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The OPAL feasibility study: Online parenting intervention for mothers

Submission date
28/02/2025

Recruitment status
No longer recruiting

Registration date
11/03/2025

Overall study status
Ongoing

Last Edited
11/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Up to 27% of mothers experience mental illness during the perinatal period, which includes pregnancy and the baby's first year of life. There are specialist perinatal mental health services that support mothers with their mental health. In Greater Manchester Mental Health NHS Foundation Trust (GMMH) alone, 3,186 women were referred in 2023-2024. About 84% were offered an assessment, but only ⅓ to ¼ of these mothers were accepted and offered psychological interventions or support with mother-baby bonding. Although mothers may also benefit from parenting programmes, which could increase their confidence and competence, such programmes are not routinely offered in these services. As there is also an increasing need for digital solutions to improve maternal mental health. Using a self-paced, pre-recorded online version of a parenting programme, the Triple P Positive Parenting Programme for Baby (termed 'online-BabyTP'), the aim of this feasibility and acceptability study is to explore 1) if it is feasible to recruit these mothers, 2) how well they engage with online-BabyTP and what supports their engagement and 3) what helps or hinders their participation.

As part of this non-randomised, mixed methods study, we will recruit mothers who have been referred to GMMH's perinatal specialist service. Consented participants (i.e., mothers) will be asked to complete questionnaires about their mental health, parenting confidence and bond with their baby pre- and post-intervention. We can offer up to 100 women access to the 7 sessions of online-BabyTP, which they can complete at their own pace in 10 weeks. We will support their engagement with encouraging text messages and four phone calls. Furthermore, we will also interview 10-20 mothers and 5-10 staff to find out more about the acceptability of this type of intervention. These findings will help the research team to apply for funding for a full-scale trial.

Who can participate?
Mothers of infants aged up to 12 months old, or pregnant mothers in their third trimester, who are receiving care from Greater Manchester Mental Health NHS Foundation Trust (GMMH)'s Specialist Perinatal Community Mental Health Service. Mothers must be at least 18 years old or over, have a sufficient level of English to engage with the intervention (parenting programme),

complete questionnaires and take part in an interview. Mothers can have any mental health diagnosis. The study is also open to health care professionals working at the Specialist Perinatal Community Mental Health Service.

What does the study involve?
Consented participants will be asked to complete questionnaires about their mental health, parenting confidence and bond with their baby at study enrolment and at 12 weeks after starting the intervention. We can offer up to 100 women access to online-BabyTP to complete over 10 weeks. We will support their engagement with encouraging text messages and four phone calls. Furthermore, we will also interview 10-20 mothers and 5-10 staff to find out more about the acceptability of this type of intervention.

What are the possible benefits and risks of participating?
We hope that having access to the intervention will help parents, although 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. The study questionnaires and interviews will involve participants sharing information about themselves, their baby and wellbeing. Some people might find this upsetting. Participants can stop or pause participating in the study at any time.

Where is the study run from?
The study is run from the Perinatal Mental Health & Parenting Research Unit (PRIME-RU), Greater Manchester Mental Health NHS Foundation Trust. The sponsor (overseeing organisation) of this research is the University of Manchester.

When is the study starting and how long is it expected to run for?
March 2025 to February 2026

Who is funding the study?
The study is funded by the UKRI Impact Accelerator Account (IAA) with support from the Wellcome Translational Partnership Award (TPA) and the NIHR Manchester Biomedical Research Centre (BRC) in the form of a research grant (‘Translation Manchester – Confidence 4 Translation’ pathway).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
352080

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 66769, MR/X502868/1

Study information

Scientific Title
The OPAL feasibility and acceptability study of an online parenting intervention for mothers with mental health difficulties

Acronym
OPAL feasibility study

Study objectives
As this study is a feasibility study, we do not plan to test any hypotheses.

The aims are:
1. To examine the feasibility of recruiting and then engaging women with perinatal mental health difficulties, who are mothers of babies (birth to one year postpartum) or in their third trimester of pregnancy, in an online parenting intervention (the Triple P Positive Parenting Programme for Baby, delivered online via pre-recorded sessions, referred to here as online BabyTP)
2. To explore the acceptability of this type of intervention in mothers and perinatal mental health staff

We are also interested in exploring:
3. Factors associated with engagement and retention
4. Any solutions to attrition
5. If there is any change over time in outcome measures in terms of mental health, wellbeing, maternal competency/efficacy and the mother-infant bond

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/02/2025, Wales Research Ethics Committee 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 292 2940931; Wales.REC1@wales.nhs.uk), ref: 25/WA/0041

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Perinatal mental health

Interventions
BASELINE ASSESSMENT

After consent has been obtained, participants (i.e., mothers) will be asked to provide demographic information, including information about their child and family circumstances via a 'Background Questionnaire'. The questionnaire asks for details of their ethnicity, the age and sex of their baby, family/household composition, and the participant's marital and employment status. Participants will also be asked for brief (self-reported) details about characteristics and experiences that may predict attrition and outcome, such as psychiatric history (how long they have been involved with mental health services; when they first experienced mental health problems, etc.), educational attainment, and family support. Participants will only be asked to provide this information at baseline assessment.

Participants will also be asked to complete a few brief validated questionnaires, chosen according to their relevance, their psychometric properties, and widespread use in relevant research. With the exception of the wellbeing questionnaire, we have used these questionnaires with mothers with mental health problems in a previous study:

The brief 21-item Depression, Anxiety and Stress Scale (DASS-21) to assess their mental health and mood.
The 7-item Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) to assess their wellbeing.
The 10-item Maternal Self-Efficacy Scale (MSES) to assess their parenting competence and confidence.
The 25-item Postpartum Bonding Questionnaire (PBQ) to assess the mother's perceived bond with her baby.
Participants will be given the choice of online completion on their own (via Qualtrics) or with the support of a researcher via a phone or video call (via MS Teams or Zoom). The initial baseline assessments are anticipated to take up to 30 minutes.

POST-INTERVENTION ASSESSMENT

The same four validated questionnaires used at baseline assessment will be used at 12 weeks. In addition, we will ask participants to complete an intervention satisfaction questionnaire that has

been used in other BabyTP studies (i.e., the Client Satisfaction Questionnaire). The Triple P Online Management system will allow the CI/project manager to monitor participants' progress through the programme and aggregate data (e.g., how many sessions were completed, or whether specific sessions were consistently not completed across participants). Finally, the type and duration of standard care that mothers have received during the intervention phase will be recorded to examine what other treatments mothers were offered and then accessed, to test the feasibility of using TAU as a comparative arm for a future trial.

THE INTERVENTION (SELF-DIRECTED TRIPLE P)

Online BabyTP, informed by Online TP and the principles underpinning its successful implementation in several countries, was developed post-COVID to facilitate parental access and support without the need for group meetings. Online BabyTP is already offered to parents by some of the 75 Family Hubs in Local Authorities in the UK. TripleP UK report that there is parental engagement but those are parents who do not have a mental health diagnosis.

Online BabyTP is a self-paced interactive intervention, consisting of seven sessions. It is highly accessible (via laptop, tablet or phone) to parents of infants. Digital poverty should not be a barrier for mothers to engage, because Online BabyTP can be accessed using a mobile smartphone, which most people of childbearing age own. Sessions cover advice on parenting, bonding and mother-baby interaction, and brief psychological coping strategies. The intervention was designed to allow parents to learn the core parenting strategies with ample opportunities to practice these skills. If mothers wish to share the content of the online sessions with their partner or another family member or friend, they can do so by watching it together. The intervention is self-paced, so mothers can decide if they want to go through the intervention on a weekly basis or more quickly.

All eligible mothers who consented and completed our baseline assessment measures will be offered a code to access the intervention and 10 weeks to complete it. They will be offered encouraging prompts via text or email messages to support their engagement as well as four brief phone calls to check on their progress (prior to session 1 to help with access, then after sessions 1, 3, and 5). Researchers will be trained in BabyTP by the CI who is an accredited Triple P practitioner and has delivered BabyTP to mothers with mental health problems. Researchers will also have completed the online intervention themselves in order to be able to answer any questions participants may have about the programme.

POST-STUDY SUPPORT

All participants who were offered a code to access online BabyTP and started the intervention (activated the code) will retain access for 12 months. Furthermore, the TripleP Online Management System allows the research team to track the use of codes offered, monitor parental progress through the intervention, and view aggregate data in a user-friendly format.

There will be an optional withdrawal interview for participants that choose to discontinue taking part, when they will be asked for brief reasons for this. We will emphasise their right to withdraw without giving us any reason. It will be made clear on the PIS that this will be used for research purposes.

PROCESS EVALUATION

A subgroup of 10-20 mother participants will be invited to take part in semi-structured interviews from week 7 when we assume they might have completed Online BabyTP or

disengaged from it. Participants will be sampled purposively; we will try to include mothers from a variety of backgrounds and with varying degrees of engagement with the intervention. We will provide mothers with a separate participant information sheet and take separate consent prior to the interview.

For the interviews, we will use a topic guide focused on understanding the acceptability of the intervention and participant experience. The topic guide has been informed by public contributors. Each interview is anticipated to be completed within a single meeting (via an online call), lasting up to 60 minutes, and will be audio recorded and video recorded. As with baseline and follow-up assessments, interviews will be arranged to accommodate participants' needs (and those of their child[ren]) and consideration will be given to time, working hours, and childcare responsibilities. Interviews will be transcribed verbatim. Recordings will be made using secure software (Zoom or MS Teams). During transcription, all participant identifying information will be removed to protect participant confidentiality. Data will be analysed using Framework Analysis.

A sample of perinatal specialist mental health team members (5-10) who referred participants to the study will be asked to take part in a qualitative interview to explore their decision making around referrals, their experience of facilitating study engagement and their perception of the intervention and its possible implementation into services. In the early stages of the study, staff will be offered to attend a study overview session which will cover additional information on BabyTP (facilitated by the CI and by a Triple P UK representative) so that staff can ask questions about the study and the intervention. This session may be video recorded to be shared with staff that could not attend.

Staff participants will be sampled purposively based on their job roles and years of experience. These interviews will also follow a topic guide, focused on understanding the barriers and facilitators of successful staff involvement. Their demographic information will also be collected (age, gender, ethnicity, role, length of time in role, whether they are a parent). Interviews will be transcribed verbatim. Recordings will be made using a secure software (MS Teams). During transcription, all participant identifying information will be removed to protect participant confidentiality. Data will also be analysed using Framework Analysis.

Intervention Type
Behavioural

Primary outcome(s)
We will collect the following primary outcome data to assess feasibility:
1. Number of eligible referrals
2. Number of participants consenting to take part
3. Number of participants completing baseline assessments
4. Number of participants enrolling in the intervention (i.e., starting the first online session)
5. Number of participants engaging with the intervention
6. Number of sessions being completed by participants
7. Number of participants completing the intervention (all 7 sessions)
8. Number of participants completing the study assessments post-intervention
9. Percentage of each assessment's completion

Key secondary outcome(s))
We will collect the following secondary outcome data at baseline and at 12 weeks post-intervention offer, to assess the intervention's clinical promise:

1. Mental health and mood will be measured using the brief 21-item Depression, Anxiety and Stress Scale (DASS-21) (Lovibond & Lovibond, 1995; Henry & Crawford, 2009).
2. Wellbeing will be measured using the 7-item Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) (Stewart-Brown et al., 2009).
3. Parenting competence and confidence will be measured using the 10-item Maternal Self-Efficacy Scale (MSES) (Teti & Gelfand, 1991).
4. The mother's perceived bond with their baby will be measured using the 25-item Postpartum Bonding Questionnaire (PBQ) (Brockington et al., 2001).

An embedded process evaluation to assess the intervention's acceptability with 10-20 mothers and with 5-10 Specialist Perinatal Mental Health Service staff will be conducted using semi-structured 1-1 interviews.

Completion date
28/02/2026

Eligibility

Key inclusion criteria
Participants for the main feasibility study will be women/mothers or birthing people:
1. Aged 18 years or over
2. Mother/parent of an infant aged birth to 12 months, with whom they live, or have parental responsibility or expectant person in the third trimester of pregnancy
3. Accepted for treatment for a perinatal mental health problem by a member of the Perinatal Specialist Service for Mental Health within Greater Manchester Mental Health NHS Foundation Trust Trust (GMMH) (e.g., on the psychology pathway)
4. With sufficient English fluency to engage with intervention and complete assessments (and take part in interviews)
5. Owning or having access to a smartphone, laptop, computer or tablet (to view the intervention)
6. Capable of giving informed consent

Staff participants for interview aspect of this study only:
1. Qualified health care professional within the Perinatal Specialist Mental Health Team at GMMH (e.g., clinical or counselling psychologist, CBT therapist, nursery nurse, team leader, etc.)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Participants for the main feasibility study will be women/mothers or birthing people:
1. Inpatient at the time of recruitment

Staff participant for interview aspect of this study only:
1. Been in post for less than 6 months

Date of first enrolment
01/04/2025

Date of final enrolment
12/12/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Only anonymised quantitative study data will be made available for sharing in line with funder requirements via the University of Manchester's supported institutional research data repository,Figshare, (https://figshare.manchester.ac.uk) to other bona fide researchers. Consent for this sharing of anonymised data will be obtained from participants. Quantitative data will only be shared once all outputs from the study are published. Qualitative data will not be shared due to the risk of identification of participants and the potentially sensitive nature of the data.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Main study version 3	08/02/2025	11/03/2025	No	Yes
Participant information sheet	Mothers interviews version 3	08/02/2025	11/03/2025	No	Yes
Participant information sheet	Staff interviews version 3	08/02/2025	11/03/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes