RADAR-Engage: Protocol for a two-armed randomized controlled trial exploring the effects of in-app components on engagement with a symptom tracking platform among participants with major depressive disorder

Abstract

Background: Multi-parametric remote measurement technologies (RMTs) comprise smartphone applications and wearable devices for both active and passive symptom tracking. They hold great potential for understanding current, and predicting future, depression status. However, the promise of using RMTs for relapse prediction is heavily dependent on user engagement, defined as both a behavioral and experiential construct. A better understanding of how to promote engagement in RMT research through various in-app components will aid in providing scalable solutions for future remote research, higher quality results and applications for implementation into clinical practice.

Objectives: To provide the rationale and protocol for a two-armed, randomized controlled trial to investigate the effect of insightful notifications, progress visualization and researcher contact details on behavioral and experiential engagement with a multi-parametric mHealth data collection platform-RADAR-base.

Methods: The study aims to recruit a total of 140 participants upon completion of their participation in the Remote Assessment of Disease and Relapse- Major Depressive Disorder (RADAR-MDD) study London site. Data will be collected via three weekly tasks through an active smartphone app, a passive (background) data collection app, and a Fitbit device. Participants will be randomly allocated at a 1:1 ratio to receive either (A) an adapted version of the active app that incorporates insightful notifications, progress visualization and access to researcher contact details; or (B) the active app as usual. Statistical tests will test the hypotheses that participants using the adapted app will complete a higher percentage of weekly tasks (behavioral engagement; primary outcome) and score higher on self-awareness measures (experiential engagement).

Results: Recruitment commenced in April 2021. Data collection will be completed in September 2021. The results of this study will be communicated via publication in early 2022.

Conclusions: This study aims to understand how best to promote engagement with RMTs in depression research. Findings will help determine the most effective techniques for implementation into both future rounds of the RADAR-MDD study and, in the longer-term, clinical practice.

Trial registration: NCT04972474

Introduction

Background

The last decade has seen a monumental increase in the use of mobile technology in healthcare (mobile health; mHealth) research and clinical practice [1]. One such application of mHealth is the use of remote measurement technologies (RMTs), which provide real-time, longitudinal health tracking through a combination of smartphone apps for active symptom reporting tasks (active RMT; aRMT) and mobile/wearable sensors for passive data collection (passive RMT; pRMT) [2]. Multi-parametric RMT data has the potential to be informative about current clinical state by reflecting patients' daily experiences in-situ. It may also offer predictions by detecting subtle shifts in physiological, behavioural or environmental variables that occur before a change in clinical state [3], [4].

RMTs may be particularly relevant for recurrent conditions. Major depressive disorder (MDD) is a mental health disorder characterised by persistent low mood and anhedonia, often following a trajectory of remission and relapse over time [5]. The economic burden of MDD is currently estimated at $326 billion [6], with increased risks of comorbidities and healthcare use associated with high relapse rates [7]. RMTs can collect information on a wide range of factors associated with MDD (mood variability, sociability, activity, cognition, sleep) [2]. Raw, passive sensor data can be translated into low-level features, higher-level behavioural markers and, ultimately, clinical state [8]. Previous work has found ambulatory self-reporting of mood symptoms [9] and multi-parametric RMT measures of location, device usage and sleep across a 30-day period [10] to be clinically valid assessments of individual depression trajectory.

The benefits of using RMTs for MDD symptom tracking are two-fold. First, given the suggested biases [11] towards mood-congruent information in symptom reporting in depression, such data presents a more accurate picture of symptom variability. Second, continuous monitoring of symptom recurrence could provide the temporal resolution needed to detect indicators of future depressive episodes [4]. Therefore, the use of RMTs in MDD could hold great potential for understanding current, and predicting future, depressive state.

Remote Assessment of Disease and Relapse- Major Depressive Disorder (RADAR-MDD)

RADAR-MDD is a longitudinal, multi-site, prospective cohort study that is investigating the feasibility and predictive validity of RMT data in identifying predictors of MDD relapse [2]. It is part of the wider RADAR-CNS program [12] and uses the open-source mHealth platform, RADAR-base [13] to collect aRMT data (fortnightly tracking of mood, self-esteem, speech through an active smartphone app), pRMT data (GPS, Bluetooth interactions, ambient noise and light through a passive smartphone app; heart rate, step count from a wrist-worn wearable) and three-monthly outcome assessments (web-based) in participants with MDD. A core research team provided an initial enrolment session and support throughout a two-year, remote follow-up period. Data collection from 623 participants across London, Amsterdam and Barcelona sites concluded in April 2021. Results will explore whether multi-parametric RMTs can feasibly provide clinically relevant information and, if so, pave the way for translation of the platform into routine clinical practice and self-management of MDD.

Engagement with RMTs in research

The promise of research like RADAR-MDD depends heavily on user engagement. Engagement with mHealth technologies can be defined as 1) a behavioral construct, measured by objective, completion statistics and 2) an experiential construct, measured by focused attention and interest when interacting with the technology [14]. Qualitative studies suggest that service users endorse the use of RMTs in mental healthcare [15], [16]. Successful recruitment into the RADAR-MDD study also suggests widespread interest in using remote symptom tracking for research [17]. However, past studies have reported varying rates of behavioral engagement during follow-up. Studies using app-based symptom tracking in depressed cohorts reported low rates of data completion [18], [19]. A wider review of RMT for health management found large variations in aRMT and pRMT usage times [20]. Preliminary data from RADAR-MDD indicate that 55% of participants completed at least half of aRMT questionnaires, and 52% provided wearable data for over 75% of participating days [21]. Iterative work on the RADAR-base platform has also addressed the challenges of deciphering between low user engagement and technical issues with the technology [22].

Behavioral engagement with RMTs in research is vital to reduce data missingness and bias, and to enhance quality [23], [24]. An understanding of experiential engagement with RMTs however, and with the act of symptom tracking itself, could prove of equal benefit for data completeness and longer-term adherence. In work using multi-parametric RMTs in bipolar disorder, experiential engagement measures (self-awareness of emotional health, learning about symptoms) positively correlated with increased behavioral engagement with symptom tracking via a smartphone app and Fitbit [25]. A holistic approach to measuring engagement is necessary for understanding current lack of, and promoting future, engagement with RMT studies.

There are several methods available to promote engagement within RMTs themselves. Alongside the presence of a contactable research team, previously associated with increased engagement [17], [24], in-app components work remotely within the technology. Push notifications are prompts which appear on the smartphone screen and can be varied by content and timing [26]. Following Fogg's behavioral model [27], notifications provide a trigger to perform a behavior, such as completing tasks on a manual food logging app [28]. Adding theoretically informed notification content, such as insights or tips for using self-monitoring, can further motivate completion of mood scales [29]. Effects of notification frequency on engagement show mixed results [26], [30], [31]. Data visualization is also a common technique used in mood monitoring apps [32]. Visually displaying data completion allows users to revisit progress and may prompt the 'action' of continued data input [33]. This might be especially effective given that anticipatory pleasure is thought to predict motivation for reward in depressed individuals [34]. It is unclear which combination of in-app features can promote behavioral and experiential engagement with a multi-parametric symptom tracking app in depression. Findings in this field would go some way to providing scalable solutions for engagement in RMT studies, higher quality results and applications for implementation into clinical practice.

Study Aims and Objectives

This study aims to test the effect of in-app components in a multi-parametric RMT platform on engagement with active and passive symptom tracking in MDD. A two-armed randomized controlled trial will compare the RADAR-base active app as usual with an adapted app with insightful notifications and progress visualization, aimed at promoting behavioral and experiential engagement. Engagement will be measured as a) provision of symptom tracking data collected through RMT over the 12-week study period, and b) the degree to which participants feel experientially engaged with symptom tracking via the platform. It is hypothesized that participants using the adapted app will be better engaged in monitoring their symptoms, as measured both by behavioral engagement (completion of mood questionnaires) and

experiential engagement (measures of attention, aesthetic appeal and self-awareness). Process evaluation measures will also reveal participant experiences of the engagement strategies used.

Methods

Ethics Committee Approval

This study was approved by the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee at King's College London (reference number: RESCM-20/21-21083) and registered as a clinical trial (reference number: NCT04972474).

Study Design

This study is a 12-week, 2-arm randomized controlled trial with 1:1 randomization. A summary of the study design is given in Figure 1. A 12-week period was chosen to align with the original structure of the RADAR-MDD study [2]. Participants will be recruited from RADAR-MDD, provide baseline data (T0) and be randomized at enrolment (T1) to one of two arms: A) adapted app that includes insightful notifications and progress visualization (active arm), or B) active app as usual (control arm). Both the control and active arm will be delivered through the RADAR-base active app, which collects data in combination with a passive data collection app and a Fitbit Charge device (see [13] for a full overview). In both arms, participants will be asked to complete three tasks each week via the app and wear the Fitbit device throughout the study. The primary outcome is the percentage of weekly tasks completed over 12 weeks of follow-up.

Upon completion of the study, 20 participants (N=10 from each arm) will also be invited at random to complete a qualitative interview overviewing their experience of participating.

The study will be conducted using a combination of the RADAR-base platform, including the management portal Web application [13], and the Research Electronic Data Capture (REDCap) [35]. Due to the COVID-19 pandemic, participation will be fully remote.

Eligibility criteria

Inclusion Criteria

Participants will be included if they (i) participated in RADAR-MDD and gave consent for future research contact; (ii) experienced at least one episode of MDD in the two years preceding RADAR-MDD enrolment; (iii) are willing and able to continue to use an Android smartphone and Fitbit Charge device for a 12-week period (both provided for use in RADAR-MDD); and (iv) feel comfortable completing an enrolment session remotely, either via email instruction or video call.

Exclusion Criteria

Participants will be excluded if they have been diagnosed with a comorbid psychiatric disorder since enrolment into RADAR-MDD: bipolar disorder, schizophrenia, psychosis, schizoaffective disorder, or dementia. This will be checked with the participant via email during the recruitment process.

Recruitment

The study will recruit participants from the RADAR-MDD London site cohort. The study will recruit participants through the RADAR-MDD database of the London site. Contact details will be extracted from the RADAR-MDD REDCap system for those who have provided consent to be contacted for future research contact. This will include any participant who enrolled in the study during the 31 months of recruitment (November 2017- June 2020; n=345).

Participants will be invited to take part via an email that will explain the study and provide the participant information sheet. Interested participants will respond via email. They will then be asked the eligibility questions, again via email. If eligible, participant details will be entered into the study REDCap system, which will initiate sending of a personalized link to the online consent form and baseline questionnaires (T0). Once these have been completed, the participant will receive a second link to an online booking system, whereby they can book a timeslot for an enrolment session. Enrolments will be conducted across April and May 2021. On the day of enrolment, participants will receive an email (or a video call, depending on their preference) outlining instructions for downloading the study apps and unique QR codes for registering them to the platform (T1).

Interventions

Upon enrolment into the study, participants will be asked to (i) complete three tasks per week via the active app; (ii) allow the passive app to run in the background on their smartphone; and (iii) wear the Fitbit device as much as possible. The active app tasks are as follows:

- Patient Health Questionnaire-8 (PHQ-8) [36], an 8-item questionnaire assessing variability of depressive symptoms over the last week;
- Rosenberg Self-Esteem Scale (RSES) [37], a 10-item questionnaire assessing variation in self-esteem;
- A speech task, during which the participant records themselves reading aloud a short paragraph of text.

In both arms, the weekly questionnaire tasks, the passive app and Fitbit device remain the same. The study is designed such that the enrolment process is identical for both arms, to ensure 1) that participants not primed to the study arm they are assigned to, and 2) that both arms are comparable to RADAR-MDD.

Control condition

Participants in the control arm will receive one notification at 9am, 10am and 11:30am time points on the day that a questionnaire task is due, which reads ‘Questionnaire Time. Won’t usually take longer than 3 minutes.’. They will not be able to view any data, aside from through the Fitbit app.

Active condition

Development of the adapted app

The design of RADAR-MDD, including the active app, was heavily informed by service user involvement [38]. The current study used behavior change theory and further patient public involvement (PPI) work to inform its design.

To establish how best to promote the behavior of symptom tracking it is useful to draw on theories and models of behavior change. The Behavior Change Wheel (BCW) [39] presents a framework for the development of strategies to promote a target behavior. Previous work was used to identify key health-, user- and technology- related barriers to engaging with symptom tracking in MDD [15], [20] (Figure 2). Following the COM-B model, *psychological capabilities*, such as lack of symptom insight and perceived utility of the research, *automatic motivations,* related to motivational difficulties and low mood, and *physical opportunities,* such as inability to answer questionnaires at a specific time and unsure if the data has been logged, presented the most pertinent barriers. Following the BCW, suitable intervention functions thus included education, incentivization and enablement [39]. As such, it was decided that an engaging app should include reminder notifications with information on the potential impacts of symptom tracking, from a credible source. It should also include incentivizing feedback on behavior, in the form of data visualization. Finally, users should be provided with researcher contact details should they need to report technical issues or receive support.

The progress visualization component was further informed by service user involvement (Simblett et al., in preparation) [40] (Figure 2). Simple, clear graphical representations of data were preferred, presented on a white background with colored data points. Users expressed an interest in positive reinforcement based on reaching achievements, e.g. step count goals, and/or simply entering data, coupled with a visual representation of completion, e.g. a color change. They also requested the choice to view or hide visualizations. Therefore, the visualization component was designed to comprise a separate section of the app that users can choose to view, with a simple, colored graph showing (non)completion at each weekly time-point. Completion is denoted by a green dot, non-completion by a red dot.

In-app components

Participants in the active arm will receive the same notification time points as the control arm, alongside the following additional content (Figure 3):

- Theoretically informed notifications: Additional sentences included in the notifications, covering the proposed benefits of remote symptom monitoring for emotional self-awareness, clinical practice and research.
- Progress visualization: Participants will be able to view their questionnaire task completion through the app, visualized as a graph that is accessible from the main app homepage.
- Research team contact details: Additional text on the app homepage will provide a contact phone number, email address and contact times for the research team.

Data collection and follow-up procedure

A summary of measures and data collection timepoints is outlined in Table 1.

Baseline questionnaires will comprise questions on contact information, socio-demographics, recent service use, physical and mental health history and comorbidity, including presence of depression, and recent life events. The research team will also manually pull data pertaining to participation in RADAR-MDD for each participant, e.g. participation length, completion rates. At the 12-week post-baseline follow-up, participants will receive a personalized link to repeat several of the baseline questionnaires. Responses received more than three weeks after baseline or follow-up will not be recorded.

The research team (KW) will monitor incoming data streams to ensure that the app is functioning correctly. Participants will not be contacted by the team once enrolment is complete, aside for a check-in email at the 6 week point to ensure the app is functioning correctly. Participants will not be withdrawn from the study based on non-engagement; however, participants will be made aware that they can withdraw at any point.

Suicidal ideation will also be monitored at baseline (T0) and follow-up (T2). Participants who report ideation or intent at either time point will be contacted via phone-call, advised to contact their treating physician and emailed a list of appropriate signposting.

Upon completion of the study, participants will view a debrief page, explaining that the study aimed to test the effectiveness of notifications and progress visualizations on engagement with the platform. Both arms will be outlined, identifying arm assignment and end-point instructions.

Table 1. A summary of measures and data collection points across the 12-week follow-up period.

	Baseline (T0)	End-point (T2)	Weekly	Continuously
REDCap survey				
Consent	X			
Contact Information	X			
Current Study Devices	X			
Socio Demographics	X			
Social Environment	X			
Medical History	X			
Lifetime Depression Assessment Self-report (LIDAS) [41]	X			
Inventory of Depressive Symptomatology (IDS-SR) [42]	X	X		
The World Health Organization Composite International Diagnostic Interview Short-Form (CIDI-SF) [43]	X	X		
Generalised Anxiety Disorder-7 (GAD-7) [44]	X	X		
Work and Social Adjustment Scale (WSAS) [45]	X	X		
Brief Illness Perception Questionnaire (BIPQ) [46]	X	X		
Life Events [47]	X	X		
Client Service Receipt Inventory (CSRI) [48]	X	X		

User Engagement Scale (UES; adapted for mHealth use) [49]	X	X		
Emotional Self-Awareness Questionnaire (ESQ) [50]	X	X		
mHealth App Usability Questionnaire (MAUQ) [51]	X	X		
Active app measures				
Patient Health Questionnaire (PHQ-8) [36]			X	
Rosenberg Self-Esteem Scale (RSES) [37]			X	
Speech Task			X	
Passive app measures				
GPS, Bluetooth, Ambient noise/light				X
Fitbit				
Heart rate, Step count				X
Process evaluation				
App Usage Metrics				X
Qualitative interviews		(X)		

Outcome Measures

Primary outcome measure

The primary outcome measure will be behavioral engagement with the RADAR-base system. This will be measured as the percentage of weekly PHQ-8 questionnaires that are completed over the 12-week follow-up period. Completion of one PHQ-8 task is defined as completion of the full 8 questions.

Secondary outcome measures

Secondary outcome measures will be:

1. Experiential engagement with the RADAR-base platform, measured with the User Engagement Scale (UES) [52], adapted to mHealth use [49]. The UES is a 30-item questionnaire measuring four factors of experiential engagement with mHealth apps: focused attention, perceived usability, aesthetic appeal, and reward. The UES has been widely adopted and shows good reliability and construct validity [53].
2. Experiential engagement with the RADAR-base platform, measured by the Emotional Self-Awareness Questionnaire (ESQ) [50]. The ESQ is a 33-item questionnaire measuring recognition, contextualization and decision-making in relation to one's own emotions. The ESQ has a reliability of .92 and shows significant positive correlations with the Emotional Intelligence Test [50].

3. System usability, measured via the mHealth App Usability Questionnaire (MAUQ) for Standalone Apps used by Patients [51]. This will be assessed at T2 only, asking participants to reflect solely on their experiences over the last 12 weeks. The MAUQ comprises 18 questions relating to immediate and long-term usability of the app, including for healthcare management (overall Cronbach alpha = 0.914).
4. Combined adherence to the active and passive (Fitbit) components of the system. This will be measured as follows: adherence rate for the active app measured as the proportion of participants with over 50% of completed data across all three weekly questionnaire tasks, and adherence rate for the passive Fitbit measured as the proportion of participants with over 50% of study days with any recorded data. These measures were chosen to align with data availability reporting in RADAR-MDD [21], previous literature [25], and the minimum amount of data sufficient for performing predictive analyses.

Additional data collection

Passive data through the RADAR-base passive app will also be collected, however these will not be analyzed as part of this trial. This additional data will be collected for two reasons: 1) to emulate the RADAR-MDD as closely as possible, and 2) for use in future analyses. The passive app collects information on phone location, battery level, Bluetooth devices, and background noise and light. Participants can opt out of using any of the study apps during participation.

Process evaluation measures

Process evaluation measures will also be collected, in order to further understand interaction with the RADAR-base system. Quantitative measures will be obtained regarding app usage: notification interaction, app initialization, specific module viewing and viewing time. These will be available from the RADAR-base platform back-end.

At the end of the follow-up period, 20 participants will be randomly invited to participate in a semi-structured telephone interview with a member of the research team, discussing their experiences of participating in the study. Discussions will comprise perceptions of the arm the participant was randomized to, experiences of the in-app techniques used, suggestions for further improving engagement with the system, and views on engagement with RMT systems for symptom tracking in research, clinical care and self-management (Supplementary Material 1).

Sample Size

A power calculation was performed based on preliminary data from RADAR-MDD. A total of 132 participants are needed to detect a difference of 25% completion of PHQ-8 tasks between the control and active arms, with 80% power and 95% confidence intervals, at the 12-week endpoint. Allowing for 10% attrition (based on previous research [21] but accounting for a much shorter follow-up period in this study), we will aim to recruit 140 participants. A total of 345 participants will be available to be contacted from the RADAR-MDD study cohort; assuming 50% acceptance of invitation (given the recruitment from a previously motivated cohort) a target of 140 participants should be feasible.

Randomization

Randomization will occur after baseline data collection, when the REDCap randomization module initiates the generation of a QR code from the RADAR-base management portal, assigned to the participant identifier. Each participant will be randomly allocated at a 1:1 ratio to either the control or active arm. Simple randomization will be used, whereby an allocation table with a random sequence of 1,2 will be generated and uploaded to REDCap. This will be carried out by a team member external to the core research team (YR) and therefore concealed from the main researcher (KW) before enrolments.

Blinding

Individual participants will have previously used the RADAR-MDD app, and therefore cannot be blinded since they might recognize new features of the app. However, arm assignments will not be explicitly revealed to participants until study debrief.

The researcher (KW) will be unblind to allocation to ensure that remote enrolments have been carried out correctly. All measures are conducted via the app or online REDCap system, to avoid detection bias in assessments [54]. The trial data manager (DL) will be blind to arm allocation. No other individuals will have access to the dataset for data monitoring or analysis purposes; all tasks will be carried out by the main researcher (KW).

Data management

All data collected via the Fitbit device and smartphone apps will be encrypted and uploaded to a secure server maintained by King's College London, in accordance with the process cited in [13]. The REDCap system sits on the King's College London Rosalind server. Only members of the RADAR-Engage team will have access to identifiable data. Qualitative interview data will be temporarily stored on the King's College London server, transcribed anonymously and subsequently deleted.

Statistical analyses plan

All data, including those from withdrawn participants (unless they request for their data to be deleted), will be included in the final analysis. Demographic and clinical characteristics at baseline and follow-up will be summarized by arm using appropriate summary statistics, e.g. mean and standard deviation for continuous variables; counts and percentages for categorical variables. Data completeness for all measures and outcomes will be summaries.

The primary outcome will be analyzed using 2-sample t-tests to assess whether mean percentage of PHQ-8 completion in each arm is statistically different.

For the secondary outcomes, experiential engagement (as measured by the UES and ESQ) will be collected at T0 and T2, thus will be calculated as a change from baseline. This will be assessed using repeated measures mixed modeling, to explore whether experiential engagement is statistically different between the two arms. App usability scores (MAUQ) and whole system adherence rates will also be compared. Complete case analyses will be used; if less than 20% of responses to each single questionnaire are missing, mean imputation will be used to provide a total score.

All analyses will be conducted under the intention-to-treat (ITT) principle. Threshold for statistical significance will be $P = 0.05$.

Process evaluation analyses

Qualitative interviews will be transcribed and coded by nVivo software [55]. Grounded theory thematic analysis will provide an exploration of participant experiences across the two arms and with the additional, in-app components. Descriptive statistics will be reported for app usage statistics alongside this.

Dissemination

This study will be reported following the CONSORT (Consolidated Standards of Reporting Trials) checklist [56]. The results of this study will be communicated via publication.

Results

This study will begin recruiting and enrolling participants across April and May 2021. Data collection will be completed by September 2021. Data analysis will commence in 2022. The results of this study will be communicated via publication in mid-2022.

Discussion

The use of RMTs for symptom tracking in MDD research holds great potential for relapse prediction and personalized healthcare. Understanding current, and promoting future, engagement with RMTs in research studies is of upmost importance for producing high quality results, only amplified by the shift to remote healthcare monitoring during the COVID-19 pandemic [57]–[59]. While previous work has explored the impact of specific in-app components in encouraging data completion [25], [26], [32], [33], to our knowledge this study is one of the first to explore the promotion of engagement with a multi-parametric RMT system for MDD symptom tracking. Within the framework of the RADAR-base system, this work uses the questionnaire app as the participant-facing conduit for promoting behavioral and experiential engagement with active and passive RMT in a large-scale research study, incorporating theoretical notifications and progress visualization.

Findings of the current work will, firstly, go some way towards understanding how best to promote engagement in subsequent rounds of the RADAR-MDD study. The ability to collect sufficient data remotely, relying less heavily on a core research team whilst also minimizing burden on the user, is a hugely valuable asset to RMT research. This study also represents the first attempt to recruit and follow-up participants completely remotely using RADAR-base and, if successful, will pave the way for fully remote recruitment across a range of conditions. Secondly, this work will shed light on experiential engagement with RMT symptom tracking. Findings here could uncover new methods for measuring and promoting engagement in MDD research. Thirdly, studying behavioral and experiential engagement in a research context can act as a proxy for understanding engagement in a clinical context [60]. Taken together, these findings could have wider implications for RMT research studies across health conditions, alongside the implementation of RMT data collection in clinical settings.

A key strength of this study is its grounding in a previous research project, using a system which has already been well-documented, designed and developed for the purpose of RMT data collection [21], [61], [62]. It also takes an additional theory-driven and user-centered approach to adapting components

of the system to promote optimal user engagement. However, we remark on three main limitations. First, our ability to recruit and retain a sufficient number of participants for power analyses may be hindered by participation fatigue, given that many will have completed up to two years in the previous study. It is also unclear as to the effects of the COVID-19 pandemic on participant willingness to engage in research studies. Second, it should be considered that recruiting from an existing study cohort, with prior understanding of the system, could create a ceiling effect for engagement, such that participants are already highly motivated to engage in symptom tracking. App literacy has also been noted as a key facilitator of mHealth app engagement [63]. Nonetheless, there is good reason to believe that the new, in-app components can encourage engagement over and above the moderate data availability reported in RADAR-MDD [21]. Third, while concerted efforts were made to include health-, user-, and technology-related barriers to engagement in the app development process, we acknowledge that this is not all-encompassing. Certain aspects of depressive symptomatology, for example low mood or motivation [34], could affect engagement with the RADAR-base system in ways which might not be mitigated by theoretical notifications or progress visualization. To this end, we have also included process evaluation measures to further understand how participants interact with the components and gain insight for future improvements.

Funding

The RADAR-CNS project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115902. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA (www.imi.europa.eu). This communication reflects the views of the RADAR-CNS consortium and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein. The funding body have not been involved in the design of the study, the collection or analysis of data, or the interpretation of data.

This paper also represents independent research part funded by the National Institute for Health Research (NIHR) Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Acknowledgements

This research was reviewed by a team with experience of mental health problems and their carers who have been specially trained to advise on research proposals and documentation through the Feasibility and Acceptability Support Team for Researchers (FAST-R): a free, confidential service in England provided by the National Institute for Health Research Maudsley Biomedical Research Centre via King's College London and South London and Maudsley NHS Foundation Trust.

Finally, we would like to thank all members of the RADAR-CNS patient advisory board, who all have experience of living with or supporting those who are living with depression, epilepsy or multiple sclerosis.

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