



Online Parenting Intervention for Perinatal Mothers (OPAL) Study

PARTICIPANT INFORMATION SHEET (PIS) (Mothers)

Invitation to take part in a research study

You are being invited to take part in a research study to **use a self-paced parenting programme**.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others 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?

The University of Manchester and Greater Manchester Mental Health (GMMH) NHS Foundation Trust will run the study.

It will be led by Anja Wittkowski (anja.wittkowski@manchester.ac.uk), a researcher from the Division of Psychology and Mental Health, University of Manchester and a Perinatal Clinical Psychologist from GMMH.

The project managers are Holly Reid and Henna Lemetyinen. Contact Holly if you have any questions about the study on **[phone number]**, or Henna on **[phone number]**. Alternatively, you can send an email to **[update]**@gmmh.nhs.uk.

What is the purpose of the research?

This study aims to find out if using a parenting programme is helpful and easy to use by mothers with mental health difficulties in the perinatal period (i.e., during the pregnancy or 1 year after birth). The parenting programme is called the **Triple P Positive Parenting Programme for Baby (online version)**.

It is an **online programme** of 7 interactive sessions (with video clips to watch) that parents work through at their **own pace at home** using a computer, tablet or their mobile phone.

We are looking for **up to 100 mothers** to take part.

Am I eligible to take part?

You have been invited to take part because

- You are a **mother of a baby aged 0-12 months, or you are in the third trimester of your pregnancy.**
- You are currently experiencing mental health difficulties.
- You are under the care, or on the waiting list, of **the Perinatal Specialist Mental Health Service** at Greater Manchester Mental Health NHS Foundation Trust (GMMH).
- You are **18 years old or older.**
- You are **fluent enough in English** to engage with the parenting programme and complete online questionnaires and, possibly, to take part in an additional interview.
- You either **own or have access to a smartphone, tablet, laptop or desktop** to view the parenting programme.
- You can give **informed consent** to participate in the study.

Will the outcomes of the research be published?

- We will publish the results of this study in an **academic journal**.
- The results may also be presented in **conferences**.
- We may publish **anonymised direct quotes** from your interview, should you take part later.
- Anonymised data may be made available to other researchers.
- You will **not be identified** in any of these uses.

We can **send you a summary** of the results if you allow us to keep your contact details. If you give us consent, we will store your contact details for 5 years after publication.

Disclosure and Barring Service (DBS) Check

All members of the research team have undergone an appropriate level of DBS check.

Who has reviewed the research project?

All research in the NHS is looked at by an independent group of people, called a **Research Ethics Committee** to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by **Wales REC 1**.

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

- You will speak with a researcher on the phone or online (MS Teams or Zoom) to find out if you are eligible to take part.
- If you are not eligible, or do not want to take part, a researcher will ask you a few questions about **your background** (e.g., your age, ethnicity, number of children, etc.) and your **reason for not taking part**. Answering these questions is **optional**. If you choose to give us this information, we can find out why women decide not to take part.
- If you are eligible and you would like to take part, we will ask you to **sign a consent form**.
- We will ask for your consent to access your medical records and add a copy of your consent form. This means your clinical team will be able to see that you are taking part in this study, but they will not be informed about anything else and no data will be shared with them.

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- Next you will fill in some **questionnaires** about your background (e.g., age, ethnicity, family background, etc.), your mental health and wellbeing, how you perceive your parenting skills and bonding with your baby. Completing these questionnaires will take about **30 minutes**. We will ask you to complete the same questionnaires 10 weeks after starting the programme.
- After this you will be given access to the online parenting programme. You can work through it at your own pace, but ideally you complete it within 10 weeks. You will receive encouragement via text or email and a friendly researcher will call you 4 times to support you with your progress and answer any questions you have.

Study assessments

- You will be asked to **fill in questionnaires** with a researcher at the start of the study and again **after about 10 weeks**, because we would like to see if things change over time.
- You can choose to complete these questionnaires **online** (with a link being send to you) or with a researcher (on MS Teams or Zoom or over the phone).
- You will be involved in this study for **10-12 weeks in total** (the study overall will last for 12 months).
- We will ask you for permission to audio or video record some assessments. You can say no to us recording assessments and still take part in the study.

End of study interview (optional)

- Some participants will be invited to take part in an **additional interview** towards the end of the study to find out what they liked and disliked about the study. **This is optional. You can say no to taking part in this interview and still take part in the overall study.**
- We will ask you to read a separate information sheet and sign a separate consent form later if you are interested in taking part in this additional interview.
- Like the assessments, these interviews can be conducted online (Zoom, MS Teams), over the telephone, or in your home. This will take around 1 hour. This interview will be recorded and transcribed (typed out in full). You can ask us to stop recording at any time.
- We will only interview **10-20** of the mothers that take part in the overall study. Due to small numbers, we might not be able to interview you, even if you express interest. If this is the case, we will inform you via telephone call, text message or email.

What are the benefits of taking part?

We hope that having access to the online programme will help you, but we cannot promise this. The information we get from this study may help us to **improve the care** of mothers with mental health difficulties in the future.

Please note that taking part in this study will not impact any of your usual NHS care. You would access the online programme *in addition to* your NHS care.

What are the risks of taking part?

The assessments involve talking about yourself and your baby and how you are feeling which you may find upsetting. You can **pause or stop participating in** the study at any time. You are **free to withdraw** from the study at any time.

Will I be compensated for taking part?

No. However, if you agree to take part in an **interview** about your experiences of the programme and taking part in the study, you will be given a high street voucher worth £20.

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 take part or not. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a **consent form**. If you take part, you can **stop participating in the study at any time**. This will not affect your usual care. We will use the data we have collected already in our research unless you tell us not to.

To stop, you should contact the project manager and let us know. You can choose to withdraw without giving us any further information. If you decide to withdraw, we will ask you to take part in an **optional withdrawal interview**, so we can learn from your reason for withdrawing. If you choose to answer these questions, the information will be used for research. You will not be identified.

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:

- Name
- Address
- Contact details
- Date of birth
- Ethnicity
- Record of consent
- Details of your perinatal team and/or GP
- If you agree to your assessment(s) being recorded and/or an interview, audio recordings of your voice (and face if video recording is used).

Under what legal basis are you collecting this information?

For the proper running of a research study, we need to keep a record of who is participating, and we may need this information to contact you. This purpose for recording your personal information is allowed under our UK data protection legislation.

What are my rights regarding the data you collect about me?

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://documents.manchester.ac.uk/display.aspx?DocID=37095) (<https://documents.manchester.ac.uk/display.aspx?DocID=37095>)

You can also ask a member of the research team for more information.

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

In accordance with data protection law, The University of Manchester and Greater Manchester Mental Health NHS Foundation Trust (GMMH) are the Data Controllers 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 way:

- Any **information** (name, address, telephone number, date of birth, audio recordings) that could **identify you** will be kept **confidential** and **stored securely** at the University of Manchester or GMMH in locked filing cabinets (paper copies) or on password protected secure servers (electronic copies). This personal information will be stored separately from research data.
- Your name will not be on study documents (except the consent form), you will be identified **by a study number** only. The research team will have access to the key that links this ID number to your personal information.
- Your **consent form will be retained for 5 years** in a locked cabinet on University of Manchester or GMMH premises for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on University of Manchester or GMMH servers in a digital folder only accessible to the study team and used only for the purposes described above.
- Your **clinical team** (including your GP, case manager and/or perinatal mental health team) will be **informed that you are taking part** in this study, but they will not be able to see any data we collect.
- If you tell us anything that suggests **you or someone else is at risk of harm**, we may have to **inform authorities**, such as your **GP or the police**. We will involve you in this decision as much as possible.
- We may pass on your **contact details to our Admin Team** so they can **send you a shopping voucher as a thank you** for taking part in the end of study interview. If you give us consent, **we will keep your contact details for up to 5 years**.
- We may use a University of Manchester approved external service to transcribe (type out) your interview. **Anyone who transcribes your interview will have a duty of confidentiality to you**. Any personal identifiable information will be removed from the final transcript.

- When you agree to take part in a research study and **with your informed consent**, the information about you may be **provided to researchers running other studies** here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research) (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research>). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.
- Please also note that individuals from 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. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

International transfers regarding sharing data outside the UK

- If you agree to take part, a member of the research team will log into the secure Triple P Online Management System and enter **your first name, last name, and email address to issue an access code to you.**
- Following this, you will receive an automated registration email with a link **to create an account in the Triple P Online Management System** and you can start to watch Triple P online for Baby.
- At this point, the website would provide you a **Global Privacy Notice** from Triple P (2024), which outlines how your information is used and stored by Triple P International.
- Triple P will use your information for **administrative support purposes**, such as creating your user account and assisting you with any difficulties in accessing your account. **Access to your personal information will be restricted.**
- After the access to the programme expires after 12 months, Triple P International will retain the data in identifiable form **for up to 2 years**, after which it will be **anonymised.**
- Triple P International will store information about you in **private databases hosted on Amazon's global infrastructure located in Australia**, which is outside the European Economic Area.
- Triple P International must follow **UK data protection legislation** to keep your information safe.

Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact the Project Managers, **Holly Reid** on [phone number] or **Henna Lemetyinen** on [phone number] or email at [\[update\]@gmmh.nhs.uk](mailto:[update]@gmmh.nhs.uk)

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL

Email: research.complaints@manchester.ac.uk

Telephone: **0161 306 8089**.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk, call **161 275 7789** or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information, You can either call **0303 123 1113** or contact them via a webchat on their website (<https://ico.org.uk/concerns>).

Contact details

If you have any queries about the study or if you are interested in taking part then, please contact the Project Managers, **Holly Reid** on [phone number] or **Henna Lemetyinen** on [phone number] or email at [\[update\]@gmmh.nhs.uk](mailto:[update]@gmmh.nhs.uk). You can also contact the Chief Investigator, Anja Wittkowski by email: Anja.wittkowski@manchester.ac.uk.