Research Protocol: Digital Assessment of Wellbeing in New Parents (DAWN-P)

Contents

Introduction

The mental health of new parents around the time of the birth of their baby has been identified as a key priority in the NHS Long Term plan. At present, there is no nationally implemented method for monitoring parents' mental health, although the use of the Edinburgh Postnatal Depression Scale (EPDS) has been recommended. This is a paper based questionnaire administered by health visitors in the postnatal period. For the purposes of this project, we contacted health visitors in Manchester to find out how they use EPDS in practice. Currently, health visitors only use the questionnaire if they feel there is a need during visits, and the questionnaire is not kept (only the overall score). Since almost 20% of mums develop postnatal depression, more systematic and thorough screening is needed.

We developed an app version of the EPDS which takes less than 2 minutes to complete on a smartphone. We anticipate that this will be a more accessible and practical method of conducting this important assessment. This project is a feasibility study to find out whether an app would be a feasible, acceptable, valid and safe way to monitor perinatal mental health in women and their partners.

We aim to recruit 20 women and their partners in late pregnancy (after 36 weeks gestation) and ask them to use the app. The app will prompt completion of the EPDS once per day until 6 weeks postnatally. Participants' responses on the app will be transferred to a secure server at the University of Manchester. Participants will be invited to complete a paper version of the EPDS at the beginning and end of the study to check validity. They will also be asked to complete a questionnaire measuring the acceptability of the app and to take part in a brief qualitative interview at the end of the study.

Background

The mental health of new parents around the time of the birth of their baby has been identified as a key priority in the NHS Long Term plan (Section 3.16; NHS England, 2019). Almost 20% of mums develop postnatal depression during the three months after giving birth (Gavin et al, 2005). For fathers, the rate of depression peaks slightly later, with 7.7% of fathers developing depression in the first three months, rising to 26% in the 3-6 months postpartum (Paulson and Bazemore, 2010). Early detection and treatment can reduce the risk of severe postnatal depression developing (Davies et al, 2003).

At present, there is no nationally implemented method for monitoring parents' mental health, although use of the Edinburgh Postnatal Depression Scale (EPDS; Appendix A) has been recommended (Davies et al, 2003; NICE, 2014). This is a widely-used paper-based questionnaire, typically administered by health visitors in the postnatal period. The EPDS shows moderate validity in both mothers (Eberhard-Gran et al, 2001; Gibson et al, 2005) and fathers (Edmondson et al, 2010). For the purposes of this project, we contacted health visitors in Manchester to find out how they use EPDS in practice. Currently, health visitors only use the questionnaire if they feel there is a need during visits, and the questionnaire is not kept (only the overall score). Since so many new parents develop postnatal depression, more systematic and thorough screening is needed.

Smartphone apps have been shown to be acceptable for monitoring symptoms of a range of mental health problems such as depression (Firth et al, 2017), psychosis (Berry et al, 2016) and bipolar disorder (Nicholas et al, 2015). Apps have a number of advantages over paper based questionnaires: they can be accessed at times and places convenient to the individual, since smartphones tend to be carried on one's person and their use is often integrated within daily life (Ben-Zeev et al, 2013). Monitoring with an app is less resource intensive, meaning that assessments can be more frequent, reducing the risk of retrospective recall bias since the period to be recalled is shortened (Ben-Zeev et al, 2012). Native smartphone apps also have advantages over web-based systems as they are less dependent on a good data or Wifi connection and therefore more accessible in rural locations and for low income users (Ben-Zeev et al, 2013). Moreover, native apps are widely used in the general population so they may be a low stigma way of assessing mental health (Berry et al, 2019; Bucci et al, 2018) and they can include automated features such as reminders, generation of graphs and secure upload of data.

There has been no research to date examining the feasibility, acceptability, validity and safety of using a smartphone app to screen for depression in new parents during the early postpartum period. For clarity: feasibility relates to whether people will actually use an app for this purpose; acceptability concerns to whether people like using an app for this purpose; validity examines whether the app measures what it is supposed to measure, by comparing it with current gold-standard assessments; safety evaluates whether there are any adverse effects of using the app.

We searched the literature for studies or study protocols testing smartphone apps to screen for postnatal depression in new parents and found none published to date. Although we found one study (Jiménez-Serrano et al, 2015) describing the development of an app for this purpose (within the Spanish healthcare system), the app's feasibility, acceptability and validity have not yet been tested. We found several studies examining the use of one-off screening using a tablet device in the postnatal period (e.g. during clinic visits), but none using a smartphone app to screen on a repeated measures basis postnatally. Similarly, we found a number of studies (Hantsoo et al, 2017; Faherty et al, 2017; Tsai et al, 2014; Krishnamurti et al, 2017) and one protocol (Belisario et al, 2017) using a smartphone app to screen for depression during pregnancy but not during the postnatal period. Overall, there appears to be a gap in the literature in terms of screening for postnatal depression using a smartphone app.

Therefore, we developed an app version of the EPDS (the ClinTouch DAWN-P app) which takes less than 2 minutes to complete on a smartphone. We anticipate that this will be a more accessible and practical method of conducting this important assessment than using paper based questionnaires. This project is a feasibility study to find out whether an app would be a feasible, acceptable, valid and safe way to monitor perinatal mental health in women and their partners.

Aim

The aim of the study is to investigate whether it is feasible, acceptable, valid and safe to use a smartphone app to screen for depression in new parents during the early postnatal period.

Study Objectives

Primary research question

1: Is it feasible to use a smartphone app to screen for postnatal depression in mums and their partners during the 6 weeks postpartum? (measures of feasibility will include: percentage of eligible individuals recruited to the study; dropout rate; percentage of app-based assessments completed during the app-use phase; percentage of participants completing at least a third of app-based assessments; percentage of participants completing at least half of app-based assessments; timing of responses during the 2 hour response period)

Secondary research questions

2. Do mums and their partners find it acceptable to use a smartphone app for this purpose? (abridged Mobile App Rating Scale and qualitative interviews)

3. Is it valid to use a smartphone app for this purpose? (comparison of app based assessment with gold-standard paper questionnaire assessment)

4. Is it safe to use a smartphone app for this purpose? (adverse events will be monitored throughout the study)

5. What are participants' experiences of using an app for this purpose? (qualitative interviews)

6. Who is most likely to use an app for this purpose? (analysis of baseline clinical and/or demographic predictors of app engagement during the study)

7. How long do participants use an app for this purpose? (analysis of pattern of app use over time during the study)

Design

This is a longitudinal feasibility study comprising:

- A baseline meeting for app setup and training.
- A 6-10 week follow up period in which participants are asked to use the app once per day to answer questions about their mental health (from late pregnancy until their baby is 6 weeks old).
- A follow-up meeting, to debrief, conduct questionnaires and a brief qualitative interview.

Participants

Inclusion and exclusion criteria

We aim to recruit 20 women in late pregnancy from the Antenatal Assessment Unit and the Antenatal Clinic at St Mary's Hospital. Their partners will be invited to participate where applicable.

Inclusion and exclusion criteria for pregnant women are as follows:

- Inclusion: after 36 weeks gestation, aged over 18 years and fluent in English, under the care of Manchester University NHS Foundation Trust
- Exclusion: current stillbirth (women experiencing a stillbirth during the study will be withdrawn from the study), fetal abnormality, or multiple pregnancy

Inclusion criteria for partners: male or female partners of a mum participating in the study, aged over 18 and fluent in English.

Recruitment and consent

Clinicians at St Mary's hospital will identify potential participants by reviewing the medical records of pregnant women attending the Antenatal Assessment Unit and/or the Antenatal Clinic (both non-emergency settings). Clinicians identifying potential participants will be part of their direct care team; they will provide initial information about the study, either verbally or using the initial information sheet (Appendix B). Posters (Appendix B) will also be displayed in St Mary's hospital to allow potential participants the opportunity to self-refer to the study.

Clinicians approaching potential participants about the study will make it clear that taking part is completely voluntary. If the person decides not to participate, the clinician will ask them to briefly state their reasons for not wanting to do so. The clinician will reiterate that participation is voluntary and make it clear that they are under no obligation to supply this information about their reasons for declining to participate. If the potential participant gives reasons for declining to participate, this reason will be entered completely anonymously into a spreadsheet (Appendix Q). A summary of this information will be reported anonymously in final study reports and will be used to inform future studies (e.g. if most people declined to participate because the smartphone app asked them to answer questions too often, a future version of the study might use an adapted version of the app with less frequent questions).

If the service user is interested in participating, the clinician will either:
a) ask the potential participant to complete a consent-to-contact form (Appendix L) and pass on their contact details to the research team and provide initial information to confirm eligibility;
or
b) complete the informed consent process for the study themselves and then pass the participant's details on to the research team, along with the signed consent form (Appendix D).

If the potential participant is interested, the clinician or a researcher will provide a Participant Information Sheet (Appendix C). Where possible, the participant will have at least 24 hours to

read the information before having the opportunity to discuss it with the clinician/researcher. In this face-to-face meeting they will have the opportunity to discuss the information and ask any questions. If the potential participant wishes to take part they will be asked to sign a consent form (Appendix D).

When a pregnant woman has consented to take part in the study, she will be asked if she has a partner who would potentially be interested in participating. If so, separate consent will be sought from the partner.

The participant information sheet will make it clear that the participant is free to withdraw from the study at any time without giving a reason. Demographic and clinical information will be retained in the event that the participant withdraws. Data provided during the study will be retained unless the participant requests otherwise. Participants who withdraw during the app use phase of the study will be asked if they would be willing to take part in a qualitative interview. As this is a feasibility study it is important that the views of withdrawing participants are represented in the qualitative interviews if at all possible in order to inform future studies. However, it will be made clear to the participant that it is up to them whether they take part in qualitative interviews; they are under no obligation to do so.

DAWN-P smartphone app

App design

The software for the ClinTouch DAWN-P app will be based on that of the original ClinTouch app. ClinTouch is a smartphone-based platform for a range of m-health interventions designed to help people with mental health disorders to monitor their own symptoms and prevent relapse. We have been developing and testing it since 2009. Using “experience-driven design”, it has been developed with patients, clinicians and NHS health professionals and an academic team with software engineers at the University of Manchester, funded by MRC grants of £1.5m. It can be deployed in any long term mental or physical health condition. It works as a personalised smartphone application which triggers, collects and wirelessly uploads symptom data to a central server several times daily. We have shown that it is acceptable and feasible for people with mental health problems over extended periods. We have shown that the data collected are valid as measured against gold-standard rating scales. However, it has not yet been specifically tested for screening for emerging mental health conditions in a sample of parents during the postnatal period.

The DAWN-P app will alert participants once per day (using a beep and a visual notification on the phone screen) and ask them to complete a series of questions about their mental health: namely, the ten items from the Edinburgh Postnatal Depression Scale (Appendix A). Each question will be displayed on the screen along with the four possible responses, chosen via radio buttons (see Figure 1). After each alert, participants will have a 2 hour response window in which to answer the questions. Their responses will be uploaded to a secure server at the University of Manchester. The research team will be able to log in via a password-protected web interface to view participants’ responses.

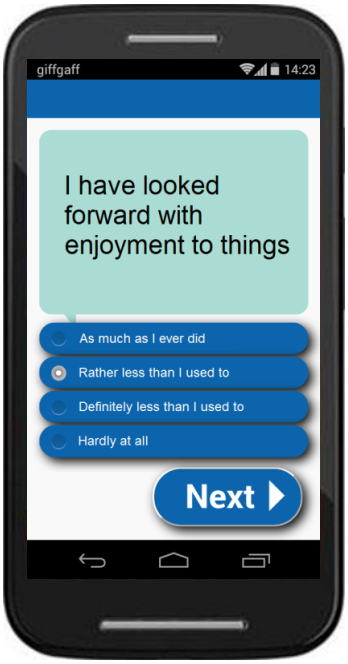

Figure 1: Mock-up of a question from the DAWN-P app

App registration

The original ClinTouch app was ruled not to be a Type 1 medical device by the Medicines and Healthcare products Regulatory Agency (MHRA). The same would apply to the ClinTouch DAWN-P app; thus, it does not require registration with MHRA.

According to the MHRA guidance document entitled 'Medical device stand-alone software including apps' (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717865/Software_flow_chart_Ed_1-05.pdf), the app does not have a 'medical purpose' (pg.10 of the guidance) and does not 'work in combination with one or more devices' (pg. 6), so is not classed as a medical device. For the purposes of the present study, the app is analogous to a paper diary, being used purely to collect data rather than to make a diagnosis or prompt participants to seek help.

App setup and training

At the beginning of the study, the DAWN-P app will be installed on the participant's phone (if suitable) or they will be lent a study phone to use for the duration of the study. In cases where the participant is lent a phone, all phones remain the property of Affigo for the duration of the study and participants will sign a form confirming that they will return the phone on completion of or withdrawal from the study.

The clinician/researcher will train the participant in how to use the app. Participants will spend some time familiarising themselves with the app, in the presence of the clinician/researcher, and will answer some practice questions on the app to check that they feel confident in using it. They will have the opportunity to ask the clinician/researcher any questions about the app at this stage. At the end of the initial app setup and training meeting, participants will be given a paper version of the EPDS and a stamped addressed envelope to take home with them.

Data collection

Demographics and casenote data

Participants (pregnant women and partners) will be asked to complete a demographic questionnaire (Appendix M) during the app training session, including the following: age, gender, ethnicity, employment status, whether English first language, past psychiatric history (any history of major depression, previously prescribed psychiatric medication, previously referred for talking therapy).

For participating pregnant women, the following additional information will be gathered from casenotes: BMI, past psychiatric history as reported in casenotes (any history of major depression, previously prescribed psychiatric medication, previously referred for talking therapy), answers to mental health screening questions at booking appointment (NICE, 2014: section 1.5.4), details of current childbirth (mode of delivery, live/still birth, any major obstetric complications), parity (total number of pregnancies reaching viable gestational age).

App-reported data

Participants (mums and their partners) will be asked to answer the ten EPDS questions, via the app, once per day until their baby is 6 weeks old. The questions are likely to take a maximum of 2 minutes to complete on each occasion. As not all births will occur on the due date, the exact length of time that participants are asked to use the app for will vary to some extent:

- Someone giving birth at 36 weeks would complete the app for 6 weeks in total
- Someone giving birth at 38 weeks (their due date), would complete the app for 2 weeks before and 6 weeks after the birth (8 weeks in total).
- Someone giving birth at 40 weeks gestation would complete the app for 4 weeks before and 6 weeks after giving birth (10 weeks in total).

Telephone calls

The researcher will phone the participant at the end of the first week and then fortnightly after that (e.g. at the end of weeks 3, 5 and 7 for someone giving birth on their due date) to thank them for participating, troubleshoot any technical difficulties with the app, ask whether they have any queries or concerns, and encourage them to continue participating. If applicable, these phone calls will provide an opportunity for the participant to tell the researcher that they are no longer able to participate in the study for any reason, including, but not limited to, the unlikely event that the participant's baby's contracts a serious illness or dies.

After the first week of app use, participants will be asked to complete the paper version of the EPDS that they were given in the baseline meeting. The researcher will send them a text message (from the researcher's work mobile phone) to remind them to do so (see Appendix N for text message template). In the 1 week phone call, the researcher will ask the participant to either read out their answers from the questionnaire during a phone call, or alternatively to email an anonymous photograph of the questionnaire to the researcher. Participants will then be asked to return the original paper copy in the stamped addressed

envelope. Answers from the paper based questionnaire will be compared to app-reported answers from the previous week to check the validity of the app-based measure.

In the final phone call, the researcher will arrange a face-to-face follow up meeting with the participant.

Follow-up meeting and qualitative interview

At the end of the app use phase of the study, the researcher will arrange a follow up meeting with the participant to debrief and return the study phone (if applicable). During this meeting they will ask the participant to complete a paper version of the EPDS (for further validity checks against app-based assessment) and an abridged version of the Mobile App Rating Scale (Gumley et al, 2019; Appendix E) to assess app acceptability.

Participants will also be asked to take part in a brief qualitative interview exploring their experiences of using an app for screening for postnatal depression and their views on the acceptability of this screening method. Informed consent will be gathered for this using a separate consent form (Appendix F), including specific consent to audio-record the interview. Women and their partners will be interviewed separately.

As many participants as possible will be interviewed, including some who dropped out of the app-use phase of study. This will ensure that a balance of views are gathered regarding the acceptability of the app-based screening. For individuals who dropped out of the app use phase, the Research Associate will emphasise that participation in the qualitative interview is entirely voluntary and it is up to the participant whether they want to do so. If the individual does not wish to participate, the Research Associate will thank them for their participation to date and assure them that their decision not to participate in the qualitative interviews will not affect the care that they receive from the NHS Trust. As stated above, separate consent will be sought for qualitative interviews in order to be sure that participants fully agree to participate.

Interviews will be conducted by a Research Associate (EE) experienced in conducting and analysing qualitative interviews and with personal, lived experience of postnatal depression. Interviews will last around 30 minutes and will be audio recorded. A detailed topic guide is given in Appendix G. Throughout the interview, the approach will be flexible in terms of the order of questions and the vocabulary used, and probe questions will be used where applicable to prompt further elaboration by the interviewee. It is worth noting that the example questions and topic guide are necessarily preliminary. Topics may be further developed during the course of the interviews. The researcher will make brief notes after each interview on a proforma (Appendix H), including, for example, any important contextual details during the interview and whether any alterations to the topic guide are needed for the next interview. Audio recorded interviews will be transcribed verbatim and analysed using framework analysis.

Adverse events

To assess the safety of the app, adverse events will be monitored throughout the study. As is standard practice for this type of study, we will complete the Health Research Authority form (https://www.hra.nhs.uk/documents/1087/safety-report-form-non-ctimp.docx) to report any serious adverse events.

We will also record all untoward medical occurrences or clinical indications, their relatedness to the DAWN-P app, their seriousness and intensity and whether or not the event was anticipated, as recommended by Bradstreet and colleagues (2019).

Outcome measures

Primary outcome measure

The feasibility of using a smartphone app to screen for postnatal depression in mums and their partners during the 6 weeks postpartum.

(Research question 1: Is it feasible to use a smartphone app to screen for postnatal depression in mums and their partners during the 6 weeks postpartum?)

Measures of feasibility will include: percentage of eligible individuals recruited to the study; dropout rate; percentage of app-based assessments completed during the app-use phase; percentage of participants completing at least a third of app-based assessments; percentage of participants completing at least half of app-based assessments; timing of responses during the 2 hour response period.

Secondary outcome measures

2. Qualitative (interviews) and quantitative (abridged Mobile App Rating Scale) data on acceptability (Research Question 2: do mums and their partners find it acceptable to use a smartphone app for this purpose?)

3. App based assessment of postnatal depression using a digital version of the Edinburgh Postnatal Depression Scale will be compared with a gold-standard questionnaire version of the Edinburgh Postnatal Depression Scale. (Research question 3: Is it valid to use a smartphone app for this purpose?)

4. Occurrence of adverse events (Research question 4: Is it safe to use a smartphone app for this purpose?)

5. Qualitative interview data on participants' experience of using the app. (Research question 5: What are participants' experiences of using an app for this purpose?)

6. Baseline clinical and demographic information and measures of app engagement. (Research question 6: Who is most likely to use an app for this purpose?)

7. Pattern of app use over time during the study. Research question 7: How long do participants use an app for this purpose?)

Data analysis

Research Question 1

Question: Is it feasible to use a smartphone app to screen for postnatal depression in mums and their partners during the 6 weeks postpartum?

Analysis: we will provide a descriptive summary of the following: percentage of eligible individuals recruited to the study; dropout rate; percentage of app-based assessments completed during the app-use phase; percentage of participants completing at least a third of app-based assessments; percentage of participants completing at least half of app-based assessments; timing of responses during the 2 hour response period.

The a priori “accept” criterion will be >33% data points completed, with the “target” criterion being 50% of participants submitting 50% of data entries.

Research Question 2

Question: Do mums and their partners find it acceptable to use a smartphone app for this purpose?

Analysis: audio-recorded qualitative interviews will be transcribed verbatim and analysed using framework analysis, with a particular focus on a priori themes relating to acceptability (themes generated from the interview topic guide). Contextual notes written by the researcher at the time of the interview and excerpts from the researcher’s reflective journal will be used to further inform the analysis.

Descriptive statistics summarising the quantitative data from the abridged Mobile App Rating Scale will also be reported.

Research Question 3

Question: Is it valid to use a smartphone app for this purpose?

Analysis: Repeated-measures app-reported data (up to 7 data-points per person from daily assessments for one week) will be compared with a one off gold-standard questionnaire measure (Edinburgh Postnatal Depression Scale) at for two one-week periods (first and last week of the 8 week app use period) in two ways.

Firstly, mixed effects models will be used to account for clustering by participant due to the repeated measures nature of the app use data. Mixed effects models will be constructed as follows: app-reported scores as the dependent variable, a fixed effect of the gold standard questionnaire score and a random effect of participant. The fixed effect coefficient can be interpreted as the average change in app-reported score for a 1-point change in gold-standard questionnaire score. Given that the two measures use the same scoring system, the nearer the fixed effect coefficient is to one, the better.

Secondly, the average score from the repeated measures app-reported data will also be compared to the score on the gold standard measure using Spearman's correlation. This does not account for clustering by participant but will allow comparison with other app-use studies that do not use mixed effects models to assess validity.

Research Question 4

Question: Is it safe to use a smartphone app for this purpose?

Analysis: Adverse events will be monitored throughout the study; descriptive statistics will be used to summarise the number of these and whether appear to be are related to or unrelated to app use.

Research Question 5

Question: What are participants' experiences of using an app for this purpose?

Analysis: audio-recorded qualitative interviews will be transcribed verbatim and analysed using framework analysis, with a particular focus on a posteriori themes (‘emergent’ themes, not specifically determined by the topic guide but that contribute to the research question regarding participants’ experiences of using the app). Contextual notes written by the researcher at the time of the interview and excerpts from the researcher’s reflective journal will be used to further inform the analysis.

Research Question 6

Question: Who is most likely to use an app for this purpose?

Analysis: Effects of baseline clinical and demographic variables on percentage app completion will be examined using Spearman’s correlation (continuous variables), Mann-Whitney or Kruskal-Wallis tests (categorical variables).

Research Question 7

Question: How long do participants use an app for this purpose?

Analysis: The pattern of app completion will be examined with mixed effects models with a random effect of participant and a fixed effect of time and percentage app completion as the dependent variable.

General procedural issues

Financial reimbursement

Participants will receive up to £60 in shopping vouchers for participation in the study: £20 for each research visit and a further £20 on completion of the study. They will also be given £10 phone credit per month while they are participating in the app use phase of the study (up to £20).

Data monitoring and quality assurance

The study will be subject to the audit and monitoring regime of the University of Manchester.

Adverse events

Adverse events will be monitored and recorded during the study, including Serious Adverse events. As per ethics committee requirements, Serious Adverse Events will be reported to the REC immediately if they are related to the intervention and are unexpected.

Ethical and regulatory considerations

NHS Research Ethics Committee approval will be obtained before commencing research. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

Data protection and confidentiality

All participants will be allocated a unique study number. From then on, all participant data will be identified by this number only. Participant data will be stored securely and will only be accessible by the research team. Interview recordings will be transferred to a secure server at the University of Manchester. Other pseudonymised data will be kept on a secure University of Manchester server or in a locked filing cabinet (depending on the format). Personal information will be kept in a separate locked cabinet. The pseudonymisation key will be stored (separately from study data) in a locked filing cabinet in a locked office at the University of Manchester

Participants' responses to the questions on the phone app will be uploaded to a secure server at the University of Manchester (using the same system as the CareLoop study; REC reference 14/WM/0045). The informatics team who developed the system (and who will design the app) have a long experience of safeguarding the secure transfer and storage of this type of data and have previously explored the pertinent ethical issues in detail. The three general principles of information security (confidentiality, integrity and availability) are followed in the design and implementation of the system (NHS, 2009). All data transmitted to and from the server(s) will be encrypted over https with strong ciphers as detailed in the Approved Cryptographic Algorithms Good Practice Guidelines (NHS, 2012). Cipher Suites will be implemented in compliance with Section 6 ("Preferred uses of cryptographic algorithms in security protocols") of the Good Practice Guidelines. Members of the research team will be given their own individual logins for the web interface (via which participant data can be accessed) with their own username and password. Management of login accounts and passwords will be in accordance with the User Account Management Standard Operating Procedure. To ensure the safety of the data communicated, the pass phrase will be communicated to the recipient independently of the encrypted data, as recommended in the NHS Information Governance Guidelines (Department of Health, 2008). In cases where participant data is downloaded via the web interface or emailed to members of the research team for further analysis, this data will be anonymised and securely encrypted with a pass phrase of appropriate length and complexity.

In line with University of Manchester policy, data will be safely stored for 5 years after the last publication of the study and then destroyed. Consent forms will be kept as essential documents until the relevant research data are destroyed, at which point the consent forms will also be destroyed. Other personally identifiable information such as contact details will be deleted as soon as they are no longer required.

Limits to confidentiality

All participants will be informed about the limits of confidentiality during the consent process. This includes that information may be passed on to a clinician if the researcher is concerned that there is a risk to the service user themselves or to another person.

If the EPDS question (paper or app version) related to thoughts of self-harm (Q10: “The thought of harming myself has occurred to me”) is rated as “yes, quite often” or “sometimes”, the research team will pass this information on to the GP. On week days (Monday-Friday), this will be done the same day; if thoughts of self-harm are disclosed at the weekend, this information will be passed to the GP on the next working day. If a participant continues to report self-harm on the EPDS Q10, the GP will be updated once a week.

In other cases where the patient may be a risk to themselves or another person, all relevant information will be taken into account and all cases in which the researcher believes there may be cause for concern will be discussed with a consultant psychiatrist (SL) and/or consultant obstetrician (CT/GS) on the research team and information will be passed on to the service user’s GP if appropriate.

If information gathered using the paper version of the Edinburgh Postnatal Depression Scale (EPDS) suggests that the participant may be developing postnatal depression, the researcher will ask for the participant’s permission to pass this information on to their GP. If they decline, information will only be passed on if we believe there is a risk of harm to the participant or to another person.

This is not an interventional study and the app-based version of the EPDS has not yet been validated. Therefore, we will not automatically inform a participant’s GP if their scores on the app appear to be above threshold for possible postnatal depression. However, if we believe there is a risk of harm to the participant or to another person we will disclose this, as outlined above.

Risks to participants

We believe that the risks of taking part in the research are minimal. During the questionnaires we will ask participants about their mental health. For some people this may be a sensitive topic. The researchers will be aware of this possibility. They will check if participants have any concerns and provide the opportunity to discuss these if necessary. If participants find the questionnaires, interviews or using the phone app stressful, they are free to discontinue without having to give a reason. Participants can also request a break at any point if they wish. The Research Associate (Emily Eisner) is an experienced mental health

researcher who has lived experience of postnatal depression. She is familiar with the challenges encountered by new parents and by people with mental health problems.

The only other disadvantage of taking part in the study is giving up time to meet or talk on the phone with the researcher and to answer the questions on the phone app. We will make sure that all meetings with the researcher take place at a time and location that is convenient for the participant. Where possible these meetings will be combined with the participant's visits to St Mary's Hospital. We will also find out from participants when are the most convenient time(s) of day and day(s) of the week for them to receive phone calls from the researcher so as to cause minimal intrusion to their routine.

Risks to researchers (safe working procedures)

Home visits with the study population are generally likely to be low risk. The researcher will follow the School of Health Sciences (University of Manchester) policy and Trust-specific lone worker policies for home visits. A risk assessment will be undertaken regarding safety for lone home visits. If there are any concerns, the researcher will arrange a joint visit or will book a room at a local NHS service to meet the participant.

During a visit the researcher will leave contact details and a proposed time for the end of the appointment with a member of the research team. An arrangement will be made for the researcher to phone the research team on leaving the participant's home, or the person undertaking the safety check will phone at the proposed end time if they have not heard from the researcher. If attempts to contact the researcher are unsuccessful, a pre-arranged escalation procedure will be acted upon.

Peer review

This protocol has been peer reviewed by Prof Kathryn Abel, Professor of Psychological Medicine.

Statement of indemnity

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

Funding

The study is funded by two NHS Trusts (Greater Manchester Mental Health NHS Foundation Trust and Manchester University NHS Foundation Trust), via Health Innovation Manchester.

Publication Policy

The study protocol will be published, either on the clinicaltrials.gov website or as an open access publication in JMIR Research Protocols (https://www.researchprotocols.org/).

The study results will be disseminated via peer reviewed journal publication and conference presentation. We will distribute a leaflet summarising the study results to any participants who would like to receive it. We will also publicise the results within the NHS trust from which participants were recruited.

References

Ben-Zeev, D., Davis, K. E., Kaiser, S., Krzsos, I., & Drake, R. E. (2013). Mobile technologies among people with serious mental illness: opportunities for future services. Adm Policy Ment Health, 40(4), 340-343. doi:10.1007/s10488-012-0424-x

Ben-Zeev, D., McHugo, G. J., Xie, H., Dobbins, K., & Young, M. A. (2012). Comparing retrospective reports to real-time/real-place mobile assessments in individuals with schizophrenia and a nonclinical comparison group. Schizophr Bull, 38(3), 396-404. doi:10.1093/schbul/sbr171

Berry, N., Lobban, F., & Bucci, S. (2019). A qualitative exploration of service user views about using digital health interventions for self-management in severe mental health problems. BMC Psychiatry, 19(1), 35. doi:10.1186/s12888-018-1979-1

Bradstreet, S., Allan, S., Gumley, A. (2019). Adverse event monitoring in mHealth for psychosis interventions provides an important opportunity for learning. Journal of Mental Health, 28(5), 461-466. DOI: 10.1080/09638237.2019.1630727

Bucci, S., Morris, R., Berry, K., Berry, N., Haddock, G., Barrowclough, C., . . . Edge, D. (2018). Early Psychosis Service User Views on Digital Technology: Qualitative Analysis. JMIR Ment Health, 5(4), e10091. doi:10.2196/10091

Eberhard-Gran M, Eskild A, Tambs K, Opjordsmoen S & Ove Samuelsen S (2001). Review of validation studies of the Edinburgh Postnatal Depression Scale. Acta Psychiatrica Scandinavica 104, 243-249.

Edmondson OJH, Psychogiou L, Vlachos H, Netsi E & Ramchandani PG (2010). Depression in fathers in the postnatal period: Assessment of the Edinburgh Postnatal Depression Scale as a screening measure. Journal of Affective Disorders 125, 365-368.

Faherty, L. J., Hantsoo, L., Appleby, D., Sammel, M. D., Bennett, I. M., & Wiebe, D. J. (2017). Movement patterns in women at risk for perinatal depression: use of a mood-monitoring mobile application in pregnancy. J Am Med Inform Assoc, 24(4), 746-753. doi:10.1093/jamia/ocx005

Gibson J, McKenzie-McHarg K, Shakespeare J, Price J & Gray R (2009). A systematic review of studies validating the Edinburgh Postnatal Depression Scale in antepartum and postpartum women. Acta Psychiatrica Scandinavica 119, 350-364.

Hantsoo, L., Criniti, S., Khan, A., Moseley, M., Kincler, N., Faherty, L. J., . . . Bennett, I. M. (2018). A Mobile Application for Monitoring and Management of Depressed Mood in a Vulnerable Pregnant Population. Psychiatr Serv, 69(1), 104-107. doi:10.1176/appi.ps.201600582

Jimenez-Serrano, S., Tortajada, S., & Garcia-Gomez, J. M. (2015). A Mobile Health Application to Predict Postpartum Depression Based on Machine Learning. Telemed J E Health, 21(7), 567-574. doi:10.1089/tmj.2014.0113

Krishnamurti, T., Davis, A. L., Wong-Parodi, G., Fischhoff, B., Sadovsky, Y., & Simhan, H. N. (2017). Development and Testing of the MyHealthyPregnancy App: A Behavioral Decision Research-Based Tool for Assessing and Communicating Pregnancy Risk. JMIR Mhealth Uhealth, 5(4), e42. doi:10.2196/mhealth.7036

Marcano Belisario, J. S., Doherty, K., O'Donoghue, J., Ramchandani, P., Majeed, A., Doherty, G., . . . Car, J. (2017). A bespoke mobile application for the longitudinal assessment of depression and mood during pregnancy: protocol of a feasibility study. BMJ Open, 7(5), e014469. doi:10.1136/bmjopen-2016-014469

NHS England. (2019). The NHS Long Term Plan. Retrieved from https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf.

NICE (2014). Antenatal and postnatal mental health: clinical management and service guidance (NICE Guideline 192). Available at: https://www.nice.org.uk/guidance/cg192/chapter/1-Recommendations#treatment-decisions-advice-and-monitoring-for-women-who-are-planning-a-pregnancy-pregnant-or-in-2 [Accessed 19/10/19]

Nicholas, J., Larsen, M. E., Proudfoot, J., & Christensen, H. (2015). Mobile Apps for Bipolar Disorder: A Systematic Review of Features and Content Quality. J Med Internet Res, 17(8), e198. doi:10.2196/jmir.4581

Paulson, J. F., & Bazemore, S. D. (2010). Prenatal and postpartum depression in fathers and its association with maternal depression: a meta-analysis. JAMA, 303(19), 1961-1969. doi:10.1001/jama.2010.605

Tsai, A. C., Tomlinson, M., Dewing, S., le Roux, I. M., Harwood, J. M., Chopra, M., & Rotheram-Borus, M. J. (2014). Antenatal depression case finding by community health workers in South Africa: feasibility of a mobile phone application. Arch Womens Ment Health, 17(5), 423-431. doi:10.1007/s00737-014-0426-7

List of appendices

Appendix A.	Edinburgh Postnatal Depression Scale
Appendix B.	Initial study information leaflet/poster
Appendix C.	Participant Information Sheet
Appendix D.	Consent form (app use phase)
Appendix E.	Full/abridged MARS (depending what we decide)
Appendix F.	Consent form (qualitative interview)
Appendix G.	Topic guide (qualitative interview)
Appendix H.	Post interview report form (qualitative interview)
Appendix I.	Letter to GP
Appendix J.	Cover letter for initial information
Appendix K.	Follow-up reminder letter
Appendix L.	Consent to contact form
Appendix M.	Self-report demographic questionnaire
Appendix N.	Text message template
Appendix O.	Screenshot of app screen
Appendix P.	Chief Investigator's CV