



Integration of a smartwatch within an internet-delivered intervention for depression: Protocol for a feasibility randomized controlled trial on acceptance

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ABSTRACT

Background: Mood tracking is commonly employed within a range of mental health interventions. Physical activity and sleep are also important for contextualizing mood data but can be difficult to track manually and rely on retrospective recall. Smartwatches could enhance self-monitoring by addressing difficulties in recall of sleep and physical activity and reducing the burden on patients in terms of remembering to track and the effort of tracking. This feasibility study will explore the acceptance of a smartwatch app for self-monitoring of mood, sleep, and physical activity, in an internet-based cognitive-behavioral therapy (iCBT) for depression offered in a routine care setting.

Methods: Seventy participants will be randomly allocated to (i) iCBT intervention plus smartwatch app or (ii) iCBT intervention alone. Patient acceptance will be measured longitudinally using a theory-based acceptance questionnaire to understand and compare the evolution of acceptance of the technology-delivered self-report in the two groups. A post-treatment interview will explore participants subjective experience of using the smartwatch. Engagement with the intervention, including self-report, and clinical outcomes, will be measured across both groups to assess for any differences.

Implications: This is the first study investigating the evolution of patient acceptance of smartwatch self-report in an iCBT delivered intervention in a clinical sample. Through an engaging and convenient means of capturing ecologically valid mood data, the study has the potential to show that smartwatches are an acceptable means for patient self-monitoring within iCBT interventions for depression and support potential use-cases for smartwatches in the context of mental health interventions in general.

Prospectively registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT04568317).

1. Introduction

According to the World Health Organization, depression accounts for the highest degree of disability among all mental and substance abuse disorders [1]. Depression disorders contribute to significant economic, personal, intra-personal and societal costs [2–8]. Cognitive Behavioral Therapy (CBT) has become an established option for the treatment of

depression [9]. Over the past decade, low-intensity CBT has been adopted across the National Health System in the UK as a means to increase the availability of psychological therapies, and is one of the treatments offered to patients with mental health difficulties in the 'Improving Access to Psychological Therapies' (IAPT) stepped-care program [10]. Within IAPT, internet-based CBT (iCBT) is included as part of a low-intensity approach which has shown to be an effective treatment

Abbreviations: AQ, acceptance questionnaire; IAPT, improving access to psychological therapies; iCBT, internet-delivered cognitive behavioral therapy; PWP, psychological wellbeing practitioner; SAT, satisfaction with treatment measure.

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for mild-moderate levels of adult depression [11–13].

Core components of CBT for depression target behavioral activation in patients, teaching them to monitor their daily activities and experiences. Keeping a log of these supports patients in identifying patterns and relationships between their mood and behavior [14] such as sleep and physical activity. Assisting patients in achieving sleep hygiene is important as depression often co-exists with insomnia [15], with clinical studies finding that up to 83% of individuals with depression experienced insomnia symptoms [16]. In addition, there is evidence that physical activity, even to a modest level, improves depression symptoms [17]. Some iCBT programs support clients' self-monitoring of sleep patterns and activity level [18,19]. Studies have explored semi-automated monitoring as a way to improve self-report accuracy and support patient awareness and long-term engagement [20]. Preliminary evidence demonstrates that this combination of manual self-report with automated data collection has been successfully employed for monitoring of sleep and physical activity in digital mental health interventions [21–23].

Wrist-worn devices like smartwatches show potential for enhancing digital self-monitoring through (i) ecological momentary assessment due to their proximity allowing immediate interaction, and (ii) automated data captured through embedded sensors. In addition, smartwatches are becoming increasingly used by the general population to monitor health-related behaviors such as sleep and physical activity [24,25]. However, patient compliance with technology-delivered treatments is largely determined by their acceptance of the technology as that technology may raise concerns among patients [26]. Similar to any integration of technology or automated data collection for monitoring, there is a definite need to assess and understand patient acceptance as an essential “design” factor before considering deploying any such innovation [26–28].

Based on the Technology Acceptance Lifecycle model, acceptance is defined as the patients' perception and relationship with the smartwatch-delivered self-report over time [26]. This model captures the different stages of the process of acceptance – pre-use acceptability, initial use acceptance, and sustained use acceptance – to capture the evolution of user acceptance over time. Patient acceptance is evaluated with the factors provided by the Health Information Technology Acceptance Model [29]: perceived health threat, perceived usefulness, perceived ease of use, attitude, intention to use, and usage behavior.

2. Study objectives

Based on the scientific rationale for self-monitoring [30] as an important component to CBT treatment effectiveness, the main research question explores:

- What is the level of participants' acceptance of the smartwatch-delivered self-monitoring of mood, sleep, and activity level, as part of an established iCBT treatment for depression?

A secondary research question explores:

- Are there any differences between the addition of the smartwatch in comparison to the standard iCBT program in terms of engagement with the program or clinical outcomes?

We hypothesize that the smartwatch-delivered self-report will be acceptable as an addition to the iCBT intervention. No hypotheses have been established regarding the potential differences between the two groups, since this question is exploratory in nature.

3. Methods

3.1. Trial design

A CONSORT compliant parallel randomized control trial design will be used to examine the acceptance of integrating a smartwatch app into an established iCBT treatment for depression [12,31] to enhance self-report of mood, sleep, and activity level. Participants will be randomly allocated to a) iCBT intervention or b) iCBT intervention plus smartwatch. The study was approved by Research Ethics Committee (Wales REC 5 281255). This trial has been registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (NCT04568317) and is conducted in compliance with the General Data Protection Regulation (EU) 2016/679 (GDPR), and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations.

3.2. Participants and study setting

This study will be conducted within Berkshire Healthcare NHS Foundation Trust in the UK. Specifically, the study is placed at Step 2 of their IAPT service. Those wishing to access the service can do so through self-referral, GP referral or referral from allied services. Step 2 services are generally offered to individuals with mild to moderate presentations of depression and anxiety and they include low-intensity CBT-based treatments supported by trained psychological wellbeing practitioners.

3.3. Sample size

We aim to recruit a sample of 70 participants, with 35 participants per group (Fig. 1).

This aligns with the literature around desired sample sizes for feasibility studies. Indeed, Teare et al. recommend 35 subjects per group [32] and a review by Billingham et al. [61] found that the median pilot study sample size was 30 per arm for continuous endpoints.

3.4. Eligibility criteria

Users of the Step 2 service who have been assigned to the iCBT

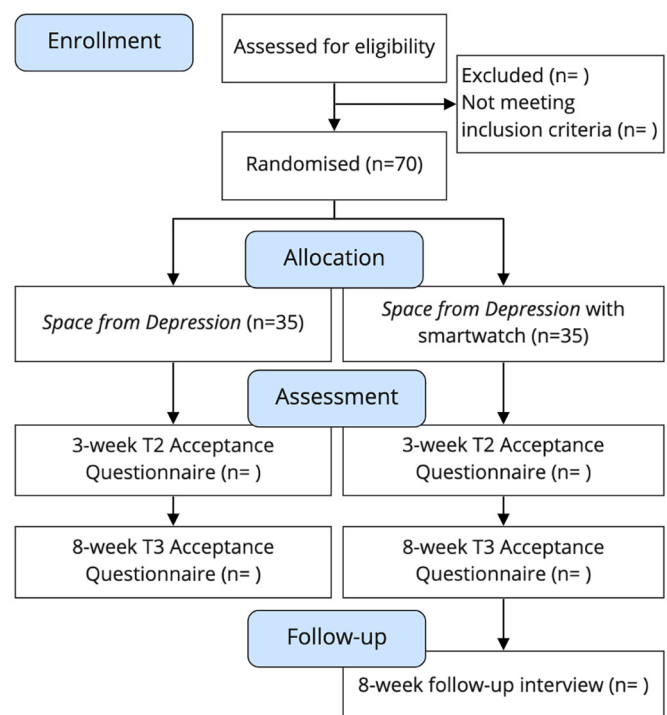


Fig. 1. Consort flow diagram.

treatment for depression and own a compatible smartphone (iPhone 6 and upwards running iOS 8) will be eligible to participate. Suitability for an internet intervention is assessed by the psychological wellbeing practitioner based on the willingness of the participants to engage in the iCBT intervention, the ability to read English, access internet, the capacity and willingness to consent, no suicidal or self-harm risk and with no specific communication needs. Individuals who do not meet the inclusion criteria or do not wish to participate in the study will be offered appropriate treatment (Table 1).

3.5. Guided Space from Depression program

The ‘Space from Depression’ program provided by SilverCloud Health [33] is an evidence-based iCBT intervention for the treatment of depression that have been shown effective in previous studies [12,31]. It consists of seven modules (see Table 2). Each module takes approximately 1 h to complete, and clients are generally recommended to complete one module per week. If lapses in engagement are noticed, the psychological wellbeing practitioner (PWP) calls the patient to troubleshoot any problems, re-evaluate homework, ensure understanding and promote engagement. The structure and content of the program modules follow evidence-based CBT principles and is delivered in a client-directed fashion. Each module incorporates introductory quizzes, videos, psychoeducational content and interactive tools, as well as personalized homework suggestions and summaries.

One of the interactive tools is the Mood Monitor, where users are encouraged to monitor their mood and reflect on several factors that might be influential, for instance, sleep or diet. To record a mood, the client selects from five weather icons (sun, sun-cloud, cloud, cloud-rain, rain) the one that best reflects their current mood. They are then incited to reflect on a list of lifestyle choices, and log the number of hours slept, quality of exercise, diet, caffeine drinks, units of alcohol and level of medication. The Lifestyle Choices chart provides a visualization of the mood alongside these factors.

3.6. Support

All clients are allocated to a PWP who is trained in the delivery of SilverCloud iCBT programs. The PWP is responsible for monitoring and guiding the client’s progress throughout the intervention. The participant receives a welcome message from their supporting PWP at their first login, highlighting elements of the program and encouraging them to engage with the program. The study will capture the first 8 weeks of treatment, during which on 6 separate occasions the PWP will login and review participants progress, providing them with feedback on the work they have accomplished. By default, supporters can view users’ weekly goals, key messages and progress milestones. Users can also choose to share journal entries with their supporter. At the end of each review period, the PWP will provide between 10 and 15 min of feedback per participant.

Table 1
Study eligibility criteria.

Inclusion criteria
• Minimum age of 18 years
• Eligible for the ‘Space from Depression’ program
• Own a compatible mobile device (iPhone 6 and upwards); owning a smartwatch is not required.
Exclusion criteria
• Suicidal intent/ideation; score > 2 on PHQ-9 question 9
• Psychotic illness
• Alcohol or drug misuse
• Previous diagnosis of an organic mental health disorder
• Currently in psychological treatment for depression symptoms
• Unstable medication regimens

PHQ-9 Patient Health Questionnaire – 9

Table 2
Outline of program modules.

Modules	Description
Getting Started	This module introduces CBT and how it can help the user understand what is going on inside them and make changes to feel better. It also presents the mood monitor tool.
Understanding Depression	This module explains the different aspects of the cycle of depression and provides the user with activities to reflect on and understand their situation.
Noticing Feelings	This module helps the user understand and identify their emotions and their association with low mood. This module also explores the impact of lifestyle choices on mood.
Boosting Behavior	This module introduces the cycle of inactivity and its role in maintaining depression. It teaches the user how to motivate themselves to engage in pleasurable activities and activities that provide a sense of achievement.
Spotting Thoughts	This module explains negative thinking and its impact on mood. It explores a number of thinking traps and encourages the user to try and identify their unhelpful thoughts.
Challenging Thoughts	An introduction to “hot thoughts” and their impact on low mood. The user learns how to tackle common thinking traps and identify alternative ways of thinking.
Core Beliefs	This module helps the user identify healthy and unhealthy core beliefs and learn strategies to challenge core beliefs and generate more balanced alternatives.
Bringing it All Together	This module teaches the user about warning signs that their mood is deteriorating, and how to plan to ensure that they stay well. It also highlights the importance of social support and continuing to use the skills and techniques that they have learned, and encourages the user to set goals for the future.

3.7. Smartwatch app integration

During the ‘Space from Depression’ intervention, users are encouraged to use the Mood Monitor and Lifestyle Choices chart to keep track of their mood and elements that may affect it, such as sleep and activity level. The Mood Monitor watch app will enhance this self-monitoring through an automated monitoring of patient’s daily sleep pattern and activity level. In addition, the Mood Monitor app will minimize the effort required to manually self-report daily mood. Table 3 details how the Mood Monitor watch app specifically facilitates self-report in the ‘Space from Depression’ intervention, compared to the original desktop/smartphone app.

The home screen of the Mood Monitor app presents a daily and weekly visualization of participant’s mood, bedtime, the number of hours slept, and step count (see Fig. 2a).

This screen gives the user feedback on their daily sleep and activity level through changing icons, and through directional arrows showing

Table 3
Smartwatch app improvements to the ‘Space from Depression’ program features.

Features	Desktop & Smartphone app	Smartwatch app
Record of mood	- Manual, 5 taps - Current and past moods (subject to recall bias)	- Manual, 1 tap - In-the-moment mood (better accuracy)
Reminders	- User chooses to schedule reminders	- User chooses reminders frequency and time ranges of availability - Random reminders are sent - Automated
Record of sleep & activity level	- Manual	
Progress visualization	- Accessible in 2 taps and 1 scroll - Weekly	- Accessible from main screen (no interaction needed) - Daily and weekly - Encouraging prompts
Tips to stay well	- Available in the different chapters of the program	- Gathered in a “tips” feature accessible from the main menu



Fig. 2. a) Home screen. b) Mood reminder. c) Reminders scheduling.

the evolution of the current day's bedtime, slept hours and step count compared to the previous day. This information is synced with their SilverCloud account and shared by default with their supporter, which may then inform the discussions with their supporter. The participant can disable the sharing of this information in their account Settings. During the intervention, prompts for participants to record mood data will appear on the watch app (see Fig. 2b). The mood data logged in the watch app will be integrated into the Mood Monitor, and Lifestyle Choices chart in participant's SilverCloud account (accessible from desktop and mobile app). On their first use of the app, participants will be prompted to choose up to four time ranges to receive reminders to log their mood (see Fig. 2c). Participants can add/remove reminders later on in the settings of the app, as well as postpone or dismiss the reminders when prompted to them. Participants can record their mood independently of the prompts, by opening the menu with a "Force Touch"¹ and selecting "Log Mood" (Fig. 3). Collected mood, sleep and physical activity data is integrated into the existing Mood Monitor tool within the 'Space from Depression' program. Participants can choose to share this information with their supporter using existing features within the program.

The smartwatch app will also include encouraging prompts for frequent and consistent self-report of mood over time to provide positive reinforcement (Fig. 4a). These encouragements also provide short educational pieces of information on the importance of sleep hygiene and monitoring mood, extracted from the 'Space from Depression' program.

Encouraging prompts are given when users have:

- gone to bed before midnight three days in a row;
- recorded 3 mood entries in a given week;
- recorded at least one mood entry each day of a given week;
- recorded a total of 15, 30, 50, 70, 100 mood entries;
- logged mood entries in the past 2 weeks, 3 weeks, and so on up to 8 weeks.

Finally, the watch app provides a *Tips to Stay Well* feature, accessible from the main menu (Fig. 4b).

The bottom button "pulses" to encourage the user to tap and move on to the next tip. The 31 tips have been extracted from the 'Space from Depression' program and approved by a clinical psychologist (NV). The aim of this feature is to give short pieces of advice regarding lifestyle choices (i.e. sleep, exercise, and diet) that may influence depression symptoms. We will measure the engagement with this feature by recording the number of times participants have accessed it.

3.8. Recruitment

Service users will be given an initial assessment by phone with a PWP at the IAPT service and they will complete the IAPT Minimum Dataset, which is a set of self-reported measures, including assessments of current depression and anxiety symptoms. Individuals who are assigned to the 'Space from Depression' will be considered for the study. Thereafter, the PWP will follow a simple set of instructions to check if a participant's mobile phone is compatible with the study (i.e. iPhone 6 and upwards). For eligible participants, the PWP will describe the trial and invite the client to participate. If they do not wish to participate, the reason for declining will be asked.

¹ Force Touch is the default interaction to open a menu on Apple Watch. A Help screen within the Mood Monitor app is available to guide users.



Fig. 3. Logging current mood.

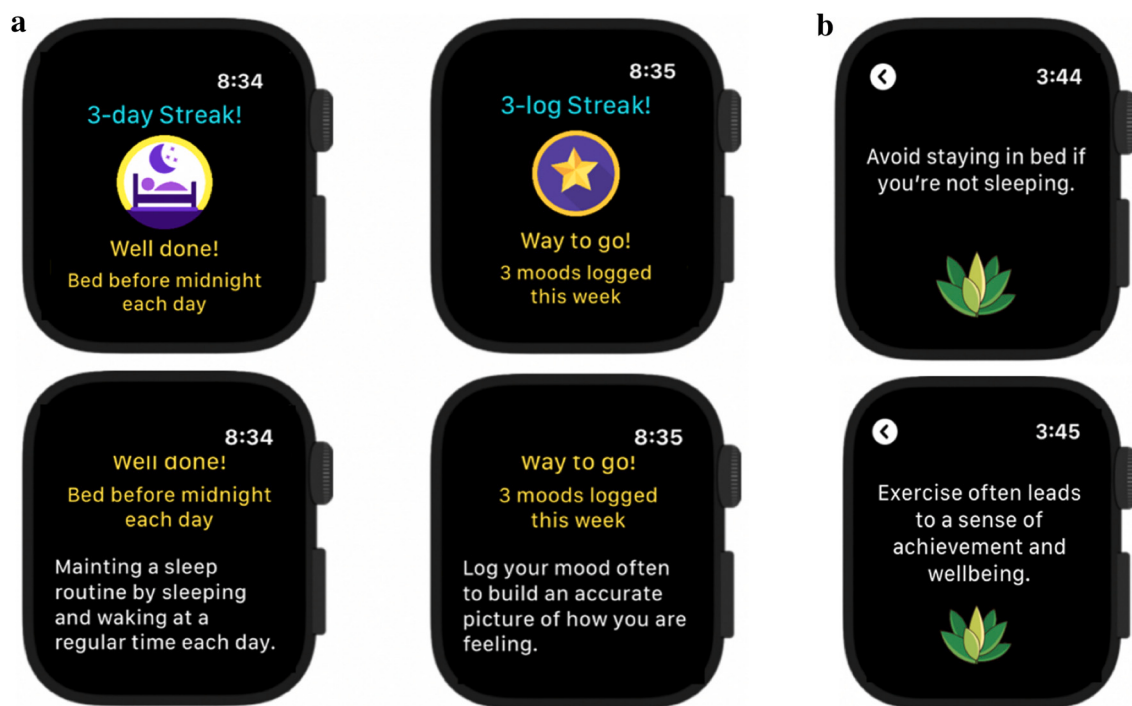


Fig. 4. a) Encouragement prompts. b) Tips to stay well.

3.9. Procedure

All participants willing to take part will receive an email with a link to an online survey. This survey will provide them with information detailing the study and the opportunity to give consent by means of a digital signature. Upon giving consent, participants will be asked to provide contact details, socio-demographic details, and answer questions relating to their familiarity with smartwatch technology. Participants who own a compatible smartwatch will be flagged. The online survey will run a simple randomization algorithm with a 1:1 allocation ratio to assign each participant to an intervention group. Participants will then be shown which condition they have been allocated to. Participants who have been flagged as owning a compatible smartwatch will be given the option to use it during the study. All participants will be asked to complete a short questionnaire (T1) regarding the acceptability and expectations of smartwatch usage, or 'Space from Depression' program usage - depending the study arm they have been assigned to. Participants on the smartwatch group will be sent a study pack including the Apple Watch SE, simple installation, use, and unpairing instructions,

and a pre-paid pre-addressed return envelope to return the watch to the IAPT service. The Apple smartwatch has been chosen for this feasibility study as iOS phones are the most widely used in the UK (over 50% of UK smartphones), and the device incorporates technical capabilities for secure logging and reading of required data [34]. Participants taking part with their own smartwatch will receive simple instructions on how to install and use the app. The installation process is largely automated and involves installing the existing SilverCloud Toolkit app from the App store.

During the intervention period, all participants will use the 'Space from Depression' program as per normal service procedures with support from a psychological wellbeing practitioner. The acceptance questionnaire will be repeated at 3 weeks (T2), and at 8 weeks (T3) with minor rewording to account for future/current/previous usage at each time point. In order to minimize non-compliance and drop-out from the study, participants will receive emails reminding them to complete each acceptance questionnaire when they haven't done so. At T3, participants who have been lent a smartwatch will be asked to unpair it from their mobile phone and return the smartwatch in the envelope provided.

Unpairing the smartwatch will delete all personal data from the smartwatch. Participants will also be given instructions on how to delete sleep and physical activity data stored on their own mobile phone should they wish to do so. Technical support, including issues with installation and unpairing, will be available through the SilverCloud platform as normal. Participants will be reminded to return the watch with scheduled reminders via phone and email. The reminders will emphasize that return of the device will enable other people to participate in similar studies. Returned devices will have a factory reset performed to erase all data, whether or not the participant has already done this. All participants will then complete a Patient Experience Questionnaire (PEQ) and Satisfaction with the Treatment questionnaire.

All participants will receive a £20 Amazon voucher upon completion of the final acceptance questionnaire (T3) and return of the watch for the smartwatch group. Participants in the smartwatch group who have indicated consent for the follow-up interview will be contacted by phone at the end of the study (8 weeks). Those who take part in the interview will receive an additional £10 Amazon voucher. We expect that 7 to 9 participants will take the interview.

3.10. Assessments

Upon giving consent, participants will be asked to complete socio-demographic details online, including information on gender, age, ethnicity, employment status, marital status, and their experience with the smartwatch technology. For each question, a “Prefer not to answer” option will be present.

3.10.1. Acceptance Questionnaire (AQ)

All participants who consent to the study will be asked to fill in the Acceptance Questionnaire (AQ) at 3 points in time: upon consent (T1), at 3 weeks (T2), and at 8 weeks (T3). The questionnaire (see Table 4) is based on the acceptance constructs identified in the Health Information

Table 4
Acceptance Questionnaire for the smartwatch group at T3.

Constructs	Item code	Measurement items
Perceived Health Threat	PTH1	I am strongly concerned about my mental wellbeing.
	PTH2	I would make efforts to manage my mental wellbeing.
Perceived Usefulness	PU1	I think that keeping track of my mood helped in managing my mental wellbeing.
	PU2	I think that keeping track of my sleep and activity automatically helped in managing my mental wellbeing.
	PU3	Overall, I think that the watch app was useful in managing my mental wellbeing.
Perceived Ease of Use	PEOU1	I think that it was easy to track my mood with the watch app.
	PEOU2	I think that it was easy to track my sleep and physical activity with the watch app.
	PEOU3	My interaction with the watch app was clear and understandable.
	PEOU4	I think that the watch app was easy to use.
Attitude	A1	I was comfortable recording my mood with the watch app.
	A2	I was comfortable recording my sleep and activity data with the watch app.
	A3	I was comfortable sharing my mood data with my SilverCloud Health supporter.
	A4	I was comfortable sharing my sleep and activity data with my SilverCloud Health supporter.
Intention to Use	ITU1	I would use the watch app again if I felt the need to monitor my mood.
	ITU2	I would use the watch app again if I felt the need to monitor my sleep and physical activity.
Usage Behavior	UB1	How would you describe your use of the watch app? [Open question]

Technology Acceptance Model [29]. The questions also provide coverage of the main constructs of the Theoretical Framework of Acceptability [27]. The wording of the AQ is adapted to the technology in question: the smartwatch for the smartwatch group, the mobile/desktop app for the treatment as usual group. Each question will be accompanied by a 5-point Likert Scale (strongly disagree to strongly agree). The result of the questionnaire will be a score from 9 to 45. The wording of the AQ will slightly change depending on the timing of its completion (see all versions in [Appendices, Tables A1–A3](#)).

At T3, a series of open-ended questions will be asked to the smartwatch group to explore additional factors that might influence the watch app acceptance: satisfaction [35–39], engagement [40,41], recommendation rate [35,41–43], sharing [35], privacy protection [44], resistance to change [45], and match with expectations [46] (see [Appendix Table A4](#)).

3.10.2. Follow-up interview

Participants in the smartwatch group who have indicated consent for taking part in the follow-up interview will be contacted after answering the final acceptance questionnaire (T3). The interview will be semi-structured and aimed at uncovering and teasing out participants' experience of using a smartwatch, as an acceptable means to monitor their mood, sleep, and activity level, alongside the ‘Space from Depression’ program (see sample of questions in [Appendix B](#)). The interview will last about 30 min and will be audio recorded.

3.10.3. Satisfaction with Treatment measure (SAT)

The SAT [47] will be used to assess patient satisfaction with the intervention as a factor of acceptance. This 5-item questionnaire has been used previously to evaluate patient satisfaction with the ‘Space from Depression’ intervention [47].

3.10.4. Objective data

The amount of mood monitor entries, sleep and activity data will be extracted. In addition, the following usage metrics will be collected.

Total time on the platform. This measure is the combination of the time spent in each session (in min) from the first to the last log-in. Time per session is calculated by taking the time from when the user logged in, to the last action the user performed in the platform, irrespective of when the session was closed.

Number of sessions. This measure corresponds to the number of times the user accessed the program. After 1 h of inactivity, the user is automatically logged out and they will be asked to log in again, which counts as a different session.

Number of tools used. This measure refers to the number of tools, out of the 9 available in the program, employed at least once by the user.

Percentage of the program viewed. This measure relates to the percentage of the total program content that the user has gone through.

Number of reviews. This measure reports the number of messages that the supporter sent to the user to encourage use of the platform and provide feedback about the progress from the last review.

3.10.5. Clinical effectiveness

This study is pragmatic as it is embedded within an existing service. The trial follows the usual procedures for IAPT, which include routine clinical assessments of patients. Thus, participants will be routinely assessed using the Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder (GAD-7), and Work and Social Adjustment Scale (WSAS) as part of the Minimum Dataset administered by IAPT [48]. The assessment will be assigned before each review and completed by the patient. These assessments will constitute patients' continuous treatment outcome scores.

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-item self-report measure of depression [49,50] that has been widely used in research and is employed as a clinical outcome measure in IAPT as part of its minimum dataset. The PHQ-9 items correspond to the diagnostic

criteria for depression defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [51].

Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 [52] is used nationally as a screening and outcome measure in IAPT and is part of the minimum dataset. The seven items measuring anxiety symptoms and severity correspond to the DSM-Fifth Edition diagnostic criteria for GAD [51].

Work and Social Adjustment Scale (WSAS). This is a five-item self-report questionnaire of functional impairment [53] that is employed nationally as an outcome measure in IAPT. It examines the experiential impact of a disorder across different life domains from the perspective of the service users. The questionnaire examines the degree of impairment caused by a disorder on a daily basis across five dimensions: work, social life, home life, private life, and close relationships.

3.11. Data analysis

Baseline demographics and outcome variables differences between groups will be analyzed through Chi-squared, Mann-Whitney and *t*-tests. For each Acceptance Questionnaire (T1, T2, and T3), descriptive statistics will be produced in order to observe the perceived health threat, perceived usefulness, perceived ease of use, attitude, intention to use, and usage behavior at these three time points. Internal consistency of the Acceptance Questionnaire will be measured through Cronbach's alpha coefficient. Linear Mixed-Model analyses will be used to assess within- and between-group differences over time for the subscales of the Acceptance Questionnaire.

Independent-samples *t*-test analyses, or non-parametric Mann-Whitney tests if data is not normally distributed, will be used to look for between-group differences in regard to several metrics (i.e. time spent, number of logins, number of tools used, percentage of program completed) along with the specific number of entries on the mood monitor. Linear Mixed Models will be conducted to explore if there are between-group differences on change in the clinical effectiveness measures (i.e. PHQ-9, GAD-7, WSAS) from baseline to post-treatment while accounting for missing data. Qualitative data including the transcribed follow-up interviews and answers to the open-ended questions in T3 in the SAT will be analyzed through a thematic analysis following the Braun and Clarke approach [54].

4. Discussion

This feasibility trial investigates the acceptance of using a smartwatch to collect more accurate and effortless self-report of mood, sleep, and physical activity in an internet-delivered CBT-based intervention for service users with depression. Patient acceptance is key to successful digital mental health interventions, as technologies that are not considered sufficiently acceptable will be rejected or abandoned. Low engagement and treatment dropout are major issues in technology-supported mental health interventions [55]. Thus, ensuring that patients are willing to use the technology and continue to use it until treatment completion is essential to the design of successful interventions [27]. Although smartwatches are increasingly employed in the general population to monitor health-related behaviors, few studies have investigated smartwatch technology as a component of existing digital mental health interventions, and to our knowledge, no study has assessed the acceptance of the use of smartwatch to deliver self-report. The current trial aims to bridge this gap by evaluating patient acceptance of the use of the smartwatch as means to self-monitor within the context of a digital mental health intervention.

This study explores the acceptance factors within the Health Information Technology Acceptance Model [29] and on the literature exploring acceptance issues specific to the context of mental health

interventions, whilst taking into account the temporal dimension of acceptance [26]. The insights gained from the follow-up interview will help further contextualize the acceptance measures. Taking a longitudinal approach and integrating a range of literature-based acceptance factors, this trial has the potential to inform the measurement of user acceptance of mental health technologies over time. Furthermore, the use of a control group undergoing the standard iCBT intervention for depression without the smartwatch will allow a more robust interpretation about whether the use of the smartwatch is producing any difference in usage and acceptance of the self-monitoring, and patients' clinical outcomes.

Smartwatch-delivered self-report has the potential to gather more accurate and complete data through Ecological Momentary Assessment – or in-the-moment assessment – of mood, and automated monitoring of the sleep and activity level. Having an acceptable and convenient means to record this data may help advance the research community's knowledge on the relationship between mood, sleep, physical activity, and clinical outcomes. In addition, the automated self-report of sleep and activity level, enabled by the passive monitoring of sensor data, may mitigate the burden associated with manual self-report [20]. Patients may also benefit from the immediate and private user interactions with the smartwatch, likely to reduce the perceived stigma often associated to the treatment of mental health difficulties [56]. Similar real-time feedback via smartwatch has been explored in the trial protocol of Dong et al. [57], and proved feasible in the subsequent clinical intervention, from which the authors concluded that smartwatch real-time feedback had the potential to support positive behavioral change in patients [58]. Moreover, by rewarding frequent and consistent self-report of mood, the smartwatch app aligns with literature showing the benefits to engagement of including game-like elements in mental health interventions [59,60].

Finally, establishing clinical feasibility will contribute to understanding the clinical utility of the smartwatch as a means to enhance self-monitoring, and for which population its use may be most suited. Most importantly, if the smartwatch-delivered and automated self-monitoring proves feasible, this will open the way to future studies to get a better understanding of the relationship between mood, sleep, physical activity, and clinical outcomes.² The findings of this trial will be used to plan future research to confirm the potential benefits of integrating a smartwatch within existing digital interventions for depression, and to investigate factors influencing patient engagement.

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Declaration of Competing Interest

The authors declare that C.E., A.E., D.R., and N.V. are employees of SilverCloud Health, developers of computerized psychological interventions for depression, anxiety, stress, and comorbid long-term conditions. G.D. is a cofounder of SilverCloud Health and has a minority shareholding in the company.

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² The smartwatch program code will be freely available under an Open Source license.

Investigator Sarah Sollesse and her team of psychological wellbeing practitioners.

Appendix A. Appendices

Table A1

Questionnaire before first use of the app (T1).

Constructs	Item code	Measurement items	
		Smartwatch group	Treatment as usual group
Perceived Health Threat	PTH1	I am strongly concerned about my mental wellbeing.	I am strongly concerned about my mental wellbeing.
	PTH2	I would make efforts to manage my mental wellbeing.	I would make efforts to manage my mental wellbeing.
	PU1	I think that keeping track of my mood with the watch app will help in managing my mental wellbeing.	I think that keeping track of my mood with the program will help in managing my mental wellbeing.
	PU2	I think that keeping track of my sleep and physical activity automatically will help in managing my mental wellbeing.	I think that keeping track of my lifestyle choices, such as sleep and physical activity, with the program will help in managing my mental wellbeing.
Perceived Ease of Use	PEOU3	Overall, I think that the watch app will be useful in managing my mental wellbeing.	
	PEOU1	I think that keeping track of my mood with the watch app will be easy.	I think that keeping track of my mood with the program will be easy.
	PEOU2	I think that keeping track of my sleep and physical activity with the watch app will be easy	I think that keeping track of my lifestyle choices, such as sleep and physical activity, with the program will be easy.
	PEOU3	My interaction with the watch app will be clear and understandable.	
Attitude	PEOU4	I think that the watch app will be easy to use.	
	A1	I will be comfortable recording my mood data with the watch app.	I will be comfortable recording my mood data with the program.
	A2	I will be comfortable recording my sleep and physical activity data with the watch app.	I will be comfortable recording my lifestyle choices, such as sleep and physical activity, with the program.
	A3	I will be comfortable sharing my mood data with my SilverCloud Health supporter.	I will be comfortable sharing my mood data with my SilverCloud Health supporter.
Intention to Use	A4	I will be comfortable sharing my sleep and physical activity data with my SilverCloud Health supporter.	I will be comfortable sharing my lifestyle choices, such as sleep and physical activity, with my SilverCloud Health supporter.
	ITU1	I intend to use the watch app until completion of my treatment.	I intend to track my mood and lifestyle choices, such as sleep and physical activity, when prompted by the program until completion of my treatment.
Usage Behavior	UB1	I decided to use the watch app because [...]	I decided to enroll in this study because [...]

Table A2

Questionnaire after three weeks of use (T2).

Constructs	Item code	Measurement items	
		Smartwatch group	Treatment as usual group
Perceived Health Threat	PTH1	I am strongly concerned about my mental wellbeing.	I am strongly concerned about my mental wellbeing.
	PTH2	I would make efforts to manage my mental wellbeing.	I would make efforts to manage my mental wellbeing.
	PU1	I think that keeping track of my mood with the watch app is useful in managing my mental wellbeing.	I think that tracking my mood with the program is useful in managing my mental wellbeing.
	PU2	I think that keeping track of my sleep and physical activity automatically helps in managing my mental wellbeing.	I think that tracking my lifestyle choices, such as sleep and physical activity, with the program is useful in managing my mental wellbeing.
Perceived Ease of Use	PU3	Overall, I think that the watch app is useful in managing my mental wellbeing.	
	PEOU1	I think that it is easy to track my mood with the watch app.	I think that it is easy to track my mood with the program.
	PEOU2	I think that it is easy to track my sleep and physical activity with the watch app.	I think that it is easy to track my lifestyle choices with the program.
	PEOU3	My interaction with the watch app is clear and understandable.	
Attitude	PEOU4	I think that the watch app is easy to use.	
	A1	I am comfortable recording my mood data with the watch app.	I am comfortable recording my mood data with the program.
	A2	I am comfortable recording my sleep and physical activity data with the watch app.	I am comfortable recording my lifestyle choices, such as sleep and physical activity, with the program.
	A3	I am comfortable sharing my mood data with my SilverCloud Health Supporter.	I am comfortable sharing my Mood Monitor with my SilverCloud Health supporter. [Option: Not encountered yet]
Intention to Use	A4	I am comfortable sharing my sleep and physical activity data with my SilverCloud Health supporter.	I am comfortable sharing my Lifestyle Choices chart with my SilverCloud Health supporter. [Option: Not encountered yet]
	ITU1	I intend to use the watch app until completion of my treatment.	I intend to track my mood and lifestyle choices, such as sleep and physical activity, when prompted by the program until completion of my treatment.
Usage Behavior	UB1	How would you describe your use of the watch app? [Open question]	How would you describe your use of the Mood Monitor and Lifestyle Choices chart? [(Open question, option: Not encountered yet]
	UB2	What difficulties (if any) did you experience while installing or using the Mood Monitor app? [Open question]	

Table A3

Questionnaire at treatment completion or 8 weeks the latest (T3).

Constructs	Item code	Measurement items	
		Smartwatch group	Treatment as usual group
Perceived Health Threat	PTH1	I am strongly concerned about my mental wellbeing.	I am strongly concerned about my mental wellbeing.
	PTH2	I would make efforts to manage my mental wellbeing.	I would make efforts to manage my mental wellbeing.
Perceived Usefulness	PU1	I think that keeping track of my mood helped in managing my mental wellbeing.	I think that tracking my mood with the program helped in managing my mental wellbeing.
	PU2	I think that keeping track of my sleep and activity automatically helped in managing my mental wellbeing.	I think that tracking my lifestyle choices, such as sleep and physical activity, with the program helped in managing my mental wellbeing.
	PU3	Overall, I think that the watch app was useful in managing my mental wellbeing.	
Perceived Ease of Use	PEOU1	I think that it was easy to track my mood with the watch app.	I think that it was easy to track my mood in the program.
	PEOU2	I think that it was easy to track my sleep and physical activity with the watch app.	I think that it was easy to track my lifestyle choices in the program.
	PEOU3	My interaction with the watch app was clear and understandable.	
	PEOU4	I think that the watch app was easy to use.	
Attitude	A1	I was comfortable recording my mood with the watch app.	I was comfortable recording my mood data with the program.
	A2	I was comfortable recording my sleep and activity data with the watch app.	I was comfortable recording my lifestyle choices, such as sleep and physical activity, with the program.
	A3	I was comfortable sharing my mood data with my SilverCloud Health supporter.	I was comfortable sharing my Mood Monitor with my SilverCloud Health supporter. [Option: Not encountered yet]
	A4	I was comfortable sharing my sleep and activity data with my SilverCloud Health supporter.	I was comfortable sharing my Lifestyle Choices chart with my SilverCloud Health supporter. [Option: Not encountered yet]
Intention to Use	ITU1	I would use the watch app again if I felt the need to monitor my mood.	I would use the Mood Monitor again if I felt the need to monitor my mood. [Option: I have not used the Mood Monitor]
	ITU2	I would use the watch app again if I felt the need to monitor my sleep and physical activity.	I would use the Lifestyle Choices chart again if I felt the need to monitor my sleep and physical activity. [Option: I have not used the Lifestyle Choices]
Usage Behavior	UB1	How would you describe your use of the watch app? [Open question]	How would you describe your use of the Mood Monitor and Lifestyle Choices chart? [Open question, option: Not used either]

Table A4

Open-ended questions for smartwatch group (T3).

Constructs	Item code	Smartwatch group
Match with expectations	MWE	How was the experience of using the watch app?
Engagement	E	How did the watch app impact how you used the <i>Space from Depression</i> intervention?
Recommendation	R	If you would recommend (or not) the watch app to other people using the <i>Space from Depression</i> program, could you explain why?
Sharing	S	How would you expect your supporter to use the information gathered through the app?
Perceived privacy	PP	How comfortable did you feel using the watch app in your daily life? When did you feel more/less comfortable using it?
Resistance to change	RTC	If you felt reluctant (or keen) to use the watch app, could you explain why?
Possible negative experience	PNE	If there were any negative aspects to your use of the watch app, could you describe these?
Watch app Features	WAF1	How did you feel about the reminders to record your mood?
	WAF2	How did you feel about the <i>Tips to Stay Well</i> (accessible from app menu)?
	WAF3	How did you feel about the encouragement prompts? If you haven't encountered any, how would you have liked to be encouraged/rewarded while using the watch app?
General feedback	GF	What do you feel could be improved about the watch app?

Appendix B. Follow-up interview (sample questions)

- Can you tell me what it was like for you to use the smartwatch with the Space from Depression program?
 - Was there anything particularly helpful?
 - Anything you liked
 - Anything that made you realize something important
 - Anything you didn't like
 - Anything unhelpful or off-putting?
 - What did you expect vs how it worked out in practice?
- How did you use the smartwatch and the program?
 - Could there have been anything to make it easier or more engaging?
 - Anything particularly helpful/unhelpful?
- Would you say the smartwatch was a helpful addition? If yes/no why?
- Anything else about your experience of using the smartwatch and space from depression program you would like to share?

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