Participant Information Sheet (pregnant participants)

Study title

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

Invitation to take part in research

We would like to invite you to take part in our research study. This information sheet tells you why the research is being done and what it would involve for you. Please take some time to read it and discuss it with other people if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

Who will conduct the research?

This research study is being led by Dr Emily Eisner from the University of Manchester (Division of Psychology and Mental Health, School of Health Sciences). The project manager is Dr Henna Lemetyinen, from Greater Manchester Mental Health NHS Foundation Trust (GMMH). The researchers who will conduct most of the study procedures are [research assistant] from GMMH and [research midwife name] from Manchester University NHS Foundation Trust.

If you would like to speak to a researcher about taking part in the study, please contact: [research assistant name] (Research Assistant). [Research assistant] can be contacted via phone [phone number] or email: [email address]

What is the purpose of the research?

In this study we want to test out a mobile phone app called CareLoop PND. This app aims to help new parents keep an eye on their mental health around the time their baby is born. We would like to talk to women and birthing people who are at least 36 weeks pregnant. We are inviting participants to help us test the smartphone app.

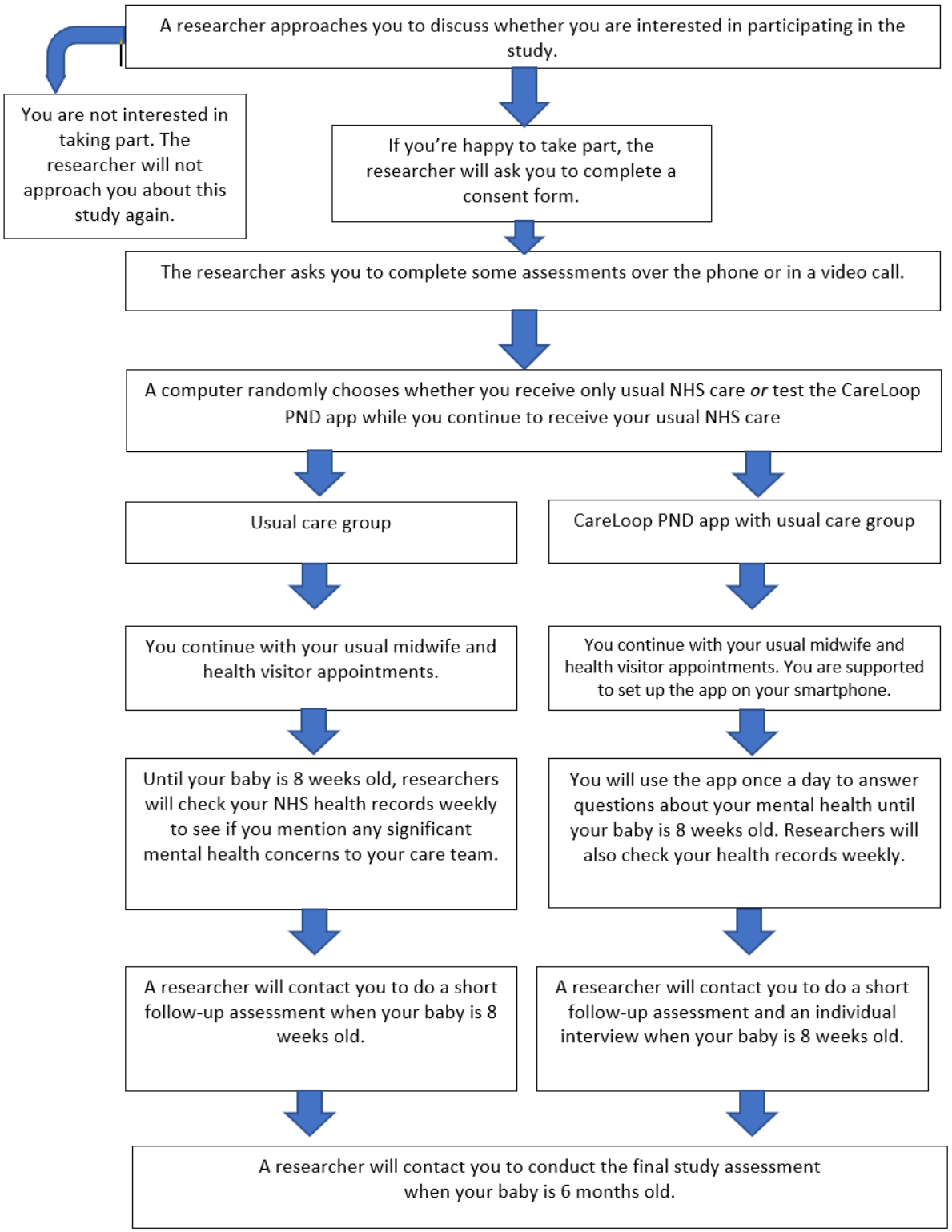
In total, we are looking for around 80 pregnant women or birthing people to participate in this study. Around 40 participants will test the smartphone app as well as their usual NHS care; the other 40 participants will receive only their usual NHS care. At the moment, we do not know for sure whether adding the CareLoop PND app to usual NHS care is helpful. This is why we need two groups – one that uses the app alongside usual care and one that has only usual care. At the end of the study, we will compare the overall health of the two groups.

The phone app has been developed by a company called Careloop Health Ltd. We have tested a previous version of the app in a group of 23 parents. They told us that the app was easy to use, they found the app helpful for their mental health, and found it reassuring that they would be contacted if they were struggling with their mental health.

What would I be asked to do if I took part?

The flow diagram on page 2 of this information sheet summarises what you would be asked to do if you took part. Further information about what you would be asked to do is given on pages 3-4 of the information sheet.

"What would I be asked to do if I took part?": summary flow diagram



Consent and baseline assessment
A researcher (research midwife or research assistant) will arrange a time to speak with you to discuss what will be involved in the study. This will be either on the phone or on an online video call platform such as Microsoft Teams. If you decide to take part, the researcher will ask you to complete a consent form. Your consent will be audio-recorded during a phone or video call with the researcher (we have sent you a copy of the form for your own reference). A researcher will read out the study consent form and ask you to verbally confirm that you agree to everything listed on it. This part of the phone call will be audio recorded as proof that you have consented to take part in the study.

The researcher will then ask you to complete some assessments over the phone/online video call. They will ask how you have been feeling recently. For example, they will ask about your mood, anxiety, and general health. The researcher will also ask for some background information like your age and gender. In total, this phone call will take about 30 minutes.

'Randomisation'
When these assessments are complete, we will use a computer to decide whether you will be in the group that receives only usual NHS care (Group 1) or in the group that tests the smartphone app with usual NHS care (Group 2). The computer decides 'randomly', which is a bit like flipping a coin or rolling a dice to see which group you will be in. After this, the study procedures will be a little different depending on which group you are in. These are described separately in the next two sections: first for the usual care group (Group 1) and then for the app group (Group 2).

Group 1: Usual care group
If you are in the usual care group, the researcher will phone you to let you know this. They can answer any questions you may have about the study at this point. You will then continue with your usual NHS care, which will include things like your usual midwife appointments and health visitor appointments.

With your permission, the researchers will briefly check your NHS health records each week. The health records check will consist of the researchers screening your GP and Health Visitor notes for any concerns of your mental health. They will start checking them when you first agree to take part in the study. They will continue to check them each week until your baby is 8 weeks old. This is to see whether you have mentioned any significant concerns about your mental health to your care team (e.g. your midwife, GP or health visitor). If the health team thinks that you may be getting unwell (in terms of your mental health), a researcher will contact you and arrange to conduct a short assessment. The assessment asks about your recent mood and about anxiety. It will take around 10 minutes.

When your baby is 8 weeks old, a researcher will phone you to conduct a short follow-up assessment (20-30 minutes). The follow-up assessments will be done similarly to your baseline assessment (i.e. typically over the phone or a video call) unless you ask to speak or meet using a different method. They will ask you about your mental health, about your relationship with your baby, and about the NHS care you have received recently.

The researcher will contact you for the last time when your baby is 6 months old. Again, they will conduct a short follow-up assessment (20-30 minutes) asking about your mental health, about your relationship with your baby, and about the NHS care you have received recently. This will be the final study assessment.

Group 2: CareLoop PND app with usual NHS care group
If you are in the phone app group, a researcher will contact you to let you know. A research midwife will then tell you how to install and set up the app on your smartphone. They will also send you written instructions and a video that helps demonstrate how to do this. The research midwife will talk you through how to use the app and ask you to complete some practice questions. In total, this phone call will take about 30 minutes. If you do not have a suitable phone, we can lend you a smartphone to use during the study.

Note: You will continue to access your usual NHS care during the study. Using the CareLoop PND app will not reduce the care you receive. If you feel unwell during the study, you should contact NHS services in the usual way to ensure you get the help you need.

We will ask you to use the app to answer questions about your mental health once a day until your baby is 8 weeks old. This will take about 2 minutes each time. When you answer questions on the app, the phone will upload your answers to a secure server at Amazon Web Services, based in the UK, where the research team will be able to access them. The research midwife will phone you 1, 2, 4 and 8 weeks after you have started using the app to check that it is working, to help with any questions or concerns and to thank you for participating.

Depending on your answers on the app, we may need to contact you one or more additional times during this phase of your study:

- If your responses on the app suggest that you may be getting unwell (in terms of your mental health), a researcher will contact you to conduct a short assessment (10 minutes). Depending on the outcome of that assessment, we may need to pass this information on to your health visiting team (and midwife, if applicable).
- If the app question about 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 need to pass this information on to your health visiting team (and midwife, if applicable). We will do this within 24 hours (if it is a weekday) or the next working day (if it is a weekend). If it is a weekend, a researcher will contact you to briefly ask how you are feeling and to signpost you to a relevant local/national helpline or to emergency services.

With your permission, the researchers will briefly check your NHS health records each week. The health records check will consist of the researchers screening your GP and Health Visitor notes for any concerns about your mental health. As for Group 1, the researchers will contact you to do a short assessment over the phone if the health team thinks that you may be getting unwell (in terms of your mental health).

When your baby is 8 weeks old, a researcher will phone you to conduct a short follow-up assessment (20-30 minutes). The follow-up assessments will be done similarly to your baseline assessment (i.e. typically over the phone or a video call) unless you asked to speak or meet using a different method. They will ask you about your mental health, about your relationship with your baby, and about the NHS care you have received recently. The researcher will give instructions for returning the mobile phone handset (if applicable). Some, but not all, participants will be invited to take part in a brief individual interview (30-60 minutes) exploring your experiences of using the app and of participating in the study. The exact interview questions will vary from participant to participant. The aim is for the researcher to understand your experiences. With your permission, we will audio record this interview. If you feel uncomfortable about being recorded at any time during the interview, please tell the researcher so they can stop the recording.

The researcher will contact you for the last time when your baby is 6 months old. Again they will conduct a short follow-up assessment (20-30 minutes) asking about your mental health, about your relationship with your baby, and about the NHS care you have received recently. This will be the final study assessment.

Audio recording of study assessments

At each time point (baseline, 8 weeks and 6 months), we will ask ten participants for permission to audio-record the assessment. If you do not want to be recorded, please just tell the researcher. The purpose of the recording is to allow the researcher's supervisors to check that the assessments are being done correctly. We will delete the audio recording as soon as it is no longer needed for this purpose.

What are the possible risks and disadvantages of taking part?

During the study we will ask about your 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 you have any concerns and you will have the opportunity to discuss these. You can request a break from the assessments or interviews at any point if you wish. If you find the interviews, phone/video calls with the researcher or using the phone app stressful, you are free to discontinue without having to give a reason.

The only other disadvantage of taking part in the study is giving up your time to speak to the researcher and to answer the questions on the phone app. We will make sure that phone/video calls take place at a time suitable for you.

What are the possible benefits of taking part?

You may have the opportunity to borrow a smartphone and to 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 your GP or other clinicians.

There are unlikely to be any other direct benefits to you but we hope that the study will be useful to new 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 stay well during this potentially challenging time.

Will I be compensated for taking part?

To show our appreciation, we will give you £20 in shopping vouchers for each part of the study you complete (up to £60). If you are in the app use group (Group 2), we will also provide £10 phone credit per month while you are using the app (up to £30). This will ensure enough internet access for completing the questions and some extra credit for your personal use.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether to join the study. We will describe the study and go through this information sheet with you. If you agree to take part, we will ask you to give consent (written or audio-recorded). If you decide not to take part, you do not need to do anything further. To inform our future studies, we will ask you to briefly state your reasons for declining but there is no obligation for you to supply this information. An anonymous summary of everyone's reasons for declining will be reported in final study publications.

You can change your mind and withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive. You can withdraw by contacting a member of the study team, whose contact information you can find at the end of this information sheet. Any assessments, interviews, meetings or phone/video calls would be cancelled and you would not receive further contact about the study. To inform our future studies, we will ask you to briefly state your reasons for withdrawing but there is no obligation for you to supply this information. No further data will be collected from the moment you withdraw. You may request that we delete data that has already been collected and we will honour this request whenever we can. However, there is some data that we will not be able to delete. Specifically, we would not be able to delete information relating to harm or risk that has been entered into your healthcare notes. We will also be unable to remove data that has already been anonymised, because we will not be able to identify your specific information at this point. This does not affect your data protection rights.

If you lose the capacity to consent to taking part in the study or experience baby loss, you will be automatically withdrawn. We will not collect any further data from you but we may keep data that has already been collected.

With your permission, we will audio record the feedback interview when your baby is 8 weeks old (for Group 2 participants only). This is an important part of the research as it helps us gather detailed information about participants' experiences of using the app and taking part in the study. However, it is important that you feel comfortable at all times during the research; if you do not feel comfortable with the interview being audio-recorded, please talk to the researchers. Once we have started the interview, you are also free to stop recording at any time.

What happens when the research study finishes?

You can decide whether you would like us to send you a summary of the research results. You may also want us to contact you about similar studies in the future. In both cases it is up to you, and you can always get in touch with us if you change your mind.

Will the outcomes of the research be published?

We will send a leaflet summarising the results to participants who would like to receive it. We will also present the results at research meetings and conferences and publish them in a scientific journal. No individual participant will be identified by name in any publication, presentation or report. We may include quotes from the interviews but we will remove any identifiable details from these.

Who is organising and funding the research?

The study is organised by the Greater Manchester Mental Health NHS Foundation Trust and funded by the National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Greater Manchester West Research Ethics Committee.

Disclosure and Barring Service (DBS) checks
The researchers have undergone satisfactory DBS checks.

What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Contact details, such as: name, address, telephone number, email address.
- Demographic information, including: date of birth/age, gender, ethnicity, current medication, diagnosis (if applicable).
- Information from medical records.
- An audio recording of the feedback interview (if applicable).
- Additionally (optional), if you take part in the interview via the MS Teams online meeting platform, we will ask for your permission to make a temporary video recording. This is because the online platform does not allow us to record audio without also recording video. As soon as possible after the interview finishes, the researcher will delete the video recording and only keep the audio recording. If you are not comfortable with video being recorded, we can use a secure, password-protected encrypted device (e.g. Dictaphone) instead.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protects your rights. These state that we must have a legal basis (specific reason) for collecting your

data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my choices about how my information is used?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (https://www.gmmh.nhs.uk/gdpr-in-research).

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, GMMH is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used.

All researchers are trained with this in mind, and your data will be looked after in the following ways:

- Only the research team will have direct access to your personally identifiable data.
- We will store your personally identifiable data separately from your research data on a secure server at GMMH.
- We will treat audio recordings as identifiable and store them on a secure server at GMMH.
- Audio recordings will be transcribed by a member of the research team, by another GMMH or University of Manchester employee or by an external transcription company (approved by GMMH). Any transcribers outside of the research team will be reminded of the guidelines regarding confidentiality and will be asked to sign a Confidentiality Agreement.
- All identifiable information will be removed from the final transcripts of audio recordings.
- We will destroy audio recordings of interviews as soon as possible after transcription.
- We will pseudonymise anything with your name in it as soon as possible after your participation. This means that we will remove all names and replace them with an ID number; only the research team will have access to the key that links this ID number to your personal information.
- Your answers to the phone app questions will be uploaded to a secure server at the University of Manchester where only the research team will have access to them. As with other research data these will be identified by a study number rather than your name.
- We will keep the de-identified data for 5 years after the final publication of the results. After this we will keep only fully anonymised aggregated data.
- Your consent form will be retained as an essential document until the other data is destroyed. It will be stored separately and will not be able to be linked to your responses and other data.
- We will only keep your contact details if you have requested to be contacted with the results, or about future research, otherwise we will destroy your contact details after you have participated.
- You will always be given the option to opt out of further contact whenever we contact you.

With your permission, we will let your GP know that you are participating in the study. Information will not be shared without your consent unless the researcher feels that either you or someone else may be harmed. In this case, the researcher has a duty to disclose this information to a relevant person (usually your GP andHealth Visitor/midwife). For example, if the question on the app 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 and Health Visitor/midwife either the same day (if it is a weekday) or the next working day (if it is a weekend). We will recommend that you consider self-referral Improving Access to Psychological Therapies (IAPT) service. We can give you the contact information for your local IAPT service. Additionally, if you live in Merseyside, we would recommend contacting your GP, who may consider referring you to perinatal Community Mental Health Service. If you live in Greater Manchester,

we would contact the relevant perinatal Community Mental Health Service to discuss whether a referral would be appropriate.

Please also note that individuals from GMMH, The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data and sections of your medical notes. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

[study lead contact details]

[project manager contact details]

If you wish to make a formal complaint, or if you are not satisfied with the response from the Chief Investigator, please contact Greater Manchester Mental Health NHS Trust Customer Care Team Manager on 0161 358 0600 or 0800 587 4793. If you have a complaint relating to your personally identifiable information, you can also contact the Information Commissioners Office: https://ico.org.uk/make-a-complaint |Telephone: 0303 123 1113. Additional information about data protection can be found here: https://www.gmmh.nhs.uk/gdpr-in-research

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the Greater Manchester Mental Health NHS Foundation Trust, Manchester University NHS Foundation Trust or St Helens and Knowsley Teaching Hospitals NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

You may also wish to contact your NHS Trust's Patient Advice and Liaison Service (PALS) if you have any suggestions, comments or concerns about the healthcare services you have received.

Manchester University NHS Foundation Trust PALS contact information
Tel: 0161 276 8686
Email: pals@mft.nhs.uk
Web page: https://mft.nhs.uk/saint-marys/patients-visitors/patient-experience/speak-to-the-pals-team/

St Helens and Knowsley Teaching Hospitals NHS Trust PALS contact information
Tel: 0151 430 1376
Email: pals@sthk.nhs.uk
Web page: https://www.sthk.nhs.uk/patient-advice-and-liaison-service-support

Further information and contact details

If you would like any further information about the study or have any questions, please contact:

[research assistant contact details]
[study lead contact details]
[project manager contact details]

Thank you for reading this information sheet!