the volume of referrals to the service and assumptions about the number of participants who would consent to the study. Unfortunately, fewer participants were recruited in the two-week period than anticipated (one individual). Hence, the recruitment strategy was altered to continuous recruitment, whereby the two staff members alternated each week who was recruiting. In the following two weeks, no more participants were recruited so the strategy was changed again, and the two staff members both recruited continuously. Following this change, there was a period whereby one to two participants were recruited per week. At this time, virtual consent was also introduced, which enabled participants to provide consent via a Microsoft Form, as opposed to Microsoft Teams (both methods were outlined in the ethical application, so an ethics amendment was not required). It was hypothesised that a Microsoft Teams call may be unduly anxiety-provoking for individuals with depression or an anxiety disorder. The first two participants consented via Microsoft Teams and the subsequent eight participants consented via the Microsoft form. In addition, one of the two recruiting staff members changed roles toward the end of recruitment, however, this had a limited impact as recruitment was closing at this time.

As outlined in the Ethical Application Process section (4.2.2), there was also a change to the sample size. Two months after recruitment started, there was a period whereby three participants consented to the study then withdrew prior to providing any treatment phase data. Hence, an ethical amendment was required to ensure that sufficient participants were recruited who provided enough data to be analysed.

4.2.9 Quantitative Analysis Rationale

The quantitative analysis for this study involved visual analysis, Kendall's Tau-U, and SMA for the SCED series; and RCSC for the pre- and post-intervention measures. Visual analysis was chosen as the primary analysis of the SCED data as it is systematic and recommended within the evidence-base (Morley, 2018; Kratochwill et al., 2010). Kendall's Tau-U was selected as it is recommended in the literature and uses a test statistic (Morley, 2018). SMA was chosen as it specifically analyses temporal relationships within SCEDs (Borckardt & Nash, 2014), which is concordant with study aim B. RCSC was chosen as it enables reliable and clinically significant change within psychotherapy research to be quantified and compared (Jacobson & Truax, 1991).

4.2.10 Qualitative Analysis Rationale

The qualitative analysis for this study entailed using FM for the interview and survey data. FM was chosen due to its ubiquity in multi-disciplinary health research, and it being a systematic approach to qualitative data analysis (Gale et al., 2013). FM was developed in the 1980s for large-scale social policy research, however, it has become increasingly popular in medical and health research (Gale et al., 2013). It has also been widely cited (in over 11,400 articles on Google Scholar, as of June 2025). Gale et al. (2013) stated that FM supports qualitative data analysis; is most suitable for interview data; the matrix provides a structured overview; and it entails a structured process; hence, it was chosen for this study to provide structure to the qualitative data, derived from interviews. FM has also been described positively by other researchers who have plauded its pragmatism, flexibility, rigor, methodical guidelines, and transparency of findings (Parkinson et al., 2016; Kiernan & Hill, 2018; Smith & Firth, 2011).

The current study followed Gale et al.'s (2013) stages of FM, involving transcription, familiarisation, coding, developing a framework, charting data into the matrix, and interpretation. The interview data was transcribed using an automated transcription service, which is a method outlined in Gale et al.

(2013). Initially, the researcher immersed themself in the data by watching each recording on one to two occasions, focusing purely on the content of the interviews. Each recording was then watched on two to three more occasions to ratify the accuracy of the automated transcription and to correct errors. After familiarisation with the data, the researcher coded the first three transcripts. Using the coding from these participants, the initial working analytic framework was started. For quality assurance, the coding and initial framework were reviewed by the research team to ensure internal consistency and to sense-check the data. This entailed ratification, providing advice and discussing disagreements. Following ratification, the data from the subsequent participants was then added to this framework to create the analytic framework. A framework matrix was then created and then the data was charted onto this matrix. In the final stage, impressions, ideas and interpretations were noted, then the data was interpreted beyond the codes. The research team also provided advice at this stage for amalgamating codes and themes and ensuring that the framework matrix was concise. Overall, the FM was applied according to Gale et al.'s (2013) procedure.

The current study was approached from the epistemological position of pragmatism, which emphasises the use of practicality, judgement and experience when attempting to gain empirical knowledge (Howe, 1998). Pragmatism entails using scientific methods that are found to be effective, and truth can be derived from "what works" (Howe, 1998). This study was approached from the position of pragmatism as this enables knowledge to be gained pragmatically, including using judgement and experience (Tashakkori & Treddlie, 1998). In addition, the aims of this study focused on effectiveness (quantitative construct) and acceptability (qualitative construct), and pragmatism is concordant with employing a mixed-methods design to investigate a combination of quantitative and qualitative components (Tashakkori & Treddlie, 1998). Gale et al. (2013) also outlined that FM is not aligned with any epistemological position, and it is designed to be a "flexible tool", which is concordant with the principles of pragmatism. Additionally, Kiernan and Hill (2018) reflected on the epistemology and methodology underpinning FM. They argued that immersion in the data, which is part of FM, is an inherently

pragmatic approach to data analysis and they also suggested that pragmatism is necessary for deciding when FM is complete. Other researchers have also argued that FM entails pragmatism, such as Parkinson et al. (2016). In conclusion, the qualitative data in this study was approached from the perspective of the theory of FM, and the epistemological stance of pragmatism. These constructs are concordant with each other, and this is the lens through which the qualitative data was interpreted.

4.3 Extended Results

4.3.1 Additional SCED Data

Table 8 outlines the full dataset for the Tau-U analysis, including baseline trend data. It demonstrates the seven significant changes between phases and that there was one unstable baseline requiring a baseline correction (for participant seven on the DERS-SF).

Table 8

Full Dataset of the Tau-U Analysis Comparing Baseline and Treatment Phases for the SCED Series Measures

Ppt	DERS-SF (ER)		PHQ-2 (low mood)		GAD-2 (anxiety)	
	Baseline trend	Tau-U statistic	Baseline trend	Tau-U statistic	Baseline trend	Tau-U statistic
1	Tau= -0.488, p=0.172	Tau= -0.143, p=0.655	Tau= -0.329, p=0.447	Tau=0.000, p=1.000	Tau= -0.700, p=0.062	Tau= 0.020, p=0.949
2	Tau= -0.176, p=0.570	Tau= -0.625, p=0.013*	Tau= -0.210, p=0.467	Tau= 0.358, p=0.156	Tau= 0.285, p=0.332	Tau= 0.292, p=0.249
3	Tau= -0.293, p=0.448	Tau= 0.364, p=0.205	Tau= -0.378, p=0.377	Tau= 0.584, p=0.042*	Tau= -0.586, p=0.095	Tau= 0.143, p=0.618
4	Tau= -0.389, p=0.411	Tau= -0.222, p=0.606	Tau= -0.548, p=0.247	Tau= 0.111, p=0.796	Tau= -0.775, p=0.071	Tau= -0.333, p=0.439
5	Tau= -0.090, p=0.788	Tau= -0.213, p=0.450	Tau= 0.248, p=0.486	Tau= -0.938, p=0.001*	Tau=0.000, p=1.000	Tau= -1.000, p=0.000*
6	Tau= 0.150, p=0.759	Tau= 0.604, p=0.029*	Tau= 0.000, p=1.000	Tau=0.000, p=1.000	Tau= 0.000, p=1.000	Tau=0.000, p=1.000
7	Tau†= -0.760, p=0.005	Tau†= 0.702, p=0.000*	Tau= -0.447, p=0.164	Tau= -0.871, p=0.000*	Tau= 0.000, p=1.000	Tau= -0.286, p=0.242

†The baseline was not stable, and a baseline correction was required.

*p<0.05

Figures 8, 9, 10, 11, 12, and 13 outline the non-significant SCED graphs for the participants. These were not included in the journal paper due to them demonstrating non-significant effects and not adding additional information. In Figure 8, participant one's ER (DERS-SF), low mood (PHQ-2) and anxiety (GAD-2) SCED graphs are shown. These demonstrate that there was limited difference between phases, with stability across phases yet limited phase contrast, no immediate change in the treatment phases, and overlapping data between phases.

Figure 8

SCED Graphs for Participant One's Measures

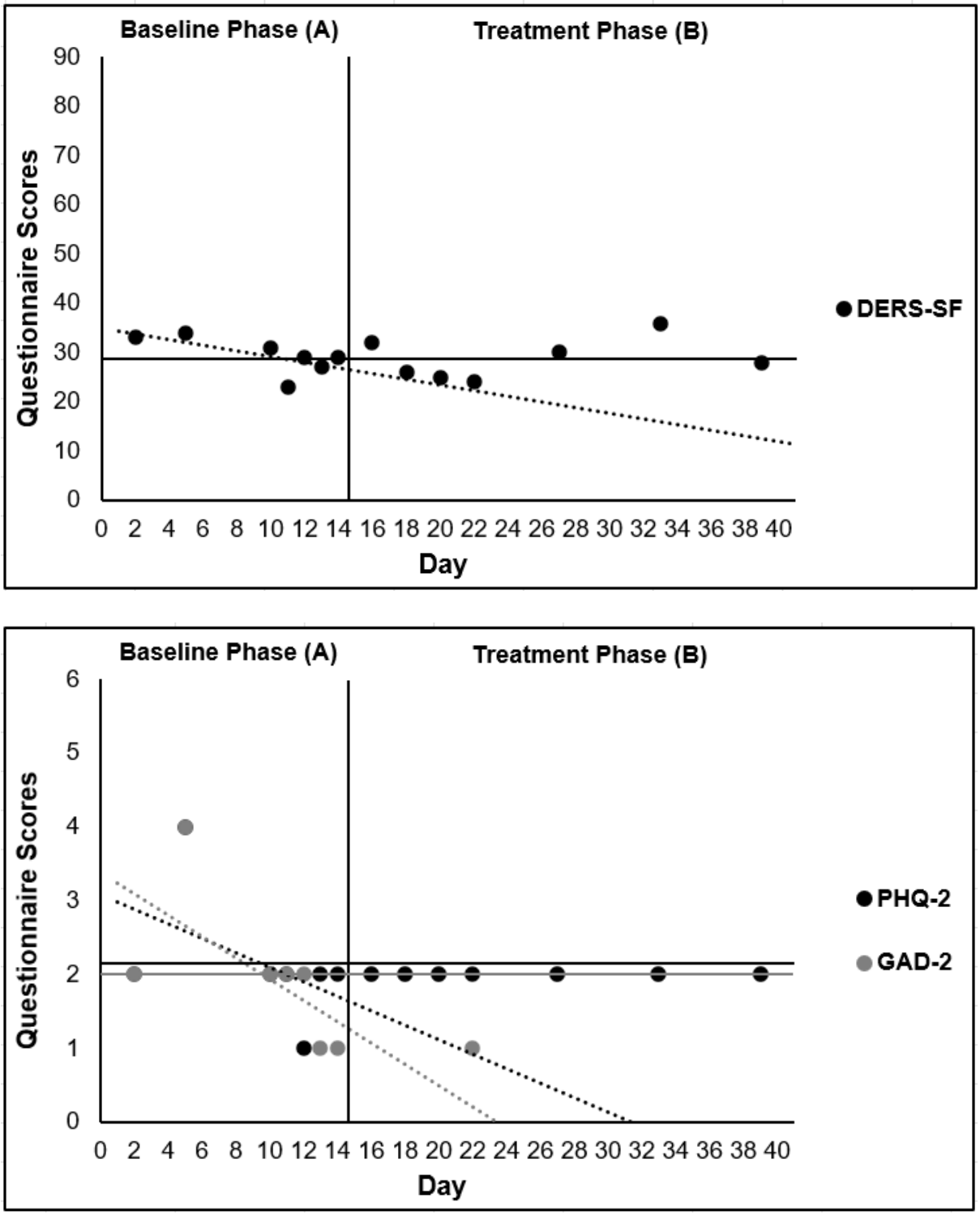


Figure 9 demonstrates participant two's low mood (PHQ-2) and anxiety (GAD-2) SCED data. These illustrate that there was limited difference between phases,

with stability across phases yet limited phase contrast, no immediate change in the treatment phases, and overlapping data between phases. The patterns of her data for low mood (PHQ-2) and anxiety (GAD-2) were particularly unclear.

Figure 9

SCED Graphs for Participant Two's Measures

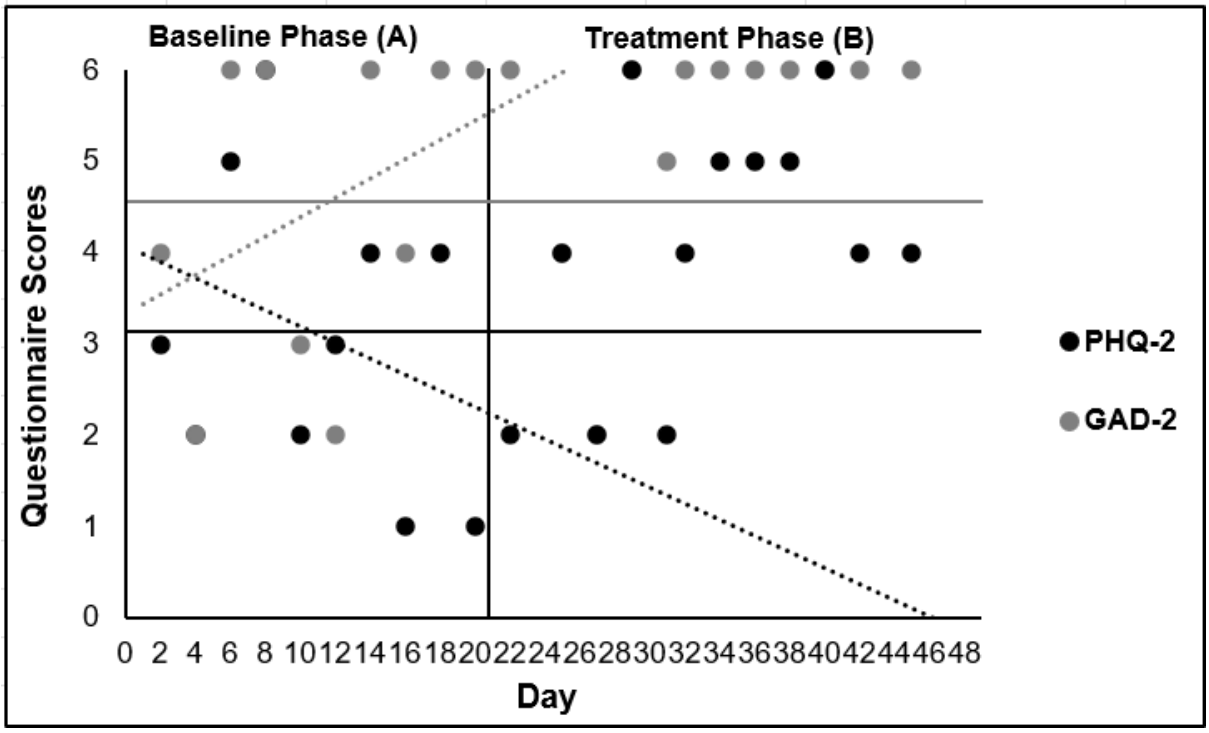
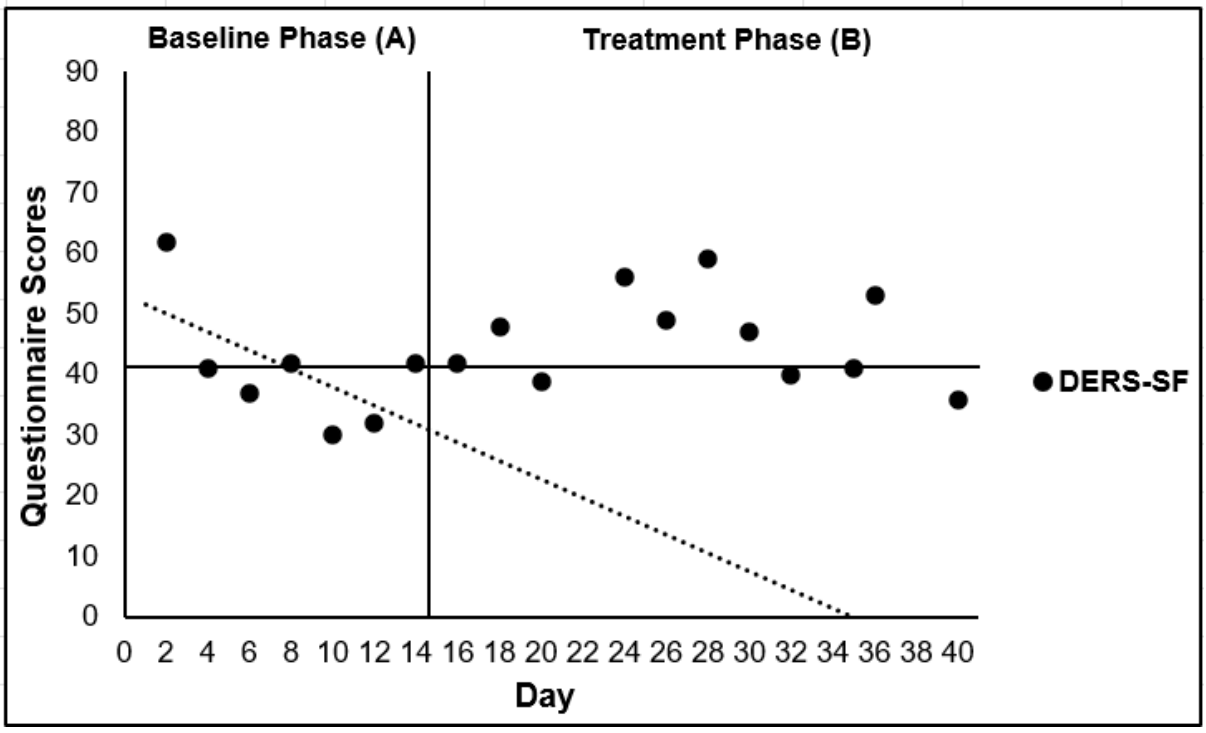


Figure 10 outlines participant three's ER (DERS-SF), low mood (PHQ-2) and anxiety (GAD-2) SCED data. These demonstrate that there was limited difference between phases, with stability across phases yet limited phase contrast, no immediate change in the treatment phases, and overlapping data between phases. On the ER (DERS-SF) graph, one would have expected the scores to decrease in the treatment phase (as per the median line), however, they remained quite constant throughout this phase. Similarly, the baseline phases on the low mood (PHQ-2) and anxiety (GAD-2) have a different trend than the treatment phases of these measures.

Figure 10

SCED Graphs for Participant Three's Measures



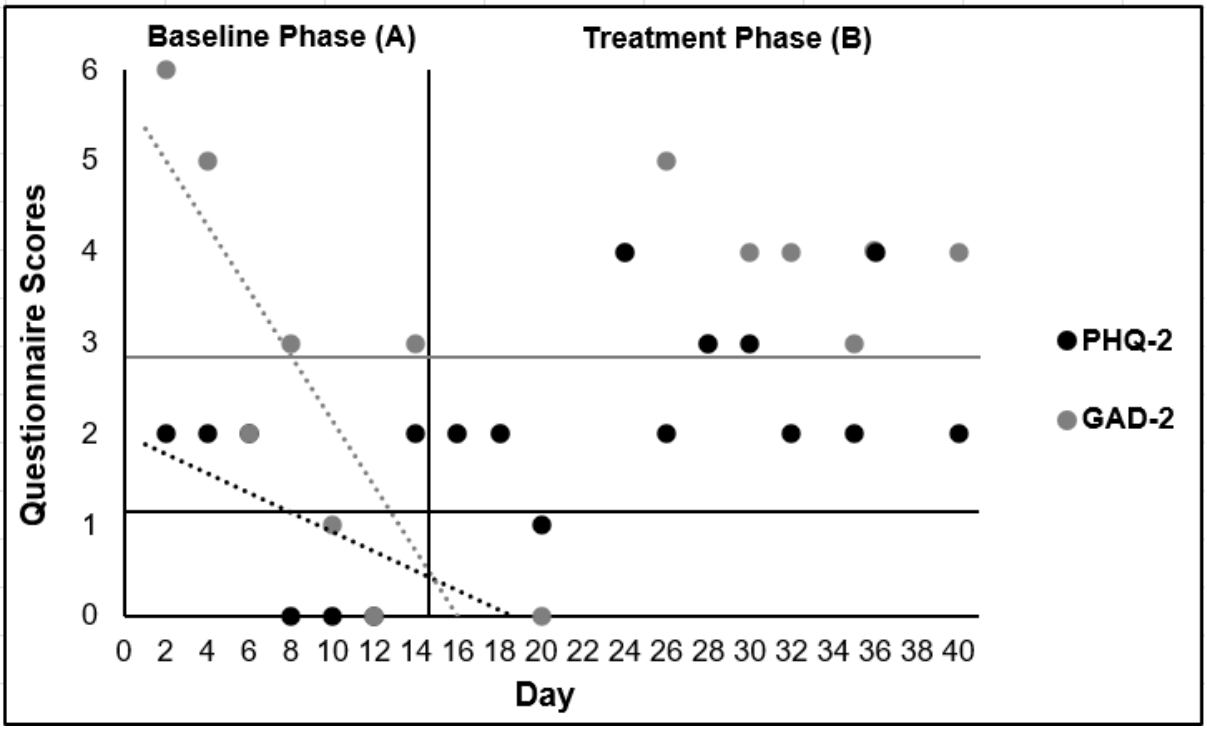
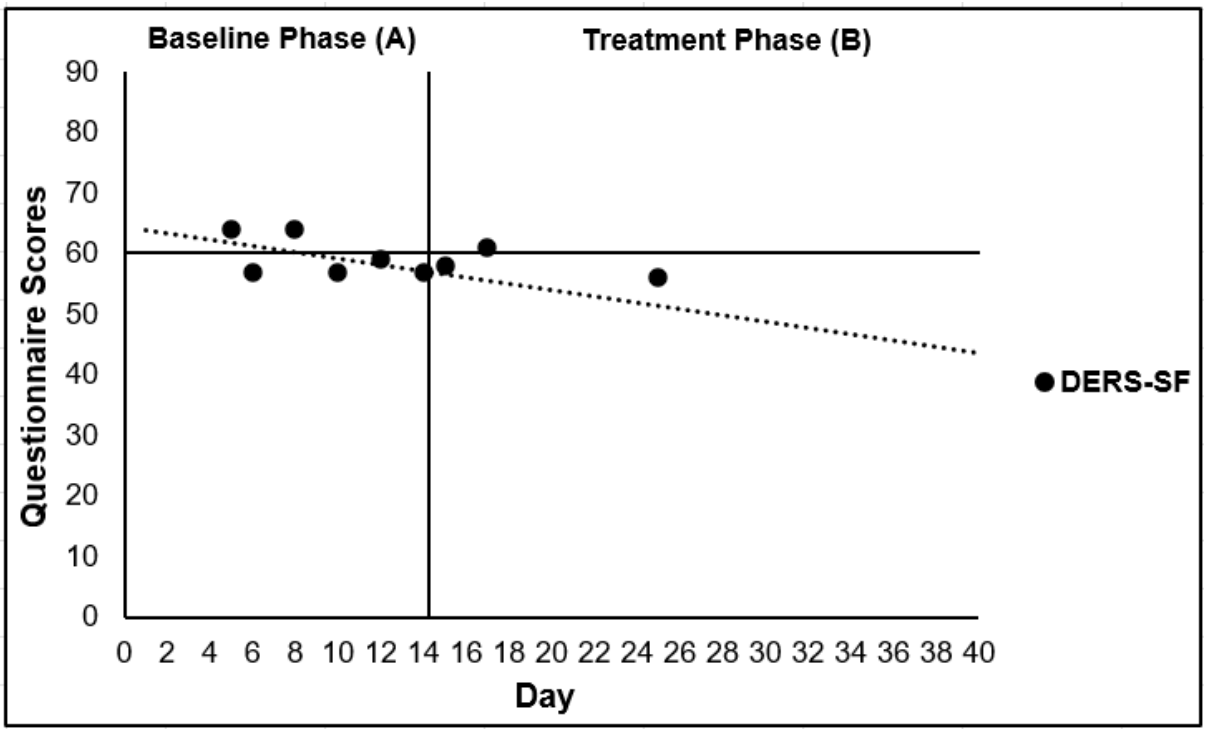


Figure 11 demonstrates participant four's ER (DERS-SF), low mood (PHQ-2) and anxiety (GAD-2) SCED graphs. These show that there was limited difference between phases, with stability across phases yet limited phase contrast, no immediate change in the treatment phases, and overlapping data between phases. It is worth noting that participant four only completed three data points within the treatment phase, hence, the lack of data on the graphs.

Figure 11

SCED Graphs for Participant Four's Measures



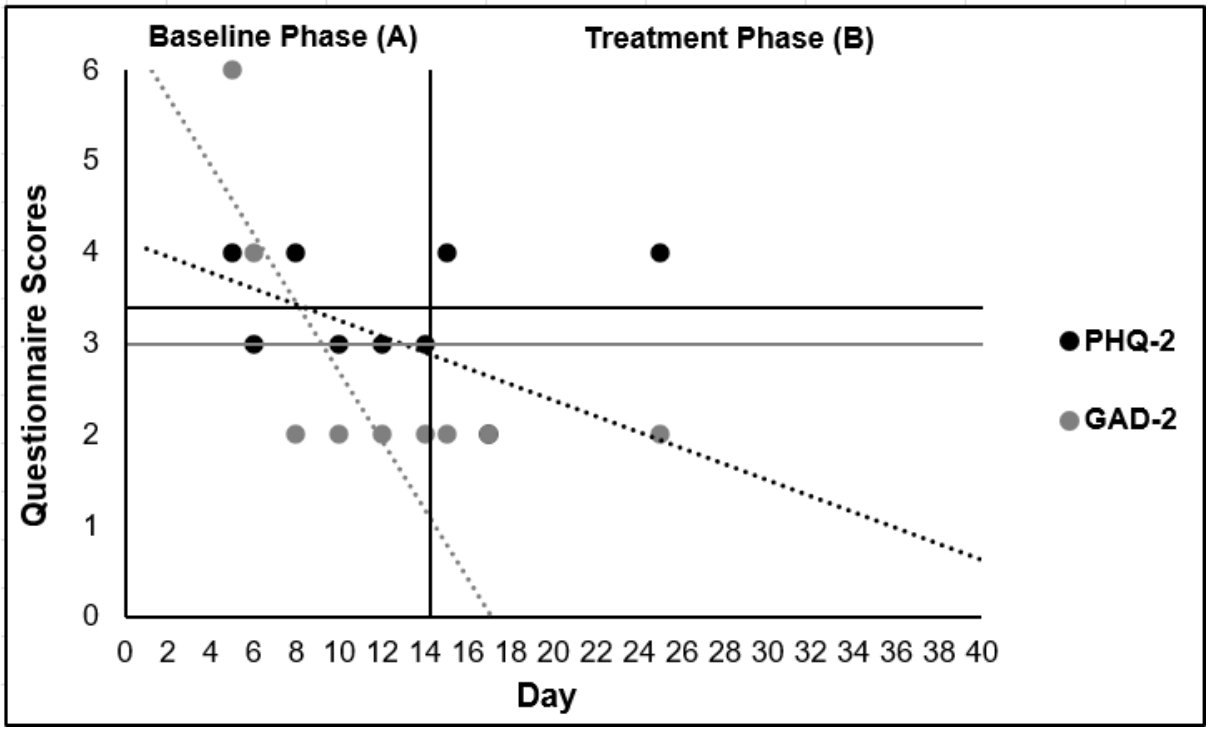


Figure 12 outlines participant five's ER (DERS-SF) data. This demonstrates that there was limited difference between phases, limited phase contrast, no

immediate change in the treatment phases, and overlapping data between phases. In addition, the baseline phase data was quite homogenous, however, the treatment phase data had more heterogeneity.

Figure 12

SCED Graphs for Participant Five's Measures

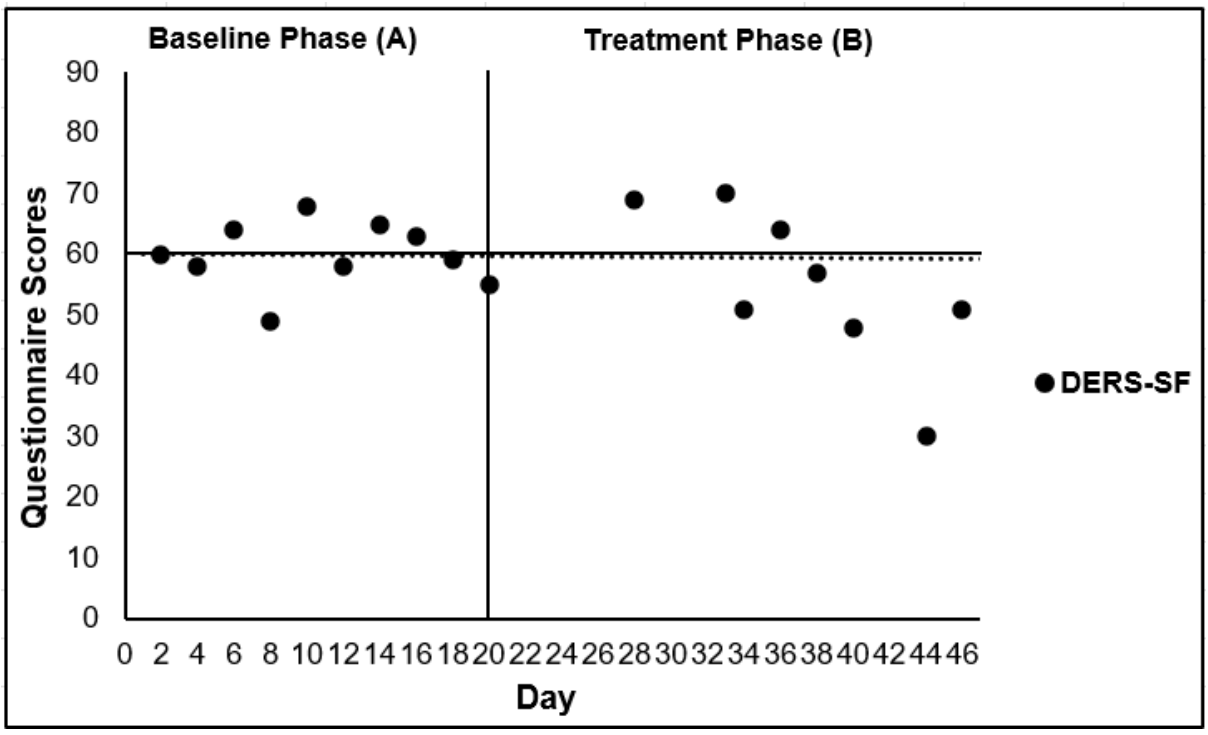
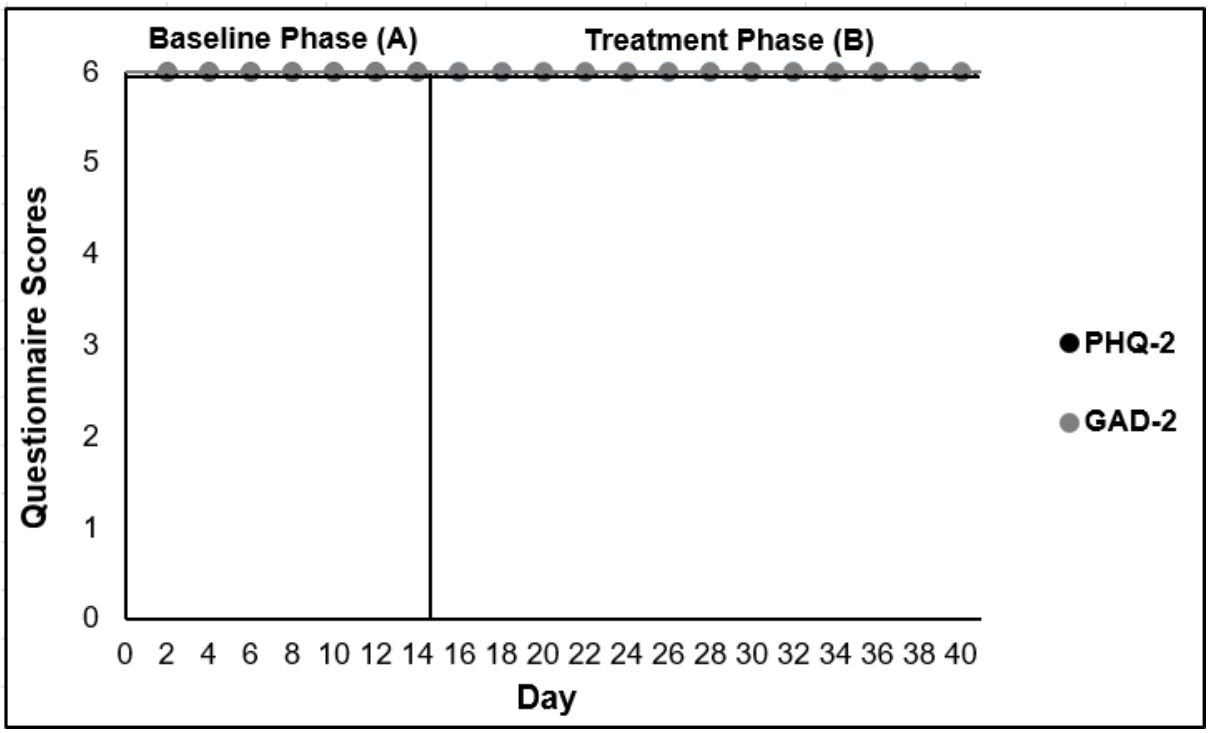


Figure 13 demonstrates participant six's low mood (PHQ-2) and anxiety (GAD-2) SCED data. This demonstrates that there was no difference between phases, with stability across phases and no phase contrast, no change in the treatment phases, and overlapping data between phases. As a result of this constant within the data (attaining the highest possible scores on both measures throughout), her low mood (PHQ-2) and anxiety (GAD-2) Tau-U statistics, and SMA were not calculatable.

Figure 13

SCED Graphs for Participant Six's Measures



4.3.2 Additional RCSC Data

Table 9 outlines the full dataset for the RCSC, including data for each participant on each measure. It is worth noting that the sub-scales for the CERQ-short (cognitive reappraisal measure) were mapped onto the targets of Betwixt, and 'putting into perspective', 'refocus on planning', 'acceptance', and 'rumination' were the focus of this analysis. All the six subscales for the DERS-SF (ER measure) were included. These measures were divided into their subscales for the RCSC to provide more detailed data about the theoretical components of Betwixt.

Table 9

Full Dataset of the Reliable and Clinically Significant Change Analysis of Pre- and Post-Intervention Measures

Participant and measure		Pre	Post
P2			
DERS-SF	Strategies	13	12
	Non-acceptance	15	12
	Impulse	6	6
	Goals	14	14
	Awareness	12	14
	Clarity	6	6
CERQ-short	Perspective	4	4
	Planning	5	5
	Acceptance	10	8
	Rumination	6	5
SCS-SF		26	28
PHQ-9		15	16
GAD-7		16	17
SWEMWBS		17	18
WSAS		34	24^{R+}
P3			
DERS-SF	Strategies	10	4^{R+}
	Non-acceptance	10	5^{R+}
	Impulse	10	4^{R+}
	Goals	13	5^{R+}
	Awareness	10	14
	Clarity	9	4^{R+}
CERQ-short	Perspective	5	4
	Planning	5	4
	Acceptance	6	4
	Rumination	7	4
SCS-SF		14	20
PHQ-9		15	11
GAD-7		21	7^{R+C+}
SWEMWBS		17	13
P4			
DERS-SF	Strategies	11	10
	Non-acceptance	13	10
	Impulse	7	7
	Goals	13	11
	Awareness	9	11
	Clarity	11	7
CERQ-short	Perspective	6	4
	Planning	6	5
	Acceptance	7	4
	Rumination	4	2
SCS-SF		25	38^{R+}
PHQ-9		22	13^{R+}
GAD-7		15	4^{R+C+}
SWEMWBS		15	22^{R+C+}
WSAS		22	15^{R+}
P5			
DERS-SF	Strategies	14	10

	Non-acceptance	14	7[R+]
	Impulse	4	6
	Goals	15	12[R+]
	Awareness	3	12[R-]
	Clarity	10	4[R+]
CERQ-short	Perspective	2	3
	Planning	2	8[R+]
	Acceptance	2	3
	Rumination	10	5[R+]
SCS-SF		12	16
PHQ-9		26	7[R+C+]
GAD-7		16	6[R+C+]
SWEMWBS		7	24[R+C+]
WSAS		40	17[R+]
P6			
DERS-SF	Strategies	14	15
	Non-acceptance	8	14[R-]
	Impulse	4	4
	Goals	13	15
	Awareness	9	8
	Clarity	7	11
CERQ-short	Perspective	2	2
	Planning	2	4
	Acceptance	7	8
	Rumination	9	7
SCS-SF		15	30[R+]
PHQ-9		24	23
GAD-7		20	19
SWEMWBS		11	18[R+]
P7			
DERS-SF	Strategies	3	3
	Non-acceptance	5	3
	Impulse	4	3
	Goals	6	6
	Awareness	7	3
	Clarity	5	5
CERQ-short	Perspective	2	5[R+]
	Planning	4	6
	Acceptance	4	5
	Rumination	6	6
SCS-SF		49	46
PHQ-9		14	7[R+C+]
GAD-7		10	5[R+C+]
SWEMWBS		17	24[R+C+]
WSAS		8	6

[R]Significant reliable change

[C]Clinically significant change

[+]Significant improvement

[-]Significant deterioration

4.3.3 Additional SMA Data

SMA was completed to assess the cross-correlations within participants between their ER (DERS-SF) scores and low mood (PHQ-2) and anxiety (GAD-2) scores. Only the significant results were reported in the journal paper, and Table 10 outlines the full dataset of the SMA. Participant three had two significant positive correlations, participant five had two, and participant seven had three. Participants one, two, and four had no significant correlations. SMA could not be calculated for participant six due to the aforementioned constant within her low mood (PHQ-2) and anxiety (GAD-2) data (attaining the highest scores on the measures throughout). Hence, for participants three, five and seven, there were at least some cross-correlations between their ER, and psychological distress scores. There were no such cross-correlations for participants one, two, and four. Though overall, there was an ER-low mood (DERSSF-PHQ2) correlation at Lag0 of 0.41 and an ER-anxiety (DERSSF-GAD2) correlation of 0.42.

Table 10

Simulation Modelling Analysis Full Dataset

Ppt	DERS-SF and PHQ-9			DERS-SF and GAD-7		
	Lag-1	Lag0	Lag+1	Lag-1	Lag0	Lag+1
1	r=0.45, p=0.042	r=0.32, p=0.129	r=0.20, p=0.242	r=0.38, p=0.082	r=0.46, p=0.049	r=-0.01, p=0.490
2	r=-0.13, p=0.282	r=-0.00, p=0.509	r=-0.02, p=0.455	r=-0.07, p=0.384	r=-0.03, p=0.438	r=-0.36, p=0.045
3	r=0.27, p=0.142	r=0.69, p=0.001*	r=0.21, p=0.210	r=0.48, p=0.027	r=0.61, p=0.006*	r=-0.02, p=0.469
4	r=-0.14, p=0.371	r=0.19, p=0.338	r=0.12, p=0.407	r=0.21, p=0.247	r=0.42, p=0.094	r=0.11, p=0.355
5	r=0.48, p=0.035	r=0.47, p=0.037	r=0.59, p=0.008*	r=0.59, p=0.005*	r=0.49, p=0.030	r=0.44, p=0.044
6	†	†	†	†	†	†
7	r=0.67, p=0.01*	r=0.77, p=0.002*	r=0.74, p=0.003*	r=0.52, p=0.024	r=0.49, p=0.038	r=0.31, p=0.141

*Significance at the Bonferroni-corrected alpha significance level of p=0.017

†Participant six had a constant in her PHQ-2 and GAD-2 data, hence, correlations and significance levels could not be calculated

4.3.4 Reflexivity

Olmos-Vega et al. (2023) defined reflexivity as “a set of continuous, collaborative, and multifaceted practices through which researchers self-consciously critique, appraise, and evaluate how their subjectivity and context influence the research processes”. Hence, due to the nuanced nature of qualitative data, there was a need to reflect on my subjective experience and context as a researcher. To mitigate the impact of my biases, I kept a reflective diary throughout the study to ascertain my reflexivity. Regarding the sample, I have lived experience of depression and anxiety, and I have previously accessed a different NHS Talking Therapies service. In my diary, I reflected on whether this was why I selected this client group for the study, though I do not feel that this bias confounded my reasoning or interpretation of the study. In addition, my supervisors felt that this client group was the most logical group to recruit from, due to the type of conditions and uni-professional context.

Another potential area of bias was Elitsa’s involvement in the study: Elitsa is an app developer, and she created Betwixt. Throughout the study, she provided information and app access; however, she was not involved in data collection or analysis. As a result of her not being involved in the data or having any interaction with the PIC site clinicians or participants, this risk should have been minimised. In addition, I have only had brief interactions with her as the researcher, mostly via email, to minimise the risk of bias. Prior to the study, Elitsa had approached the University of Nottingham to request independent empirical testing of Betwixt (please refer to extended paper section 4.1.3 for more detail). I was aware that she had wanted independent testing, which enabled me to feel comfortable with the potential of finding negative results. At the start of the research, the research team and Elitsa created a research agreement, which outlined that the research would be independent and that positive, mixed, or negative results would be submitted for publishing. In addition, I have not yet consulted Elitsa to provide her with the results of the study, to minimise any bias whilst authoring this paper. Throughout my reflective diary, I considered how Elitsa’s involvement could have biased the study; however, I feel that precautions were taken to mitigate this risk.

Throughout the study, I informed the PIC site clinicians (during training, presentation in Appendix 5.12) and participants that I was independent, and not affiliated with the app. I did this to encourage the clinicians and participants to feel able to discuss any negative views of the app, without fearing that they would cause offence. I reflected in my diary that this appeared to be effective as the participants intermittently discussed perceived disadvantages of Betwixt during their check-in calls.

Throughout the study, I had interacted with the participants during the consent process, sending of surveys, and weekly check-in calls. This could have been an area of bias as the participants may have wanted to provide positive data, due to their relationship with me. Hence, the study was designed with an independent interviewer collecting the qualitative data. The interviewer had no vested interest in the project, minimising the risk of them biasing the questions. In addition, the participants were told that the interviewer was independent, hopefully enabling them to feel able to truthfully discuss their views of Betwixt. I also gave the interviewer no information about the participants (other than their name and contact details for logistical purposes) or their data, so as not to bias her interviewing.

I have somewhat of a vested interest in the study succeeding as it partially fulfils the requirements of my doctorate. However, I reflected in my diary upon not needing a positive result, that any result would be beneficial to the field of clinical psychology. Having an independent interviewer and reflecting on my own vested interest in the study enabled me to mitigate this bias. Finally, I did not use Betwixt until the end of data collection, to minimise the risk of my opinion affecting how I approached the recruiting clinicians, participants, or interviewer. I hold a somewhat positive view of Betwixt, as I found it interesting, though it is worth noting that I was not experiencing clinical symptoms. There were some aspects of Betwixt that I found negative, for example, some of the vocabulary was complex and I hypothesised that it may not be accessible for some individuals, due to the complex language and abstract nature of the narrative. Throughout my reflective diary, I reflected on my views of Betwixt and how it may impact my conduct. I attempted to instil a neutral stance to the recruiting clinicians, participants, and interviewer to mitigate this bias.

4.3.5 Additional Qualitative Data Analysis

The qualitative results from the interviews and survey were concordant with ER theory, and theory of the two ER skills of cognitive reappraisal and self-compassion. The participants reported that Betwixt enabled them to learn and reflect (code 3.1) and gain new and more positive perspectives (code 3.2). This was in keeping with cognitive reappraisal and ER theory, for example Lazarus and Folkman (1984) stated that cognitive reappraisal entails reframing and reinterpreting situations; and Lazarus and Alfert (1964) discussed the importance of interpretating events and appraisals in ER. In addition, one participant reported that Betwixt improved their anxiety (code 3.7) and Gross (1998a) stated that effective cognitive reappraisal can improve negative emotions. Thirdly, in the interviews, the participants were asked whether using Betwixt had affected their ability to respond to stressful situations (cognitive reappraisal). Half of the participants felt that using Betwixt had improved their cognitive reappraisal (code 7.1), however, the other half felt that cognitive reappraisal was still difficult following Betwixt use (code 7.2).

Codes referring to self-compassion seemed to occur more frequently than codes referring to cognitive reappraisal, which contradicts that most ER research has focused on cognitive reappraisal (McCrae & Gross, 2020). One participant reported that using Betwixt enabled them to ‘love themself again’ (code 3.6), which is concordant with self-compassion theory (being kind and understanding toward oneself; Neff, 2003). Three participants reported that using Betwixt normalised their difficulties and enabled them to feel understood (code 1.3), which Neff (2003) outlined when discussing that “one’s experience is seen as part of a larger human experience”. Similarly, one participant reported feeling better able to cope following Betwixt use (code 1.4) and Stutts (2002) proposed that self-compassion therapies may support individuals with coping. When the participants were asked about shared values between themselves and Betwixt, one participant reported self-compassion (code 4.3) and one stated caring (code 4.4). These values appear to be related to self-compassion and Neff’s (2003) definition of this construct. Finally, the participants were specifically asked about whether using Betwixt had affected how compassionately they felt toward themselves (self-compassion). Most of the

participants felt that using Betwixt had improved their self-compassion (code 7.3) and a few felt that self-compassion was still challenging following use of the app (code 7.4).

In addition to Betwixt impacting upon the two ER skills of cognitive reappraisal and self-compassion, it also appeared to impact the participants' overall ER. Gross (1998b) and Gross and Muñoz (1995) defined ER as: Shaping one's experience and expression of emotions and regulating positive and negative emotions. The participant Lynne stated, "it made me look at what I was feeling and take stock" and Sharon stated, "I was very down on myself before, very focused on my sort of negative feelings. Whereas…as it stands today, I don't feel negative about myself at all". These quotes appear to indicate that using Betwixt enabled them to gain insight into their emotions. This was furthered by codes 3.1 and 3.2: Betwixt enabled the participants to learn and reflect; and gain new and more positive perspectives on themselves. In section 4.1.2, it was explained that the majority of the ER literature focused on intrapsychic process (as opposed to relational interactions), and that this was evident by the design and development of Betwixt. The participants overwhelmingly discussed how Betwixt had supported them on an individual basis, for example to learn and reflect on themselves (code 3.1), gain perspective on themselves (code 3.2), love themselves (code 3.6) and being more self-compassionate (code 7.3). None of the codes referred to relational processes, such as the impact of Betwixt on seeking the support of others to regulate emotions (Zaki & Williams, 2013) or attempting to change other's emotions (Niven, 2017). This focus on individual processes is congruent with the evidence-base of ER and the intrapsychic focus of the app (on cognitive reappraisal, self-compassion, values, drives, self-distancing, self-destructive behaviour, meditation, responses, strengths, negative self-talking, and reframing difficulties). In conclusion, Betwixt appeared to support the participants' ER, however, participants still reported some difficulties with cognitive reappraisal and self-compassion, following app use.

The qualitative results were also concordant with Sekhon et al.'s (2017) theoretical framework of acceptability (including affective attitude, perceived effectiveness, ethicality, intervention coherence, opportunity costs, burden, and

self-efficacy). The participants appeared to have a positive attitude toward Betwixt as they viewed it positively (code 1.1), perceived it to have positive benefits (theme 1) and they spoke positively about its features (theme two). Some burdens were reported (theme six), however, Sekhon et al. (2017) outlined that participant dropout is a key indicator of burden and there was limited dropout in this study. Half of the participants reported that Betwixt aligned with their values and some suggested shared values with the app, hence, the app appeared to be ethical for the participants (theme four). The participants appeared to have a firm understanding of Betwixt, they stated that they understood what it was aiming to do, and they viewed this positively (theme three). Some opportunity costs were reported (theme five), though the participants also reported that the effort was worthwhile (code 5.7). Regarding perceived effectiveness, most of the participants reported that Betwixt was effective (theme three) and all participants reported that it enabled them to learn and reflect on themselves. The participants also reported self-efficacy and that they felt able to continue to use Betwixt (theme four). Hence, comparing the interview and survey data to Sekhon et al.'s (2017) construct of acceptability suggests that overall, the app was deemed to be acceptable to the participants.

The qualitative results were also concordant with FM theory as there was a combination of deductive and inductive themes (Trochim, 1999), as existing ER (e.g., Gross, 1998b), acceptability (Sekhon et al., 2017) and change (Elliott, 2006) theory were used, and the participants also brought new inductive aspects. Most of the final themes were deductive and based on these theories. Theme two was a somewhat inductive theme ('features enhance experience'), as this was not asked about specifically in the topic guide. Combining deductive and inductive themes is coherent with Gale et al.'s (2013) method (Goldsmith, 2021).

The qualitative results were also concordant with the epistemological position of pragmatism (outlined in sections 4.2.3 and 4.2.10). Pragmatism emphasises practicality, judgement, experience and using "what works" when gaining empirical knowledge (Howe, 1998). The results from this study were interpreted using the foundations of pragmatism. Additionally, the researcher attempted to mitigate her biases by keeping a reflective diary and attempting to instil a

neutral stance (section 4.3.4 outlined the researcher's reflexivity and biases). Reflection and reflexivity appeared to be effective as the participants disclosed aspects of the app and study which they viewed negatively. In addition, the wider research team also provided opinions on the qualitative data analysis to ensure quality assurance.

Analysing the qualitative results, it was concluded that the participants had positive, negative or mixed views. This was ascertained as there appeared to be individual differences on views of Betwixt: Sarah, Sharon, and Lucy (participants four, five, and six) seemed to have more positive perspectives; Christine and Carol (participants two and seven) had mixed views; and Lynne (participant three) had a more negative opinion. This was deduced from watching their recordings and reading the transcripts to ascertain their overall opinion of Betwixt. Appendix 5.13 contains quotes from each of the participants, demonstrating the overall views of each participant, to contextualise the findings of this study. This includes some additional quotes which were not included in the journal paper. The participants have been grouped according to whether they had positive, negative or mixed views, and the quotes have been separated according to whether they were discussing more positive or negative opinions. The quotes pertaining to the study design and check-in calls were removed as these quotes were not deemed a reflection of the app. It is also worth noting that Lynne (participant three) completed a survey, hence, she had a smaller volume of data and quotes than the other participants who completed interviews.

4.3.6 Check-In Call Data

For the seven completer participants, there were 29 check-in calls. On 13 additional occasions, check-in calls took place via email, due to participants not answering their phones or the researcher being on annual leave (on four of those occasions participants did not reply to the emails). The mean length of the check-in calls was three minutes and 15 seconds. The full dataset for the length of the check-in calls is documented in Table 11. It is worth noting that 15 of the calls (52%) lasted less than one minute. Also, the four longest calls were from

the same participant, hence, there are likely individual differences in needs for check-in calls. The participants intermittently discussed their experience of using Betwixt during their check-in calls, including perceived benefits and limitations. This information contextualised the researcher's understanding, though it was not used as qualitative data in the analysis, which was purely derived from the interviews and survey.

Table 11

Check-In Call Duration

Call duration in minutes	Number of calls
0-5	24
5-10	2
10-15	2
15-16	1

4.4 Extended Discussion and Reflection

4.4.1 Original Contribution to Knowledge

The current study is an original contribution to knowledge, as it is the first study to have evaluated Betwixt within a clinical population. It indicates the feasibility, acceptability, and effectiveness of a narrative-based ER gaming app. It also provides recommendations for future research to further evaluate this intervention.

The design of this study was also innovative and could be replicated to evaluate mHealth apps. As previously stated, mHealth is a growing area, yet there is currently no database of recommended apps within the NHS and there is an onus on healthcare organisations to assess each app at the point of procurement (NHS Apps Library, 2021; NHS England, 2021). Hence, healthcare organisations and academic institutions could use the design of this study to initially assess whether further evaluation of an app is indicated.

In addition, the SMA results provided a novel finding, which is an original contribution of knowledge. Upon reviewing literature only one similar finding could be found: Dunn et al. (2019) used SMA to identify temporal cross-correlations between low mood and mental wellbeing. However, no studies could be found which assessed temporal correlations between ER and psychological distress. The SMA results also reinforced the assumptions of this study, that ER and psychological distress may impact each other, and that ER may be a transdiagnostic factor underlying various mental health conditions, which could be targeted through interventions.

4.4.2 Relationship to Existing Literature

The results from this study contribute to the evidence-base and are in keeping with existing literature. For example, previous literature reviews (Eisenstadt et al., 2021; Harper et al., 2025b) found that ER apps have “promising outcomes”, and that could be suggested of the current results. Eisenstadt et al. (2021) discussed the potential benefit of future studies incorporating a mixed-methods design to deduce the potential limitations of technology or app features in psychological support. The current study utilised a mixed-methods design, and found results about technology and app features, though this was specifically about Betwixt (not ER apps in general). The age group for this review was 18-45 years and, hence, three of the participants from the current study were outside of this range and the results may not have been generalisable to them. No reviews of ER apps could be found in their age group. Harper et al. (2025) also reviewed individuals aged 18-45 years, which may not be generalisable to all the participants in this study. They recommended future research, including evaluating the effectiveness and acceptability of such interventions, which was completed in the current study.

Previous research on Betwixt in a general population (Dermendzhiyska et al., 2025; Masselink & Scholten, 2025) concluded that Betwixt was acceptable and improved clinical outcomes, which is consistent with the current findings, though in a clinical population. It is worth noting that Masselink & Scholten (2025) took place within the Netherlands and, hence, the results may not be generalisable

to individuals from the UK. In addition, it researched a general population and would not be appliable to the participants of the current study.

Another important consideration is Marshall et al.'s (2019) finding that 5% of apps have been evaluated rigorously. Betwixt has been assessed in numerous studies (Dermendzhiyska et al., 2025; Masselink & Scholten, 2025), which is a benefit of the app. In addition, the current findings are coherent with Patel et al.'s (2020) findings and suggest that check-in calls may be beneficial. Finally, this study is consistent with the initiative within the NHS toward digital interventions (Streeting, 2024) and preventing worsening outcomes whilst waiting (Van Dijk et al., 2023).

4.4.3 Clinical Practice Implications

The findings demonstrate that Betwixt has promise as a clinical intervention, and that upon further evaluation, individuals on waiting lists could be directed to it. As discussed in previous sections, the design of this study could be replicated to evaluate the feasibility of other mHealth apps.

Another clinical practice implication of this study is in the application of check-in calls. Previous research has found that any human contact during an intervention increases engagement (Patel et al., 2020), and participants of the current study reported an overall positive view of the check-in calls. Hence, check-in calls could be implemented as part of guided self-help interventions, or proactive contacts could be made to support engagement.

The findings also suggest that ER apps could be used as a waiting list intervention, to prevent worsening symptoms, or perhaps to prepare an individual for talking therapy.

4.4.4 Future Research

The current study indicated that Betwixt may be beneficial for individuals from a clinical population, experiencing depression or anxiety disorders and does not seem to be iatrogenic or unsafe, as the participants did not report any harmful

or dangerous aspects to the app in their interviews or check-in calls. They reported some aspects that they did not like, however, they did not designate any of these as unsafe. Though it is worth noting that information on adverse events was not routinely collected as part of the SCED design. Additionally, Sekhon et al. (2017) outlined that acceptability includes the seven component constructs of affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy. The participants appeared to have a positive affective attitude toward Betwixt as they discussed positive views of app features (theme two) and perceived positive benefits of the app (theme one). The participants reported some burdens (theme six), however, there was limited dropout in the participants who used Betwixt, which Sekhon et al. (2017) suggested would be indicative of burden. Regarding ethicality (theme four), half of the participants reported that the app aligned with their values, and some of the participants suggested shared values between themselves and the app. For intervention coherence, the participants seemed to understand the intervention and spoke about it positively (participants discussed perceived effectiveness from theme three when asked about intervention coherence). The participants reported some opportunity costs (theme five), though half of them also reported that the effort required was worthwhile (code 5.7). Most of the participants perceived Betwixt to be effective (theme three), and all the participants reported that it enabled them to learn and reflect on themselves. Finally, regarding self-efficacy, most of the participants reported that they were able to continue to use Betwixt (theme four). Hence, using Sekhon et al.'s (2017) seven component constructs of acceptability, Betwixt was overall deemed to be acceptable in this study. Hence, future research could include a large-scale study into the effectiveness of Betwixt within a clinical population of individuals experiencing depression or anxiety disorders, such as, a randomised controlled trial or a multi-site SCED. The initial study into Betwixt in a general population (Dermendzhiyska et al., 2025) was smaller scale, before a larger scale study was completed (Masselink & Scholten, 2025). Hence, the logical next step may be to assess the effectiveness of Betwixt on a larger scale, especially as the current study suggested that it may be acceptable.

Other future research may include a longer-term study of the impact of Betwixt, such as, testing over a longer period or including a follow-up condition. This may provide interesting findings about the long-term impact of such an intervention. Betwixt could also be evaluated based upon the impact of using the intervention prior to, or concurrently with, talking therapy. This may evaluate whether Betwixt prepares clients with preliminary skills for individual therapy.

The current study recruited participants from an NHS Talking Therapies service, as these support individuals with “depression and anxiety disorders that can be managed effectively in a uni-professional context” (National Collaborating Centre for Mental Health, 2024). In future, it may be useful to evaluate whether comparable results on effectiveness and acceptability would be found in individuals with other mental health conditions, such as, psychosis, bipolar disorder, or personality disorder. If comparable results were found, the number of individuals who could be supported by such an intervention would be higher.

Given that two of the participants reported that factors outside of the study had impacted them, future research may include a specific question about this topic. Elliott’s (2006) Client Change Interview Schedule included a question about attributions of the results, and it perhaps would be beneficial to include this question in future research. This could also include observer-rated data, as well as self-reported data. The SMA results indicated that individuals may be able to use strategies to train their ER, hence, future research may include interventions which target ER, in order to improve low mood or anxiety.

4.4.5 Appraisal and Evaluation of Study

Prior to appraising a single-case design, it needs to be deemed eligible for review (Institute of Education Sciences, 2022). The eligibility criteria for review of a single-case design include: “An individual case is the unit of intervention administration and data analysis; within the design, the case can provide its own control for purposes of comparison; and the outcome variable is measured repeatedly within and across different conditions” (Institute of Education Sciences, 2022). The current study met these criteria as there were seven individual cases; the participants functioned as their own control conditions

(between the baseline and treatment phases); and the outcome variables were repeated consistently across both phases. In order to systematically appraise the journal paper, What Works Clearinghouse criteria (Monahan et al., 2011) were used. Table 12 outlines these criteria and whether they were met.

Table 12

What Works Clearinghouse (Monahan et al., 2011) Criteria for Appraising The Journal Paper

What Work Clearinghouse Criteria	
Design criteria	Criteria met?
1. The independent variable (i.e., the intervention) must be systematically manipulated, with the researcher determining when and how the independent variable conditions change.	Yes: Betwixt intervention.
2. Each outcome variable must be measured systematically over time by more than one assessor, and the study needs to collect inter-assessor agreement in each phase and on at least twenty percent of the data points in each condition (e.g., baseline, intervention) and the inter-assessor agreement must meet minimal thresholds.	Yes: All outcome measures had sufficient psychometric properties.
3. The study must include at least three attempts to demonstrate an intervention effect at three different points in time or with three different phase repetitions.	Yes: More than three participants.
4. For a phase to qualify as an attempt to demonstrate an effect, the phase must have a minimum of three data points and preference is given to 5 data points per phase.	Yes: All had three or more data points.
Relation between an independent and outcome variable	Criteria met?
5. Documenting the consistency of level, trend, and variability within each phase.	Yes: Visual analysis.
6. Documenting the immediacy of the effect, the proportion of overlap, the consistency of the data across phases in order to demonstrate an intervention effect and comparing the observed and projected patterns of the outcome variable.	Yes: Structured visual analysis.
7. Examining external factors and anomalies (e.g., a sudden change of level within a phase).	Yes: Visual analysis.
Usefulness/applicability of method	Criteria met?
8. Determining whether a causal relation exists between the introduction of an independent variable and a change in the dependent variable. For example, a research question might be “Does Intervention B reduce a problem behaviour for this case (or these cases)?	Yes: Study aims and discussion section.
9. Evaluating the effect of altering a component of a multi-component independent variable on a dependent variable. For example, a research question might be “Does adding	Not applicable: One

Intervention C to Intervention B further reduce a problem behaviour for this case (or these cases)?	intervention was tested.
10. Evaluating the relative effects of two or more independent variables (e.g., alternating treatments) on a dependent variable. For example, a research question might be “Is Intervention B or Intervention C more effective in reducing a problem behaviour for this case (or these cases)?	Not applicable: One intervention was tested.

In reference to the design criteria, the independent variable (Betwixt intervention) was systematically manipulated by the researcher as there was a baseline phase, followed by the Betwixt treatment phase. Each outcome measure was measured systematically over time, by one assessor in each case. This criterion was deemed to be met, as the outcome measures used all had sufficient psychometric properties and inter-rater reliability. Regarding the third criterion, the study used an AB design which only includes two phase repetitions, however, due to it being a case series, it included more than three participants repeating this design. All participants had at least three data points in each phase. Participant three only used Betwixt twice and, hence, her data was used as a comparison for an individual on a waiting list. Regarding the relationship between the independent and outcome variables, the phase trends were assessed during the structured visual analysis, including the level, trend, variability, immediacy of effect, proportion of overlap, consistency across data, external factors, and anomalies. Regarding the usefulness and applicability of method, the study aims, and discussion section of the journal paper outlined the causal relationship between the Betwixt intervention and outcome variables. The final two criteria were rated as ‘not applicable’ as they were referring to multi-component independent variables and this study only had one independent variable (the Betwixt intervention).

This study had numerous strengths, such as, that it fit the applicable criteria above, and all the study aims were met. The sample size was also sufficient as it exceeded the minimum requirement of three participants (Kratochwill et al., 2010) and the published average of six (Smith, 2012). In addition, as previously discussed, the results add to the existing literature and provided an original contribution to knowledge.

This study had numerous limitations: Firstly, all the participants were female. Two males were recruited; however, they withdrew prior to initiating the treatment phase. Hence, the results may not be representative of the wider population of NHS Talking Therapies patients or generalisable to individuals who are not female. To overcome this concern, one improvement could have been to have continued recruitment to include individuals who are not female, however, this would have required more time, resources, and funding. Data has found that fewer males tend to access NHS Talking Therapies services than females, however, they tend to represent 36% of referrals, as opposed to 20% in this sample (NHS Digital, 2018). Gender differences have also been found in ER, as females report using more ER strategies than males, though females tend to ruminate (ER strategy) more, which is believed to account for the greater prevalence of depression and anxiety in this group (Nolen-Hoeksema, 2012; McManus et al., 2016). It is also worth noting that more males tend to be gamers than females (Shaw, 2012), hence, it is surprising that more males did not participate, given that Betwixt is a gaming app. However, there is nuance to the gender differences in gamers, as though more males tend to be gamers than females, older female gamers (like most of the participants) tend to play for longer durations than males (Williams et al., 2009).

Secondly, the study used an AB concurrent multiple baseline design, which evaluated one intervention. An ABA design would have been more statistically robust; however, they have methodological concerns (forgetting learning from an intervention) and ethical issues (withdrawing an intervention). An alternative may have been to have used an ABAB design (two phases of no intervention, and two phases of intervention) or perhaps an ABC design (an additional intervention, as well as Betwixt). These would likely have increased statistical robustness, though there were no specific concerns about the robustness of this study, and the other designs would have required more time and resources.

Thirdly, this study relied upon self-report data, which can be subjective and susceptible to bias (Tarescavage, 2022). To potentially overcome this, observer-rated data could have been collected and compared to self-report data. This would also be in keeping with Monahan et al.'s (2011) criteria that questionnaires should ideally be completed by more than one assessor, with

inter-assessor agreement, though this would likely have required more time and resources.

Fourthly, two of the participants reported that other factors had also impacted the changes observed during the study (code 3.10). Morley (2018) identified that extra-treatment events can be a threat to internal validity in single-case methods and should be excluded to ensure that any observed changes are attributable to the intervention. In addition, interviews can be viewed as a "co-construction" whereby the interviewee's views are impacted by their context and reconstruction of events (Pasupathi, 2001). Hence, the participants may have been affected by a variety of factors including demand characteristics or social norms, which could have impacted their responses to the questions, though this would likely also be true of alternative designs.

Finally, the check-in calls may have been a confounding variable. When the study was designed, it was acknowledged that check-in calls could have complicated understanding of Betwixt-specific change processes, as the participants were interacting with the researcher. As such, the intervention was guided self-help (receiving support through check-in calls), as opposed to self-directed (no external support). Hence, every check-in call was documented to ensure that they included practical support (as opposed to therapeutic input), and the participants were asked about their experience of the calls in their interviews. The average length of the calls was quite short (three minutes), and the participants reported in the interviews that they mostly found the calls helpful.

4.4.6 Critical Reflection on Study Process

This section outlines my critical reflection on the process of this study. I used my reflective diary, which I completed throughout the study, to inform this reflection. I have ordered this section chronologically, according to the different phases of the study, including project design; ethical application; recruitment and data collection; and data analysis. It is worth noting that some of the stages occurred concurrently, for example, I started analysing the data during data collection, however, I have used these headings to structure my reflection.

Project Design. I was initially drawn to evaluating Betwixt for my thesis as I have an interest in digital technologies and how these can support healthcare. Prior to starting the doctorate, my cohort were provided with a list of potential subject areas for our theses, and I was excited about the prospect of this project from the start. I was also interested in the potential design of a SCED series, as I have previously completed a SCED for my master's degree and I had observed the utility of such a design. During this stage of the project, numerous governance decisions were made, such as, creating the research agreement with Elitsa and creating the contract. This felt positive as they outlined that the app developers wanted independent testing of Betwixt and that they would not be involved in data collection or analysis. I received generally positive feedback from independent course staff regarding my project, in both a research project proposal panel and research annual review. It felt encouraging and reassuring that my project was deemed appropriate for doctorate-level research. They also made useful recommendations, such as, for check-in calls, contingency for surveys, participant remuneration, and service user involvement, which were incorporated into the final study design. We had some difficulties regarding identifying a service as the participant identification centre. Initially, we approached the local NHS Talking Therapies service as they had previously taken interest in research and digital technology. However, it was not feasible to complete the study in their service as their waiting times were less than seven weeks, and it would probably have been unethical to delay participants' Talking Therapies treatment. Hence, we approached a different service who had a feasible waiting time and were enthusiastic about the project. This was the service that became the PIC site, and I was grateful to them for agreeing to support my study. During this time, I also completed two university assignments on my project: Research protocol and systematic literature review. The protocol was a helpful assignment as it supported me to design my study and critically consider facets of the study. I passed this assignment and received overall positive feedback (with some recommendations), which felt positive. I found the systematic literature review to be stressful as I was overly ambitious and attempted to review thousands of papers, which was not feasible due to time constraints. I sought feedback from my supervisors and limited the criteria, which made the assignment more feasible. I am grateful that I passed

this assignment, and I think that I learnt a lot about myself through this process: I can be overly ambitious and prone to taking on too much responsibility, which can lead to me feeling overwhelmed. In the future, I will attempt to be realistic about what can be achieved within a time-frame and seek advice sooner, from experts, about feasibility.

Ethical Application. The ethical application process was time-consuming, especially given that at the start I was still completing my systematic literature review. After contacting the university sponsor department, I started completing my application on IRAS. I noticed some interesting parts of this process, such as, that although it was my thesis project, I could not be the chief investigator as I was not an employee of the university. I also perceived that the IRAS system was not very user-friendly and requesting all my supervisors to authorise the document simultaneously required some organisation. After submitting my application to the sponsor, I did not receive any further communications from them. After a month, I contacted them, and they informed me that my application had been “lost”. I found this frustrating as I had attempted to be organised and prompt, yet my project may have been delayed because of something outside of my control. The sponsor department were apologetic and expeditiously reviewed my application, of which I was grateful. During this time, I also requested feedback from the local service user and carer group. The individual did so very quickly and provided detailed feedback, which I appreciated. I submitted my application on IRAS prior to Christmas 2023, which was stressful to complete within the time-frame, however, I also felt a profound sense of achievement given the previous barriers. After Christmas, I started to prepare for the REC panel with support from my supervisors. I felt quite confident in my project, though I was nervous beforehand. The panel took place via Zoom and overall, the panel felt quite positive. They asked me four questions, all of which I felt able to answer confidently, and as a result, I felt relieved. The panel asked Jacob to attend as the chief investigator and after the meeting, we debriefed. Jacob gave me positive feedback about my presentation and commented on how many people had attended. Luckily, I could only see five attendees, due to the configuration of the Zoom call, however, Jacob informed me that there were over 20

individuals present. I was grateful that I could not see all the attendees as this could have led to me feeling more nervous. Thankfully, my ethical application was approved, to which I was grateful. After the approval, there were a few months before I could start recruitment due to needing to complete PIC site capacity and capability; PIC site agreement; staff training; and inputting the surveys onto QuestionPro. This waiting time was somewhat frustrating as I wanted to start recruitment, however, it enabled me to prepare for the study and to set up systems and pathways.

Recruitment and Data Collection. I felt excited about starting recruitment and data collection. In the first week of recruitment, one participant consented, and this felt positive. There was then a period whereby there were no new potential participants and then there were some, however, they did not consent to the study. I found this challenging as I had assumed that individuals would want to participate in the study. This was quite naïve of me and was perhaps a reflection of my unrealistic expectations. In supervision, I discussed this difficulty, and we agreed to change the recruitment strategy to increase the number of potential participants. This change appeared to help, and new participants were recruited. There was then a difficult period for me as I was feeling stressed due to completing a service evaluation and various personal factors outside of work. At this time, three participants withdrew in succession, and they had not provided sufficient data (which could be analysed). I found this challenging, and I felt quite out of control at this time. Thankfully, the final three participants were recruited soon after, which was a relief. There were some challenges as one of the recruiting staff members changed roles, which meant that she was completing fewer assessments and would likely identify fewer participants. In addition, one of my supervisors was promoted and was no longer going to be supporting my thesis. I was happy for him; however, I was somewhat disappointed that he would no longer be involved, as he had been helpful throughout this process. Luckily, another supervisor with great expertise in mHealth agreed to be my new supervisor, which was appreciated. Overall, I found recruitment and data collection difficult. I felt out of control for most of the time as recruitment was dependent upon the PIC site recruiters and participants who were volunteering to take part. However, I was grateful to the PIC site, and

this experience instilled in me how valuable participants are and that they have lives outside of a study. I also spent some time in this period using Betwixt. I found it immersive and evocative, and I felt that the imagery was beautiful. I also identified some limitations of the app, such as that it was quite abstract, and the language was complex. In supervision, it was agreed that recruitment could be closed, and this was a relief for me.

Data Analysis. I had a four-week period scheduled by university for starting data analysis. Initially, I felt enthused as this was all within my control and I had data to analyse. I started analysing the completed quantitative data and this felt productive. After a few days, I started to feel anxious as it was unusual for me to spend eight hours working alone for five days per week. I discussed this with my supervisors who encouraged self-care and for me to schedule more breaks. As a result, I went to the gym every morning before work, which helped me to feel less anxious, whilst still being productive. I started to analyse the qualitative data, which was thought-provoking, though I had some difficulties with the automated transcription service, which was frustrating. I found this four-week study period helpful, and I enjoyed immersing myself in the data, especially as I had spent two years on this study. I immersed myself in the data by initially watching each recording on one to two occasions, just focusing on the content and not transcribing or coding. I then watched the recordings two to three more times to ratify the accuracy of the automated transcription and correct any errors. Finally, I read through each transcript at least once, before then coding them. By the end of the block, I felt tired, though accomplished. I then returned to placement and there were many competing demands at this time. I was stressed, and I wanted time to start drafting my thesis, though when I was able to start writing, I felt overwhelmed by the amount of writing required. I felt stressed as I had other commitments and personal demands, yet I wanted to author my thesis adequately. I discussed this in research supervision and my supervisors reassured me and supported me to look at it as a series of smaller tasks. We also reflected on my progress and that when reviewing my protocol, I felt that it was not written as well as I perceive that I write now. My supervisors supported me to gain perspective, and

I started to feel accomplished at authoring my thesis. In future, I will attempt to approach larger tasks as a series of smaller tasks.

Reflecting on this entire process, I feel proud of myself and what I have accomplished. I am proud of what I have completed, and I am grateful to everyone who has helped me.

Word count for entire portfolio (excluding references, tables, figures, appendices, and comments): 21,721

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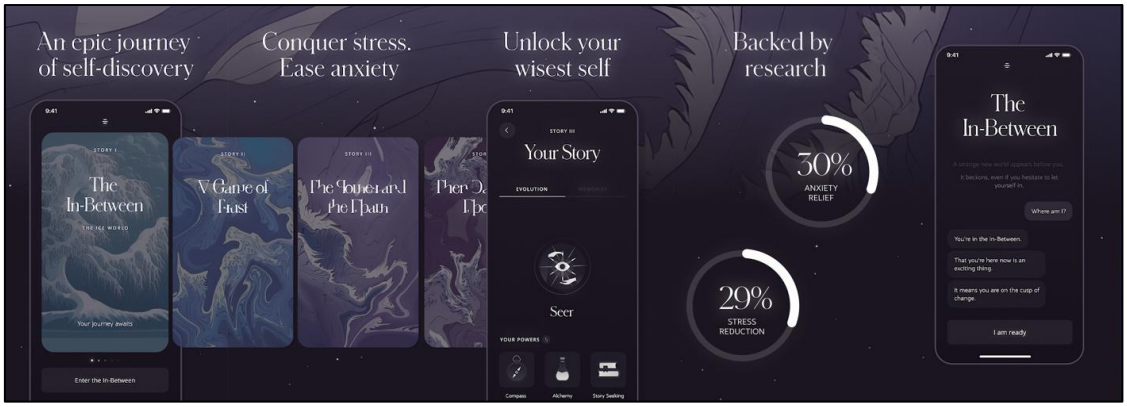
5. Appendices

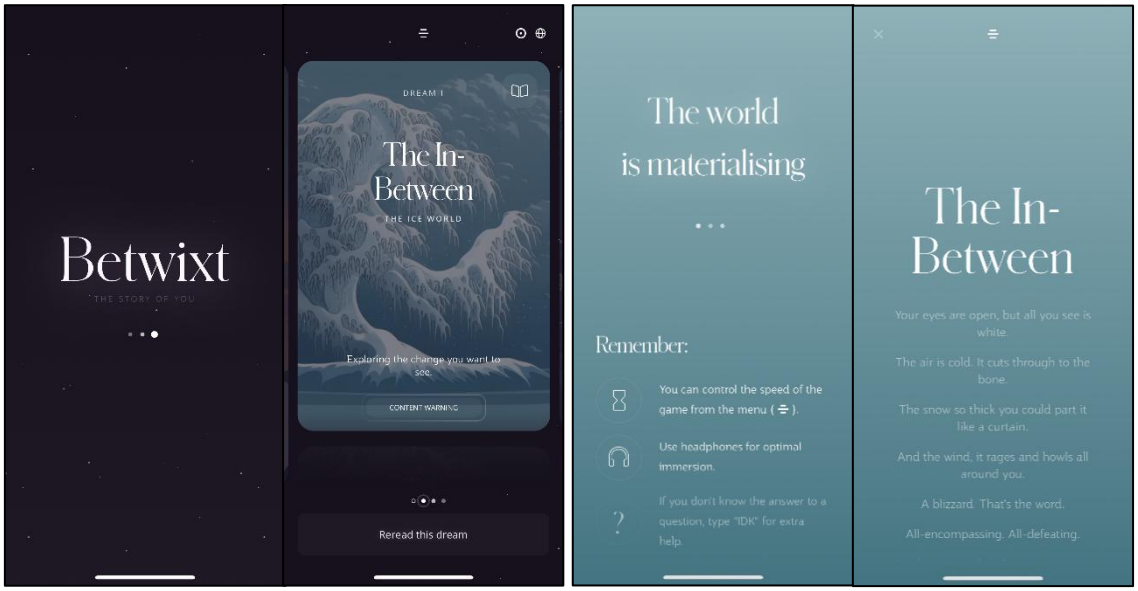
5.1 Betwixt App Imagery

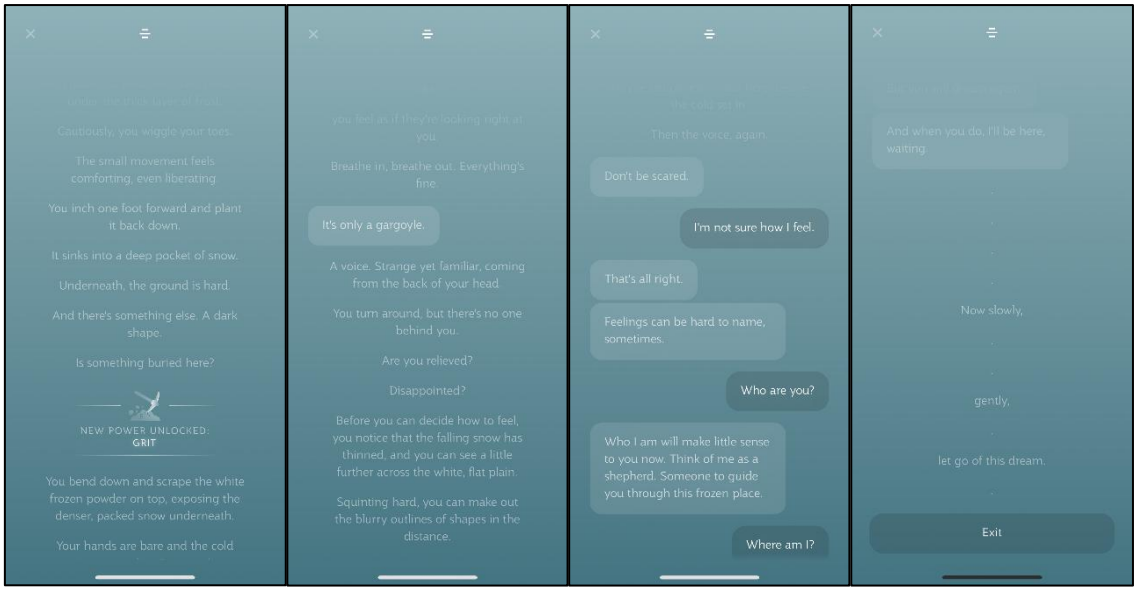
Betwixt icon:

Betwixt advertisement:



Betwixt dream imagery:





Betwixt QR codes:

5.2 Synopsis of Betwixt Content (Authored by the App Developer)

Dream	Content
1	Betwixt's first dream introduces the player to the weird and wonderful world of the In-Between — a magical landscape that responds to your thoughts and feelings, enabling immersive self-reflection action and awareness building. With the help of a mysterious guide known only as the voice, the player explores the question of what they want in life and how they'll know when they're moving in that direction. Dream one's extra info article explores the power of narrative and its role in self-development. - Primary focus: What do you want in life? How will you know you're moving in that direction? - Additional resources: The power of narrative and its role in self-development
2	In the second dream, the player deepens their relationship with the voice. They then explore the question of what they love or appreciate in the world before identifying their key personal values. Dream two's extra info article expands on prosocial behaviours such as the practice of gratitude and outlines a protocol for this, which — unlike most gratitude practices — is backed by neuroscience. - Primary focus: Key personal values - Additional resources: A protocol for gratitude based on neuroscience
3	In Dream three, the player reflects on their deeper, unconscious drives and patterns such as perfectionism, people-pleasing or overworking. At the close of this dream, the player begins some resourcing work as they mine their past for memories of safe, connected or inspiring places. Dream three's extra info article explains the concept of Drivers from Transactional Analysis. - Primary focus: Deep drives and unconscious patterns (e.g. perfectionism, people-pleasing or overworking) - Additional resources: The concept of Drivers from Transactional Analysis
4	In Dream four, the player learned how to self-distance — a simple but powerful tool for gaining perspective and processing difficult emotions or experiences. Dream four's extra info article elucidates the science behind self-distancing.

	- Primary focus: Self-distancing, a simple but powerful tool for emotion processing and stress regulation - Additional resources: The science behind self-distancing
5	Dream five asks the player to explore the connection between seemingly self-destructive behaviours and unmet needs. During their conversation with the voice in this dream, the player identifies a need they've been attempting to meet in less-than-healthy ways, and then converses with various "parts" of the personality to explore novel ways of meeting that need. Dream five's extra info article focuses on the concept of emotional literacy and teaches a simple tool for building both emotional literacy and the ability to know one's needs and how to fulfil them. - Primary focus: Self-sabotaging behaviours and unmet needs - Additional resources: Building emotional literacy and fulfilling your needs
6	The sixth dream of Betwixt is an action-packed adventure that asks the player to meditate on fear — what are they afraid of and how does that fear manifest? Dream six's extra info article discusses fear as an emotion and highlights a deceptively simple reframing protocol for times of undue nerves, such as dates, job interviews, public speaking and presentations. - Primary focus: What are you afraid of? How does this fear manifest? - Additional resources: A simple protocol to master anxiety before dates, job interviews or presentations
7	In Dream seven, the player discusses their most common reaction to threat — do they fight, flee, freeze or fawn? Armed with this information, the player deconstructs an automatic and problematic reaction to threatening people or situations, and finds a way to interrupt the pattern and take control. Dream seven's extra info article explains the four fear reactions (fight, flight, freeze and fawn/friend) in more detail and presents two zero-cost protocols for building resilience to everyday stress. - Primary focus: Taking control of automatic threat reactions (fight, flee, freeze, fawn) - Additional resources: Zero-cost protocols for building resilience to everyday stress
8	Dream eight is all about strength and skill. The player explores key moments from their life — times when they have felt engaged, inspired or

	otherwise in flow — and then uses this information to identify their own personal strengths. Dream eight's extra info article explains why it's better to focus on one's strengths than one's weaknesses and provides resources (including questionnaires) for exploring this further. - Primary focus: Your personal strengths - Additional resources: Why it's better to focus on strengths than weaknesses
9	In the ninth dream, the player discusses negative self-talk and/or self-conception with the voice and identifies the kind of narratives (limiting beliefs) at play in their life that they'd most like to rewrite. Dream nine's extra info article explains the Jungian concept of the Shadow Self and explores self-compassion as the answer to self-defeating stories. - Primary focus: Exploring your limiting beliefs - Additional resources: The Shadow Self and the power of self-compassion
10	In Dream 10, the player is given the opportunity to use self-distancing and/or creative visualisation to reframe their chosen negative story and dream up a better story to tell themselves. Dream 10's extra info article focuses on the fascinating science of memory and memory reframing. - Primary focus: Re-writing negative stories and limiting beliefs - Additional resources: The fascinating science of memory and memory reframing
11	In the final dream of Betwixt, key information from their journey gets fed back to the player, who's asked to reflect on their progress. To complete the experience, the player engages their creative mind to build a metaphorical world all of their own. Dream 11's extra info article explores the power of metaphor for personal change. - Primary focus: Architect your new home in the world - Additional resources: The power of metaphor for personal change

5.3 Research Ethics Committee Favourable Opinion Letter

Health Research Authority

London - London Bridge Research Ethics Committee
2 Redman Place
Stratford
London
E20 1JQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

30 January 2024

Dr Jacob Andrews
University of Nottingham
NIHR Mindtech, Institute of Mental Health
Jubilee Campus, Triumph Road, Nottingham
NG7 2TU

Dear Dr Andrews

Study title:	**Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?**
REC reference:	**24/LO/0079**
Protocol number:	**23064**
IRAS project ID:	**334141**

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 24 January 2024. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition
1	Please make the following changes to the Participant Information Sheet (PIS): a. Please reword the sentence "We cannot promise that the study will help you..." in the What benefits section of PIS to make it more neutral. b. In the "Who has reviewed" section of the PIS include details of London Bridge REC not just the University Ethics committee. c. Please add the flow chart 'Figure 1' from the Protocol to the PIS as an overview of the research procedures. d. In section A35 of the IRAS form it states that if the participant loses capacity, their identifiable data will be retained. Please update the PIS stating this.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Participant Debrief Form - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2023 - 2024 Evidence of Cover - Liability Insurance]	1	21 December 2023
Interview schedules or topic guides for participants [Topic Guide - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Interview schedules or topic guides for participants [Exit Survey - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
IRAS Application Form [IRAS_Form_10012024]		10 January 2024
Other [Betwixt content description]	1	10 January 2024
Participant consent form [Participant Consent Form - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Participant information sheet (PIS) [Participant Information Sheet (PIS) - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Research protocol or project proposal [Protocol - Betwixt Effective	1	21 December 2023

Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]		
Summary CV for Chief Investigator (CI) [CV Jacob Andrews - Betwixt Effective Acceptable Clinical Population Emotion Regulation]	1	21 December 2023
Summary CV for student [CV Victoria Harper - Betwixt Effective Acceptable Clinical Population Emotion Regulation]	1	21 December 2023
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [2023 - 2024 Evidence of Cover - Professional Indemnity]	1	21 December 2023
Validated questionnaire [CER-Q measure]	1	10 January 2024
Validated questionnaire [DERS-SF measure]	1	10 January 2024
Validated questionnaire [PHQ-2 and GAD-2 measures]	1	10 January 2024
Validated questionnaire [PHQ-9 and GAD-7 measures]	1	10 January 2024
Validated questionnaire [SCS measure]	1	10 January 2024
Validated questionnaire [SWEMWBS measure]	1	10 January 2024
Validated questionnaire [WSAS measure]	1	10 January 2024

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 334141	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

On behalf of

Ms Jane Smith
Chair

E-mail: londonbridge.rec@hra.nhs.uk

5.4 Ethics Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Jacob Andrews
University of Nottingham
NIHR Mindtech, Institute of Mental Health
Jubilee Campus, Triumph Road, Nottingham
NG7 2TU

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

08 February 2024

Dear Dr Andrews

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?**
IRAS project ID:	**334141**
Protocol number:	**23064**
REC reference:	**24/LO/0079**
Sponsor	**University of Nottingham**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **334141**. Please quote this on all correspondence.

Yours sincerely,
Anna Bannister

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mr Ali Alshukry*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Participant Debrief Form - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2023 - 2024 Evidence of Cover - Liability Insurance]	1	21 December 2023
Interview schedules or topic guides for participants [Topic Guide - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Interview schedules or topic guides for participants [Exit Survey - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
IRAS Application Form [IRAS_Form_10012024]		10 January 2024
Other [Betwixt content description]	1	10 January 2024
Other [PIC Agreement Document for Future Use - Betwixt Effective Acceptable Clinical Population Emotion Regulation - V1.0 21.12.2023]	1	21 December 2023
Participant consent form [Participant Consent Form - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Participant information sheet (PIS) [Participant Information Sheet (PIS) - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V2.0 30.01.2024]	2	30 January 2024
Research protocol or project proposal [Protocol - Betwixt Effective Acceptable Clinical Population Emotion Regulation - Final V1.0 21.12.2023]	1	21 December 2023
Summary CV for Chief Investigator (CI) [CV Jacob Andrews - Betwixt Effective Acceptable Clinical Population Emotion Regulation]	1	21 December 2023
Summary CV for student [CV Victoria Harper - Betwixt Effective Acceptable Clinical Population Emotion Regulation]	1	21 December 2023
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [2023 - 2024 Evidence of Cover - Professional Indemnity]	1	21 December 2023
Validated questionnaire [CER-Q measure]	1	10 January 2024
Validated questionnaire [DERS-SF measure]	1	10 January 2024
Validated questionnaire [PHQ-2 and GAD-2 measures]	1	10 January 2024
Validated questionnaire [PHQ-9 and GAD-7 measures]	1	10 January 2024
Validated questionnaire [SCS measure]	1	10 January 2024
Validated questionnaire [SWEMWBS measure]	1	10 January 2024
Validated questionnaire [WSAS measure]	1	10 January 2024

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Activities at NHS organisations will involve PIC activity only, including the identification of participants and database searches	NHS Organisations will not be required to formally confirm capacity and capability, and research procedures may begin **35**after provision of the local information pack, provided the following conditions are met. HRA and HCRW Approval has been issued The NHS organisation has not provided a reason as to why they cannot participateThe sponsor may start the research prior to the above	The sponsor has provided the appropriate model commercial PIC agreement that it intends to use as a subcontract between participating organisations and NHS organisations acting as their Participant Identification Centres (PICs).	Sponsor is not providing funding to PICs	The Chief Investigator will be responsible for all study activities performed at PICs.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access. These should confirm enhanced DBS checks and appropriate barred list checks.
	deadline if the participating NHS organisation positively confirms that the research may proceed. The sponsor should now provide the local information pack to participating NHS organisations in England and/or Wales. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please do so following the guidance available here.				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated they do not intend to apply for inclusion on the NIHR CRN Portfolio.

5.5 First Ethics Amendment for Change to QuestionPro

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Betwixt: Effective/acceptable clinical population emotion regulation?
IRAS project ID* (or REC reference if no IRAS project ID is available):	334141
Sponsor amendment reference number*:	NSA01
Sponsor amendment date* (enter as DD/MM/YY):	13 February 2024
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	This study received ethical approval on 08.02.2024. Whilst this process was underway, the researchers were sourcing access to Qualtrics (online platform used for centrally hosting questionnaires) (as outlined in the study documentation). Qualtrics no longer seems to be a feasible option, and QuestionPro will need to be used instead. No research has taken place yet and this should constitute a non-substantial change.

Project type (select):	**Specific study**	Research tissue bank Research database
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**	No
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**	Ministry of Defence (MoDREC)
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes	**No**

Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	**No**
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	**No**
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes	**No**
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes	**No**
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes	**No**
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	**No**
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes	**No**
Did the study involve children OR does the amendment introduce this?:	Yes	**No**
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**	No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	**No**

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	Amending the documentation from Qualtrics to QuestionPro.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	

Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Sarah Flynn
Email address:*	Sponsor@nottingham.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									A
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		

5.6 Second Ethics Amendment for Change to Sample Size

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Betwixt: Effective/acceptable clinical population emotion regulation?
IRAS project ID* (or REC reference if no IRAS project ID is available):	334141
Sponsor amendment reference number*:	NSA02
Sponsor amendment date* (enter as DD/MM/YY):	06 August 2024
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	This study received ethical approval on 08.02.2024. In the application, it was documented that the total sample size was eight, however, a few participants have withdrawn prior to providing any intervention phase data and, hence, their data cannot be used. The requested amendment is to change to a sample size of eight participants with replacement participants if the participants do not contribute sufficient data to the intervention phase. This should constitute a non-substantial change.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Changing from 8 maximum participants to 8 maximum participants who contribute sufficient dara to the intervention phase, with replacement for participants who do not. This can be implemented within the existing resource as the NHS site is a PIC site and the researcher is undertaking this for her doctoral thesis and can continue to recruit.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Add another change	

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Ali Alshukry
*Email address**:	sponsor@nottingham.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:				
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)				(Y)									C
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		

5.7 Participant Information Sheet

Participant Information Sheet

Final Version 2.0, 30th January 2024

IRAS Project ID: 334141

Title of Study: Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Name of Chief Investigator: Jacob Andrews

Name of Primary Investigator: Victoria Harper

This research is being carried out as part of a student study. We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have. Talk to others about the study if you wish and ask us if there is anything that is not clear.

What is the purpose of the study?

The purpose of this study is to test out a new narrative-based mental health application ("app") Betwixt, aimed at improving mental health. It consists of different stories, which are displayed in a written format, with background sound. Users are shown portions of the story, before being given options for proceeding further (e.g., 'cover your ears', 'look at the sky', or 'look down'). The story then continues, following the options chosen, and further stories and options are provided.

The study will involve using the app every two days and completing questionnaires. After using the app, interviews will be undertaken to gather feedback about using the app. Due to its narrative nature, Betwixt involves a lot of reading. This study is being undertaken as an educational project, as partial fulfilment of a doctoral qualification.

Why have I been invited?

You are being invited to take part because you are on the waiting list for Lincolnshire Partnership Foundation Trust Steps2change IAPT service. We are inviting eight participants like you to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or access to IAPT.

What will happen to me if I take part?

Following your assessment appointment, if you agree, your IAPT clinician will pass on your contact details to the researchers. They will then set up a video call with yourself to further explain the study and answer any questions you may have. You will be given plenty of time to consider whether you wish to participate, or not. The researcher will share their screen with you during the video call to record your consent if you choose to participate in the study.

Whilst waiting for the intervention with IAPT, participants will be asked to complete six questionnaires before starting the study. This should take less than an hour.

There will then be a two- or three-week period whereby you will complete three short questionnaires every two days. These should take less than 15 minutes. After this, you will get access to the Betwixt app. You will then be asked to complete a chapter of the app every two days, over a four-week period. This should take 20-60 minutes. The three short questionnaires will also need to be completed at the same time.

A researcher will call you every week for a check-in to discuss any logistical or practical issues you may be experiencing. This should take no longer than ten minutes.

At the end of the four-week period, you will be asked to complete the initial measures again. Your participation will take either six or seven weeks in total. You will then be interviewed by an independent interviewer to gain feedback about the app. The interviews will take place online (via Microsoft Teams) and these should take approximately 30 minutes. These interviews will be video and/or audio recorded, depending on your preferences as to whether the camera is kept on during the interview. The recording will then be transcribed by the University of Nottingham's automated transcription service, and they will protect your confidentiality. The researcher will then check the transcription for accuracy. Each audio recording will be deleted after transcription and the transcription process will take up to two months from recording to transcription.

All of these steps are essential requirements of this study. This study will be completed before you start your IAPT intervention.

Expenses and payments

You will be given a £15 voucher to participate in the study, if you complete all elements.

What are the possible disadvantages and risks of taking part?

Participating in this study would require time for completing questionnaires, using Betwixt, and completing the interview, over a seven-week period. This study also requires a significant amount of reading, when using Betwixt, and completing the questionnaires.

What are the possible benefits of taking part?

The study may or may not help you. The information we get from this study may help others by providing information about this type of app or improving Betwixt for the future.

What happens when the research study stops?

Your data will be analysed to deduce if Betwixt is effective and/or acceptable mental health game to people in a clinical population. You will not receive any further treatments from the research team, however, following the intervention, you should be due your intervention from IAPT.

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 can do this by contacting Patient Advice and Liaison Service (PALS), University of Nottingham.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

How will we use information about you?

The University of Nottingham are the sponsor of this study. This means we are responsible for looking after your information and using it properly. We will need to use information from you and the IAPT referrer for this research project. This information will include your name, age, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. I intend to let participants know the results of this study, so if you would like to receive this information, please let me know your contact details and consent to me holding these.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data shared in this way will be anonymised.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- reading our privacy statement https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx,
- at www.hra.nhs.uk/information-about-patients/,
- our leaflet available from www.hra.nhs.uk/patientdataandresearch,
- by asking one of the research team or,
- by sending an email to msxvh4@exmail.nottingham.ac.uk.

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, and without your legal rights being affected. If you would like to withdraw, contact msxvh4@exmail.nottingham.ac.uk and they can organise this for you. If you withdraw, you will be given an optional exit interview/survey to enable us to understand the reasons someone may stop using Betwixt and anything we may

do to make it more acceptable. After this, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained. If you lose capacity to consent during the study, you will be withdrawn from it, though your existing identifiable data will be retained.

What will happen to the results of the research study?

The results of this study will be written into a report and will hopefully be published in 2025. You will be able to obtain a copy of the published results from the researcher, if you wish. You will not be identified in any report or publication. The study will also be written up as a thesis in part toward the researcher's clinical psychology doctorate qualification.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by Health Education England.

Who has reviewed the study?

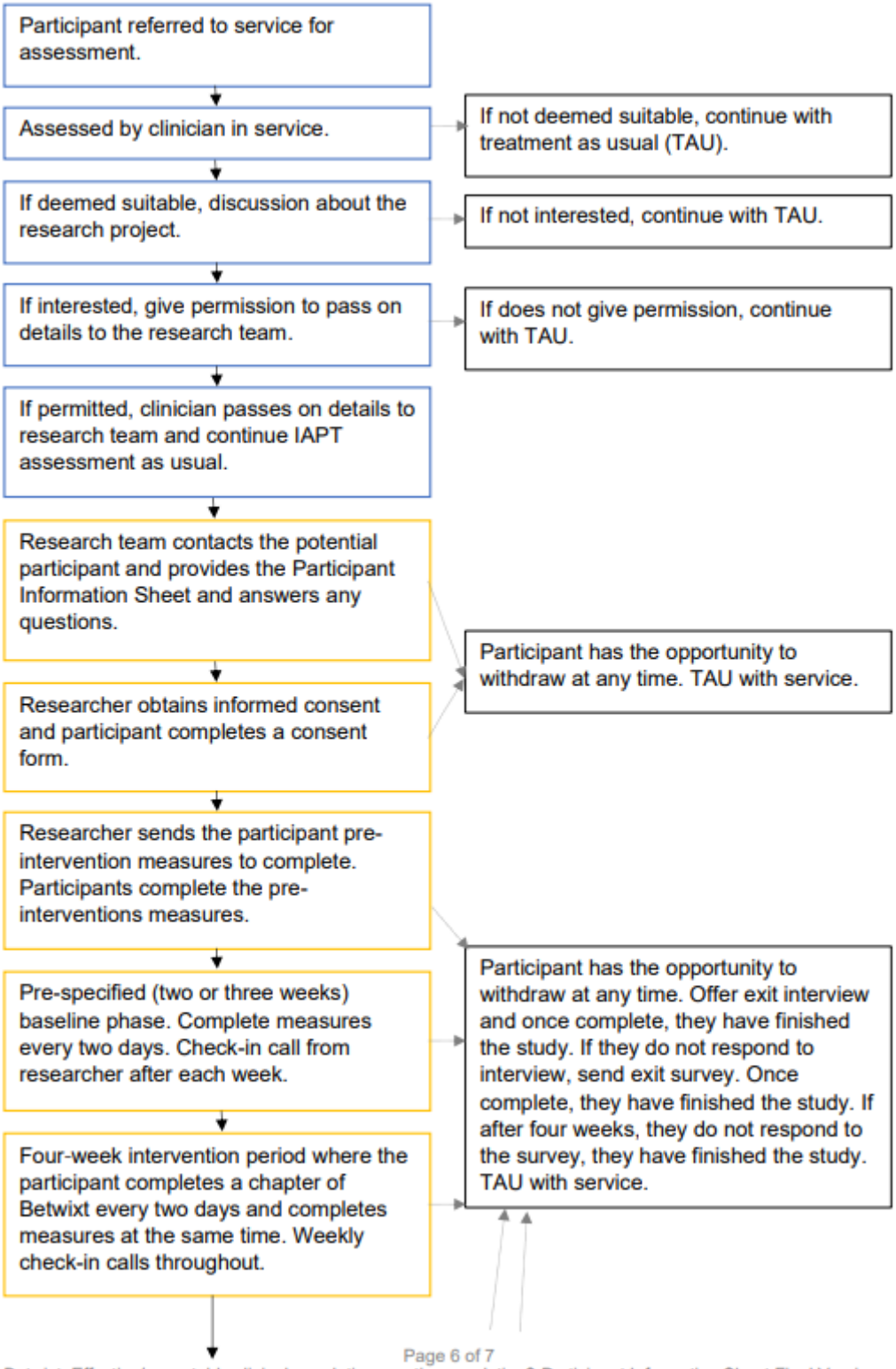
All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the University of Nottingham, and the London Bridge Research Ethics Committee.

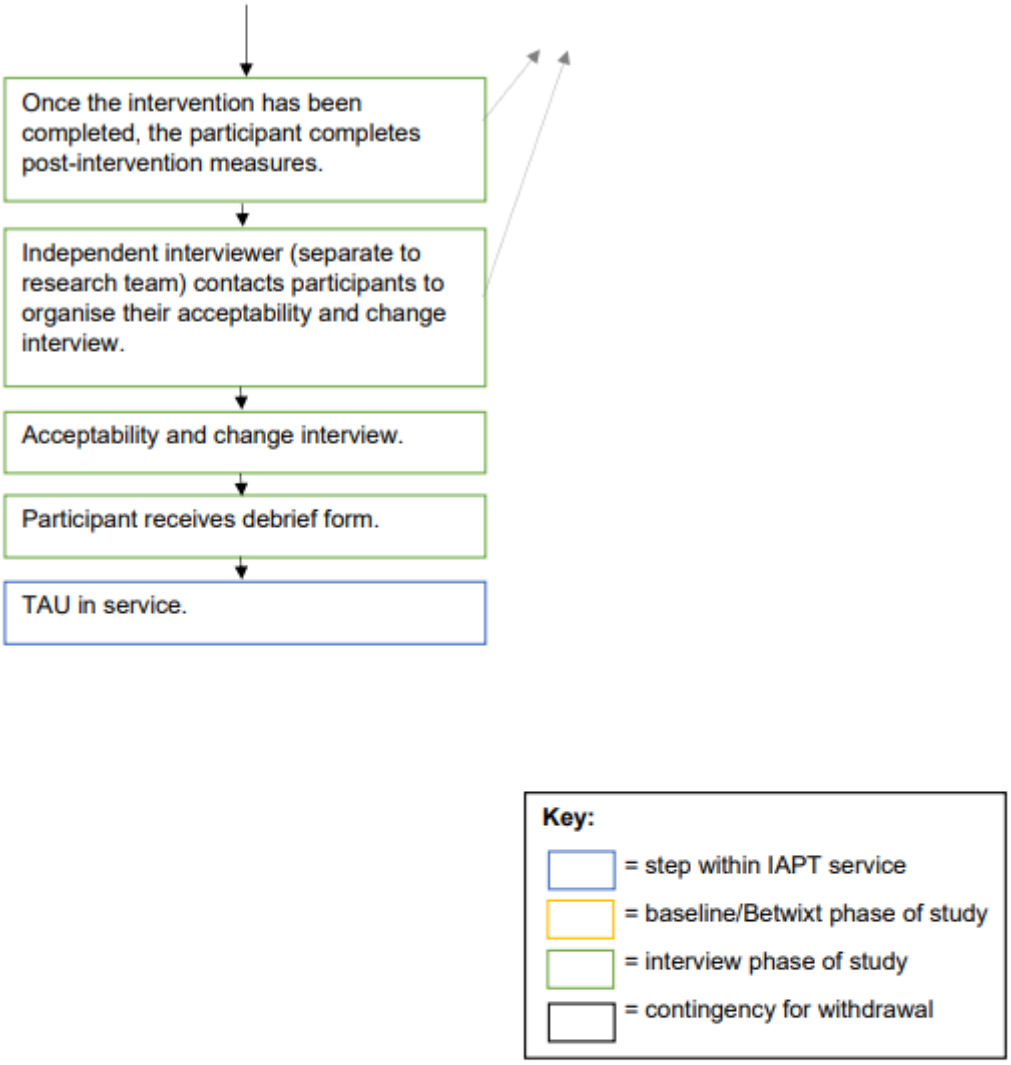
Further information and contact details:

Jacob Andrews mszja3@exmail.nottingham.ac.uk

Victoria Harper msxvh4@exmail.nottingham.ac.uk

Overview of research procedures:




Once the intervention has been completed, the participant completes post-intervention measures.
Independent interviewer (separate to research team) contacts participants to organise their acceptability and change interview.
Acceptability and change interview.
Participant receives debrief form.
TAU in service.
Key:
= step within IAPT service
= baseline/Betwixt phase of study
= interview phase of study
= contingency for withdrawal

5.8 Participant Consent Form

University of Nottingham
UK | CHINA | MALAYSIA

Participant Consent Form

Final Version 1.0, 21st December 2023

IRAS Project ID: 334141

Title of Study: Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Name of Chief Investigator: Jacob Andrews

Name of Primary Investigator: Victoria Harper

Name of Participant:

	Please initial box
1. I confirm that I have read and understand the information sheet version number 2 dated 30.01.2024 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 data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group, and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.	☐
4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports.	☐
5. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.	☐
6. **Optional**: I agree to members of the research team storing my details for the purpose of contacting me with a summary of the study findings.	Yes ☐ No ☐
7. I agree to take part in the above study.	☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

2 copies: 1 for participant, and 1 for the project note

5.9 Interview Topic Guide

University of Nottingham
UK | CHINA | MALAYSIA

Topic Guide

Final Version 1.0, 21st December 2023

IRAS Project ID: 334141

Title of Study: Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Name of Chief Investigator: Jacob Andrews

Name of Primary Investigator: Victoria Harper

"Thank you for taking part in this study. You have been using Betwixt for some time now and today we are going to discuss your experiences of using Betwixt, how it made you feel, the effort required, its effectiveness, how it fit for yourself, and your understanding and use of the app. Please provide as much detail as possible. You've already completed a consent form, is there anything you'd like to ask me about it before we start? Can I confirm we have your consent to record?" Please ensure that the participant is considering Betwixt specifically and not the experimental design, such as, completing measures every two days.

1. **Affective Attitude:** The aim of this section is to deduce how the participant felt about using Betwixt.
   "How was your experience of using Betwixt overall?"
   "How did you feel about using the Betwixt app?"
   "What emotions did using Betwixt bring up for you?"
   "Did you enjoy using Betwixt?"
   "Would you like to continue using the app now that this study has finished (with new or existing dreams)?"

2. **Perceived effectiveness:** The aim is to find out the extent to which Betwixt was perceived to achieve its purpose and what changes have occurred since using Betwixt.
   "Do you feel that Betwixt helped you? If so, in what way?"
   "Has anything changed for the worse for you since you started using Betwixt?"
   "Is there anything that you wanted to change that hasn't since you started using Betwixt?"
   "What has been helpful about Betwixt so far?"
   "Do you have any specific examples?"
   "In general, what do you think has caused the changes you described?"

"What do you think might have brought them about (including both Betwixt and factors outside of Betwixt)?"

3. **Ethicality:** The aim is to deduce the extent to which Betwixt fit with the participant's values.
   "Did Betwixt align with what is important to you?"
   "Do you feel that the Betwixt app has the same or different values to yourself?"

4. **Intervention coherence:** The aim is to identify the extent that the participant understands Betwixt and how it works.
   "What do you think Betwixt is trying to do?"
   "How do you think Betwixt tries to improve mood?"

5. **Opportunity costs:** The aim is to identify the extent to which the participant had to give up things to engage in Betwixt.
   "Did you find that you were able to make time for using Betwixt in your everyday life?"
   "Did using Betwixt stop you from doing anything?"

6. **Burden:** The aim of this section is to deduce the perceived amount of effort required to use Betwixt and if there were any limitations or problematic aspects.
   "How much effort was required to use Betwixt?"
   "Did you feel that the amount of effort required to use Betwixt was worthwhile?"
   "What kinds of things about Betwixt have been hindering, unhelpful, negative or disappointing for you?"
   "Were there things in Betwixt which were difficult or painful but still okay or perhaps helpful? What were they?"
   "Is anything missing from Betwixt that would have made it more effective or helpful?"
   "What personal factors do you think have made it harder for you to use Betwixt to deal with your problems?"
   "What things in your life situation have made it harder for you to use Betwixt to deal with difficulties?"

7. **Self-efficacy:** The aim is to deduce the participant's confidence that they can engage in Betwixt and their resources which contributed.
   "Do you feel able to continue to use Betwixt?"
   "Do you feel confident in your ability to engage in Betwixt?"
   "What strengths do you think you have that have helped you to make use of Betwixt to deal with your struggles?"
   "What things in your current life have helped you make use of Betwixt to deal with problems (e.g., family, job, relationships, living arrangements)?"

8. **Cognitive reappraisal:** The aim is to identify the extent to which the participant feels that their cognitive reappraisal has been affected because of using Betwixt.
   "After using Betwixt, have you noticed any changes to your ability to respond to stressful situations?"
   "Do you think that you would respond differently to a stressful situation following using Betwixt?"

9. **Self-compassion:** The aim is to identify the extent to which the participant feels that their self-compassion has been affected because of using Betwixt.
   "After using Betwixt, have you noticed any change to how compassionately you feel toward yourself?"
   "Have you been any kinder to yourself since using Betwixt?"

10. **Check-in calls:** The aim of this section is to identify whether the therapeutic alliance during weekly check-in calls has affected the intervention as a variable (and if so, positively, or negatively).
    "How was your experience of the weekly check-in calls?"
    "Did the check-in calls help you in any way?"
    "Did the check-in calls affect you negatively in any way?"
    "Do you think it would be helpful or not to include check-in calls if Betwixt was used in a clinical service?"

11. **Suggestions:** The final section is a catch-all to identify any important factors that have not already been captured by the previous sections.
    "Do you have any suggestions for us, regarding the research or Betwixt?"
    "Do you have anything else that you want to tell me?"

Notes for interviewer: Examples of follow-up questions:

"What was that like for you?"

"How did you find that?"

"Can you give an example of that?"

"What did you feel at that time?"

"Please can you tell me more about that?"

5.10 Exit Survey

Participant Exit Survey

Final Version 1.0, 21st December 2023

IRAS Project ID: 334141

Title of Study: Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Name of Chief Investigator: Jacob Andrews

Name of Primary Investigator: Victoria Harper

Thank you for your participation in this study. You have had some experience of using Betwixt. The purpose of this survey is to gather your feedback on changes you have noticed since using Betwixt, what you believe may have brought about these changes, and helpful and unhelpful aspects of Betwixt. Please provide as much detail as possible:

1. How was your experience of using Betwixt overall?

2. Do you feel that Betwixt helped you? If so, in what way?

3. Did Betwixt align with what is important to you?

4. How do you think Betwixt tries to improve mood?

5. Did you find that you were able to make time for using Betwixt in your everyday life?

6. Did you feel that the amount of effort required to use Betwixt was worthwhile?

7. Do you feel able to continue to use Betwixt?

8. Do you think that you would respond differently to a stressful situation following using Betwixt?

9. After using Betwixt, have you noticed any change to how compassionately you feel toward yourself?

10. How was your experience of the weekly check-in calls?

11. Do you have any suggestions for us, regarding the research or Betwixt?

Thank you for providing this feedback, it is very much appreciated. Please return this form to Msxvh4@exmail.nottingham.ac.uk.

5.11 Participant Debrief Form

University of Nottingham
UK | CHINA | MALAYSIA

Participant Debrief Form

Final Version 1.0, 21st December 2023

IRAS Project ID: 334141

Title of Study: Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

Name of Chief Investigator: Jacob Andrews

Name of Primary Investigator: Victoria Harper

Thank you for your participation in the above research project. Your involvement and contribution were very important to us and will provide valuable information about the use of the Betwixt app. Your responses to the questionnaires and interview questions remain anonymous and confidential.

If your participation in the study has raised any queries or concerns for you, please contact the researcher (details below) or the Patient Advice and Liaison Service (PALS), University of Nottingham for further support. Please contact your GP or IAPT clinician if you have any clinical concerns. We have also listed some services below if you are distressed or in crisis.

When we have analysed the results and wrote the report, we will send you a copy of the published results (if you have consented to this and provided us with your contact details). Thank you for your participation.

Best wishes,

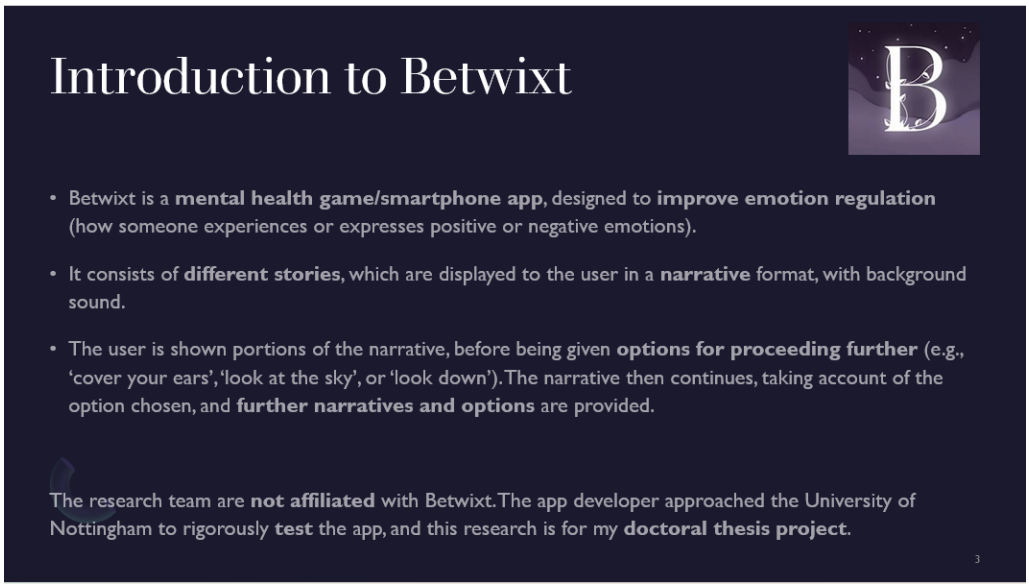
Victoria Harper

Contact details:

Victoria Harper

Msxvh4@exmail.nottingham.ac.uk

5.12 Training Presentation for Recruiting Clinicians



Introduction to Betwixt

4

Introduction to Betwixt

- Betwixt is **theory-driven** and built upon the foundations of **self-determination theory** and **social cognitive theory**.
- It is based upon **two emotion regulation skills: cognitive reappraisal** and **self-compassion**, prominent features of **CBT** and **mindfulness-based interventions**, respectively.
- A **proof of concept/acceptability** study of Betwixt found **positive results in a general population** sample (n = 26).
- A **general population randomised control trial** of Betwixt was completed and found **significant and large reductions in depression, stress, and self-reflection**.
- The rationale for this study is that the previous literature did not study a **clinical population**.

5

Study Design

The **question** being addressed in this study is: **Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?**

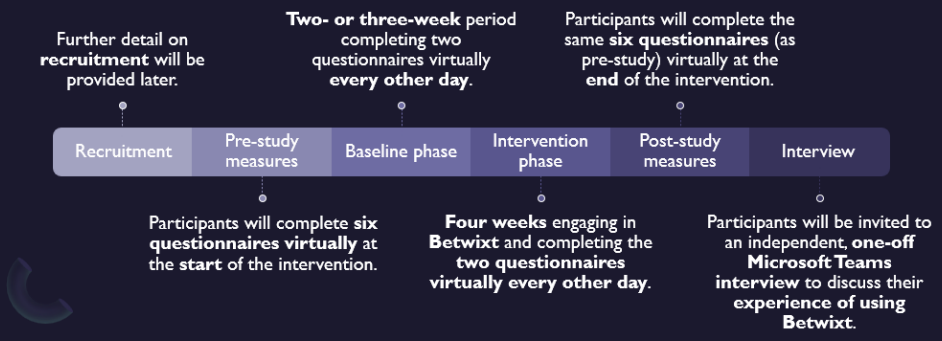
Your service will only need to **identify participants** and **give potential participant details** to the research team (further detail on recruitment later). The team will **conduct the study.**

Eight participants are required, and the study will last for **six to seven weeks** for each participant.

Participants will receive a **£15 Amazon e-voucher** as **appreciation** for their participation, if they **complete all elements** of the study.

6

Study Design (whilst on the waiting list)



7

Inclusion/Exclusion Criteria

Inclusion:

- **Adults** (aged 18 years and above. 16 and 17-year-olds are **not** able to participate).
- Currently on the **waiting list** for your service.
- Experiencing an **anxiety disorder and/or depression** when assessed by your service.
- **Own a smartphone** they can use Betwixt on.
- Comfortable with using a phone for **extended periods of time**.
- Able to **give informed consent**.

8

Inclusion/Exclusion Criteria

Exclusion:

- Sufficient **English reading ability**, due to the narrative nature of Betwixt.
- **Available** for up to seven weeks whilst on the waiting list.

Hence, the criteria are similar to that of the service. It will need to be ascertained that the participants are **adults, have a smartphone that they are willing to use for extended periods, and have sufficient English reading ability** (though the research team will confirm this too). English does not need to be the participant's first language.

9

Recruitment

Proposed start date of **Monday 8th April 2024.**

One PWP (to be identified by [redacted] as Team Manager) will approach **all** of their assessment clients **for one week.**

If more participants are required, **a different PWP** will approach **all clients for a week.** There will be a time delay before this takes place.

This can be **repeated** for the **third PWP**, if more participants are required.

10

Recruitment

1. A potential participant will **attend their assessment appointment** with the service. The PWP will **discuss the project** and ask the potential participant if they would **like more information about participating.**
2. If they would, the PWP will ensure that they are an **adult; own a smartphone that they are willing to use for extended periods; and can read English sufficiently.**
3. The PWP will **document the potential participant's details** (name, age, gender, diagnosis, phone number, and email address).
4. The PWP will **email or give the potential participant** the **Participant Information Sheet** (PIS) after the appointment and **email their details** to victoria.harper@nottshc.nhs.uk.
5. The research team will then **contact the potential participant** to provide further information and to discuss consent. If they consent, the study will begin.

11

Recruitment

Betwixt Potential Participant Information

Is the individual an adult (aged 18+)?

Do they have a smartphone that they are willing to use for extended periods?

Can they read written English sufficiently?

Name	Age	Gender	Diagnosis	Phone	Email
Example: Example Name	35	Male	Depression and generalised anxiety disorder	07777 777 777	Example-name@gmail.com

Please provide the individual with the Participant Information Sheet and inform them that the research team will contact them soon.

12

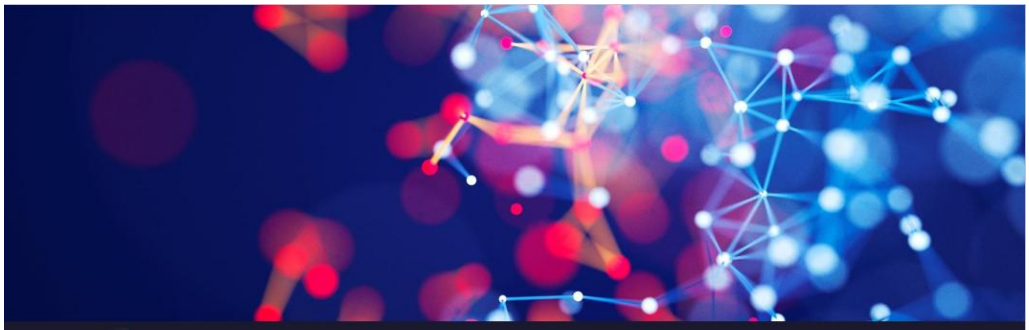
Trial Betwixt

If you would like to **trial using Betwixt** for yourself, it is accessible on **app stores** (QR codes below), where **three free dreams** are available. If you would like **full access**, please **let me know** and I will ask the app developer to provide you **full access**.

Apple:

Android:

13



Thank you for listening

Do you have any questions?

If you have **any further questions** after this meeting, please email me at Victoria.harper@nottshc.nhs.uk

I will email the **PIS, protocol, and this presentation**

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5.13 Additional Quotes Grouped by Participant Views of Betwixt

Participants with more positive views of Betwixt:

Participant	More positive quotes	More negative quotes
4. Sarah	“I found it really helped.” “It helped me to see that I'm not just one person that's going through it. There are other people, and the app sort of highlights that.” “Gives you that perspective of ‘you can do it’.” “I've never used anything like that before, I've normally had talking therapy, CBT, things like that.” “The inner voice helped me to see it, and you’re sort of having this conversation with the inner voice that is also guiding you, which I really liked.” “I liked as well during using the app, you gained like little awards so, like ‘courage’.” “I like that you were able to slow the speed and control the speed of like the story going.” “Yeah, I really did like [being able to personalise it].” “It did help with sort of seeing things in a more positive light, and the world isn't that bad. In…the dream world, things can seem a lot worse than they are. And it relates to like day-to-day life, things can seem a lot worse than they are.” “And it was interesting to be able to use an app for trying to help myself.” “While I'm waiting for some more support but using an app rather than just sitting and waiting and not being able to do anything.” “Oh yes, yeah I will carry on using it.”	“I don't really have that motivation to do it.” “But also, that [responding to stressful situations] is still something that I really struggle with.”

	“But it does make me see like you do have to be a little bit nicer to yourself at times.”	
5. Sharon	“Well, I very much enjoyed the app.” “So, when it did that, that instantly hit with me and it was almost like it did actually understand me, it almost did know me.” “And it gives you the option to wake up from the dream or carry on. And at that point, I woke up, but it was still very helpful.” “Having that background noise, I found quite relaxing, even if it was a sort of storm thing going on, that sound I liked.” “And it was really interesting to sort of hear that come out, and sort of somebody else had got it out of me, even though it was a computer programme basically, but it had pulled it out and made me think of it.” “It's making you think and it's making you look at things differently or try and make you look at things differently, but also…you are allowed to have negative thoughts, in terms of, you are allowed to feel down.” “At no point during any of the dreams did I feel sort of tense or, you know, on edge…every dream I did instantly…feel myself relaxing.” “At night, when I've gone through my day, this works best to sort of bring everything together and sort of bring, you know, relax you, bring you back down.” “So, there's a lot of aspects of my life that have improved since that day, which includes using the app. So, the app’s helped me, but then other things have probably contributed to that as well.”	“My only issue was maybe the, you know, the way it was set. I didn't mind the sort of colours, but you know, just…the continuous sort of text thing…yeah, that broken up a bit.”

	“The caring…bit, I keep bringing it up, but the caring bit is a very important bit to me, because you know…it's also really important.” “So, I think, I'm sure there's sometimes when I've done it where rather than sort of writing lots and lots of sentences, but I've literally gone for…sort of list of words... So, I just kind of abbreviated it…to the exact sort of almost bullet pointing, I think.” “The app has definitely helped [ability to respond to stressful situations]; the app has definitely helped.” “I was very down on myself before, very focused on my sort of negative feelings. Whereas…as it stands today, I don't feel negative about myself at all.”	
6. Lucy	“As I say, if it isn't broke, don't fix it. I think it's a brilliant…I don't understand why nobody thought of it before.” “For the most part, it's easy to use, it's easy to understand.” “I will keep sending it, if anybody ever says to me ‘can you recommend something?’, I would definitely recommend Betwixt.” “And I always go through the resources that come through afterwards. I honestly can't say a bad thing about it.” “Because it’s escapism, isn't it? As I say that escapism where you can go somewhere and deal with how you feel.” “When the app asked me to describe that place, that's exactly what I described as I saw it. And I found	“Some of the questions I found a little bit, ‘[I] don't know if I like that one’.” “I still find it [self-compassion] really difficult…And so, I've always been down on myself.”

	yesterday just to go in the bedroom and lie down just for half an hour and just lay there in that place." "I am learning to love myself again." "But I can deal with anxiety a lot better, it still happens, but it's…I have these mechanisms in place now." "I like the fact that it's not all face-to-face. I like the fact that you've not got a person sort of sat in the flesh right in front of you going, 'well, this is going to happen and why do you feel like this?'" "You know, even the bits that were difficult, were still positive." "So yeah, in that way, it does align with the way that I think." "I don't have a lot of compassion for myself, I don't like myself very much. And so, it did make me think, 'well, why don't you? These other people do, you should too'." "It's fitted in really well…it's always fitted in really well." "But I would say on the whole, not a huge effort." "And it's definitely been worth it, definitely." "I am starting to [respond to stressful situations] now."	

Participants with positive and negative views of Betwixt:

Participant	More positive quotes	More negative quotes
2. Christine	"I didn't want to give it up because…I wanted to get to the end of what it was actually going to get to at the end. It does make you want to read on." "I think for somebody who may be on like the start of a journey into looking…at things that are affecting them	"You do need to make sure you have time away; you are in a position where you can engage fully with it for the amount of time because it is very in-depth to be reading all that information."

	on a day-to-day basis, I think it would be very useful for that." "For the shorter term, coping with the day-to-day, I think it'd be very useful." "Some of the…descriptions of the way things were and so it is very descriptive, so you could picture it." "So, like as you went on through the journeys, how it changed colour and it was getting lighter, I thought that was really, really good." "So, it's sort of like some of it was in there already…so, it was good as a reminder of things that I had done in the past as well in like previous CBT sessions and things like that." "Not everything could fit in with the, sort of, the way that it was going to actually choose things. So, a couple of times when I've said something, it's like, actually this doesn't really fit in quite well with this." "It is for like maybe more of an anxiety issue maybe…not huge issues, just like smaller...But for low mood and anxiety, I think it's very good."	"There was some days that it was more of a struggle to fit it in, to do it as well, depending on what I was doing." "And then life took over, but I have a lot of things on. I mean, I don't know if it is because, you know, I am older and I have got like family issues, I've got like work issues, things like that." "But…it does need…some effort." "And it was a lot of reading to take in." "So, the language used, it isn't that accessible for everybody. It can get quite complicated, things like that." "But then afterwards I was thinking, well actually it would have been better if I could have like changed the size of the font and things like that." "Actually, the type of font that they used, it would have been better to be a Sans Serif rather than one with all Serif fonts with the little tails on. But again, just for accessibility for reading it." "I also…couldn't get like the full immersive experience of it either because I don't have a headset for my phone…so, I did try it with the sounds out loud, but it wasn't the same."
7. Carol	"What I liked about it, it checked that you was engaging in it… so it kind of throw these questions in to know that you were using it." "I think the app is there to try and help, it's to help with grounding, it's to help with many other things, grounding I feel more so."	"Not really [aligns with values]." "It wasn't very clear if you could put it on audio and have it read to you…if that would have been something that could have helped." "And actually, because it's a paid app and you would have to pay, I've been fortunate to engage in this app

	“I'm a chronic pain sufferer and what I found with the sound and the noise, it helped to reduce the intensity, I think it's powerful in what it does.”	free and have free roam, which has been lovely. Yeah, I wouldn't actually pay to use that app, even though it's got everything that's within it.” “I just feel it's not an app I'd recommend, I don't think it's for everyone.” “And for me, I think that having someone to talk to would have been more helpful.” “I'm not into AI, I'm not into technology, but that's me and my generation, that's where I am in my life.” “But mainly the name of it, I mean, it brings up Brexit for me, which was traumatising and yeah, just in general.”

Participant with more negative views of Betwixt:

Participant	More positive quotes	More negative quotes
3. Lynne	“It made me look at what I was feeling and take stock.”	“I’m afraid it didn’t help me much.” “I found the app and bit long and was sometimes distracted when trying to relax as it went on a bit too long.” “No, it wasn’t worthwhile.” “I found it boring I’m afraid and so was unable to use it properly as was bored and skipped.” “No, I won’t continue to use it.” “It didn’t make me kinder to myself.”

6. Conference Poster

The following page contains the conference poster for this project.

Is the Betwixt application effective and acceptable in improving emotion regulation for an adult clinical population?

University of Nottingham
UK | CHINA | MALAYSIA

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UNIVERSITY OF LINCOLN

Introduction:

Mental health has a **significant impact** on **everyday functioning**[1], and there is an **increasing demand** for **mental health services**, resulting **in longer waiting times**[2].

A **potential solution** could be **digital interventions**, particularly apps which support **emotion regulation** (ER). ER can be defined as **regulating positive and negative emotions**, dependent upon one's **personal goals**. **Systematic reviews of ER apps** have found **promising results**[3 4].

The **smartphone application 'Betwixt'** could offer a form of **interim support** to those waiting. Betwixt is a **narrative gaming app**, aimed at **improving emotion regulation** and alleged to be based upon **psychological theory**. Previous studies[5 6] on Betwixt found **positive results**, though none had investigated individuals with **mental health conditions**.

Aims:

A: Evaluate the **effectiveness** of the Betwixt intervention in improving ER, cognitive reappraisal, and self-compassion.
B: Investigate whether changes in processes targeted by Betwixt resulted in improvements in **clinical outcomes**.
C: Explore the **acceptability**, and theoretical components of Betwixt within a clinical context.

Methods:

- **Mixed-method design** to investigate the **effectiveness and acceptability of Betwixt**, within an **adult clinical population**.
- Quantitative **single-case experimental design series**, and qualitative **interviews or survey**, which focused on **acceptability** and **perceived changes** associated with **Betwixt use**.

Baseline phase (two or three weeks) → **Treatment phase** (four weeks) → **Interview or survey**

- There were **weekly check-in calls** throughout, to **troubleshoot technical issues**, and to **support app engagement**.

Participants:

- **Seven participants** completed the study.
- Participants were on the **waiting list for NHS Talking Therapies** and experiencing **clinical depression or anxiety**.
- **Average age** was **44.6 years**.
- **Gender** was **100% female**.

Results:

Findings were **mixed** regarding **improvements in emotion regulation, cognitive reappraisal, and self-compassion**.

However, there were **encouraging indications** that **Betwixt may improve clinical outcomes**.

Participant **views on acceptability** ranged from **positive to mixed**.

Discussion:

- **Findings: Upon further evaluation**, Betwixt could be a **promising intervention** for **individuals on waiting lists** for talking therapies.
- **Future research:** Should include **randomised controlled trials**, **long-term studies**, and **assessments of feasibility in more severe mental health conditions**.
- **Clinical practice implications: Betwixt** has **promise** for clinical applications, the **design of this study** could **be replicated** to assess **other apps**, **check-in calls** could be included in **other interventions**, and **targeting ER** in an intervention may **indirectly improve low mood or anxiety**.
- **Conclusion:** Indicates the **feasibility, acceptability and effectiveness** of a **narrative-based ER gaming app** for individuals with **depression or anxiety disorders**.

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