ISRCTN10781027 https://doi.org/10.1186/ISRCTN10781027

Digital assessment of wellbeing in new parents

Submission date
29/06/2023

Recruitment status
No longer recruiting

Registration date
03/07/2023

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Postnatal depression is hugely disruptive for parents and their children. Around 17 mothers and 9 fathers in every 100 experience depression in the year after their baby's birth. Parental depression can affect parents' wellbeing, the parent-infant bond and children's development. It can also affect parents' and children's long-term physical and mental health. If postnatal depression remains untreated, it has a heavy economic burden on society – around £74,000 for each case.

Medication or talking therapy can be used to successfully treat postnatal depression, but identifying who needs treatment is difficult. Around half of cases of postnatal depression are currently missed. Our study seeks to improve this vital step. Most people of childbearing age (94%) own a smartphone. We have developed a smartphone app that asks questions about parents' daily mood to help identify postnatal depression quickly and efficiently. Last year, we ran a small study and found this 'digital screening' accurately identified parents needing postnatal depression treatment.

Now we want to gather more information about our digital screening app compared to usual NHS care. For example: How much do parents use the app and what do they think about it? What are the main costs of digital screening compared to usual care? Are parents happy to complete all the assessments we plan to use? This information will help us design and run a much larger study in future.

Who can participate?
Women in the late stages of pregnancy (after 36 weeks)

What does the study involve?
We will divide participants, by chance, into two groups. The first group will receive usual NHS care. The second group will receive usual NHS care plus the digital screening app. We will gather information using questionnaires and phone interviews when participants start the study, when their babies are 8 weeks old and again at 6 months old. Assessments will ask about mood, NHS resource use and app acceptability. If a parent from either group has possible postnatal depression, they will receive an extra phone call assessment and signposting.

We will also run two sub-studies. In the first, will test the digital screening app in a group of 20 partners of pregnant women. In the second, we will interview 30 healthcare professionals to ask their views on how the app might be used as part of NHS maternity care.

Patient and Public Involvement
Over the past 18 months, we have discussed this research with Patient and Public Involvement (PPI) contributors many times. Their ideas fed directly into the study design. During the study, two people with experience of postnatal depression will lead a diverse, 8-person PPI group. The PPI group will meet every 2-3 months using a video-conferencing platform (e.g. Zoom). They will provide regular guidance on the research (e.g., recruitment strategies, app design) and will receive support/training as needed throughout.

What are the possible benefits and risks of participating?
Participants in the app arm of the study will have the opportunity to borrow a smartphone and use our phone app. Previous users have found that using the phone app regularly helped them to keep track of any changes in their mental health. However, the app is still being tested. It should not replace regular support from GPs or other clinicians. There are unlikely to be any other direct benefits to participating but we hope that the study findings will help improve the care of parents in the future. We plan to use information from the study to improve the phone app. We hope it will help new parents to recognise deteriorations in their mental health and seek help in order to stay well during this potentially challenging time.
During the study we will ask participants about their mental health. There is a chance that some people may be troubled by this. The researcher will be sensitive to this possibility. They will check if participants have any concerns and offer the opportunity to discuss these. Participants can request a break from the assessments or interviews at any point. If they find the interviews, phone/video calls with the researcher or using the phone app stressful, they are free to discontinue without having to give a reason.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2022 to October 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Emily Eisner, emily.eisner@manchester.ac.uk

Study website
https://sites.manchester.ac.uk/parenting-families-research/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Emily Eisner

ORCID ID
http://orcid.org/0000-0001-5164-2407

Contact details
Zochonis Building (2nd Floor)
University of Manchester
Manchester
United Kingdom
M13 9PL
+44 161 306 0430
emily.eisner@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320610

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 320610, CPMS 55455

Study information

Scientific Title
Digital Assessment of Wellbeing in New Parents (DAWN-P): a feasibility study of digital screening for postnatal depression

Acronym
DAWN-P

Study objectives
It is feasible to deliver a full-scale, single-blind, RCT within NHS services comparing digital postnatal depression screening and standard practice in birthing parents?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2023, North West - Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8379; gmwest.rec@hra.nhs.uk), ref: 23/NW/0064

Study design
Multi-centre interventional single-blinded randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Internet/virtual, Telephone

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Postnatal Depression

Interventions
Feasibility RCT:
Following baseline assessment, participants (birthing parents, n = 80) will be randomly allocated (1:1) using an online service (https://www.sealedenvelope.com) to usual care or digital screening with usual care. Random allocation sequences in blocks of size 4 or 6 are generated, with separate sequences generated for each Trust to maintain balanced treatment allocation. Participants in the control group will receive usual NHS care, which typically includes some midwife and/or health visitor screening of mood. The participants in the digital screening group will be asked to use the CareLoop PND app to track their mental health from study entry until 8 weeks postpartum, in addition to their usual NHS care.

Partner sub-study
Partners (n = 20) will not be randomised. They will be asked to use the CareLoop PND app from study entry until 8 weeks postpartum.

Healthcare professional sub-study:
Healthcare professionals (n = 30) will not receive an intervention but will take part in qualitative interviews only.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of delivering a full-scale, single-blind, RCT within NHS services:
1. App engagement: overall percentage of app-based assessments completed during the app-use period; percentage of participants completing >50% app-based assessments.
2. Retention: percentage of participants retained at 8 weeks postpartum; percentage of participants retained at 6 months postpartum
3. Outcome completion: percentage completion of candidate primary outcome measures for the proposed full-scale RCT

Secondary outcome measures

1. Acceptability of the study app is measured using qualitative interviews and the abridged Mobile App Rating Scale at 8 weeks postpartum.
2. Feasibility of recruitment to the study is measured at using the following metrics at baseline: number of eligible participants approached; number agreeing to participate; number declining to participate; reasons for non-participation.
3. The validity of digital screening and standard screening will be measured using the following metrics (evaluated for the period from baseline until 8 weeks postpartum): Number of positive screens identified; number of true positives (PHQ-9 >= 10 OR GAD-7 >= 10); number of false positives (PHQ-9 <10 AND GAD-7 < 10).
4. Safety of the app and study procedures will be measured in terms of the number of Adverse Events and Serious Adverse Events throughout the study period, and whether they are judged to be related to the app and/or study procedures.
5. Feasibility of the study procedures is measured using the following metrics: proportion of each outcome measure* completed at each time point (baseline, 8 weeks postpartum, 6 months postpartum)
*Outcome measures in question are: Patient Health Questionnaire / PHQ-9, Generalised Anxiety Disorder questionnaire / GAD-7, Mini International Neuropsychiatric Interview, Postpartum Bonding Questionnaire, Abridged Mobile App Rating Scale, EQ-5D and healthcare resource utilisation questionnaire.
6. Acceptability of the study procedures is measured using qualitative interviews at 8 weeks postpartum
7. The key drivers of cost for digital screening and standard care will be measured using the Healthcare Resource Use Questionnaire at 8 weeks postpartum and 6 months postpartum.
8. Qualitative data on participants' experiences of using the study app will be assessed in a qualitative interview at 8 weeks postpartum.
9. Potential clinical and demographic predictors of app engagement will be measured at baseline using the PHQ-9, GAD-7, EQ-5D-5L, a demographic questionnaire, and information gathered from medical records.
10. In partners: overall percentage of app-based assessments completed during the app-use period; percentage of participants completing >50% app-based assessments; percentage of participants retained at 8 weeks postpartum.
11. Acceptability of digital screening using a smartphone app, and likely barriers and facilitators, will be measured in one-off qualitative interviews with healthcare professionals (n=30)

Overall study start date
31/08/2022

Completion date
23/10/2024

Eligibility

Key inclusion criteria
Feasibility RCT:
1. ≥36 weeks pregnant
2. Under care of Manchester Foundation Trust (MFT) or St Helens and Knowsley Teaching Hospitals NHS Trust (STHK)
3. Aged ≥18 years
4. Sufficient English fluency to complete baseline assessments (and/or partner speaks English fluently).

Partner sub-study:
1. Partner of a pregnant participant assigned to the digital screening group, or father/non-gestational parent of a foetus after 36 weeks' gestation whose gestational parent is under MFT /SHKT care
2. Aged >18 years
3. Sufficient English fluency to complete baseline assessments

Healthcare professional sub-study
Employed in a role related to the care of pregnant and/or postnatal parents. This could include research midwives who facilitated app use, health visitors with participating women on their caseload, as well as GPs, midwives, health visitors, commissioners, psychologists, psychiatrists or other health professionals not directly involved in the study

Participant type(s)
Healthy volunteer, Patient, Health professional, Service user

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
80 pregnant women and birthing people, 20 partners, 30 healthcare professionals

Total final enrolment
118

Key exclusion criteria
Feasibility RCT:
1. Fetal abnormality
2. Major depression (PHQ-9 ≥10), generalised anxiety disorder or perinatal psychosis at study entry
3. Stillbirth, pre-eclampsia or another medical emergency requiring hospital admission (participants experiencing these conditions in relation to childbirth during the study will be withdrawn)
4. Participants in the care of MFT who live outside the Greater Manchester area
5. Participants in the care of SHKT who live outside of the St Helen’s area

Partner sub-study
1. Fetal abnormality
2. Major depression (PHQ-9 ≥10) or generalised anxiety disorder (GAD-7≥10) at study entry
3. Current stillbirth (parents experiencing a stillbirth during the study will be withdrawn), partner of a pregnant participant assigned to the 4. Treatment as usual group of the RCT

Healthcare professional sub-study:
None

Date of first enrolment
04/07/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust (MFT)
Maternal & Fetal Health Research Centre, 5th Floor
St. Mary's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Research Hub (opposite outpatients)
Level 1, Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
R&I Office, 1st Floor
Harrop House
GMMH

Bury New Road
Manchester
England
United Kingdom
M25 3BL
+44 1612710084
researchoffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will share regular updates about the study to in a newsletter mixed audiences to maximise outreach. We will publish 3 open-access peer reviewed articles in relevant journals. Findings will

also be shared via NHS and university research seminars and at two academic conferences: Society for Reproductive and Infant Psychology Conference (2024) and UK/Ireland Marcé society conference (2024)

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	05/05/2023	30/06/2023	No	Yes
HRA research summary			26/07/2023	No	No
Protocol article		12/04/2025	14/04/2025	Yes	No