

A feasibility study of Baby Triple P Positive Parenting Programme for mothers with mental health difficulties

Submission date 16/01/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 02/02/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/06/2022	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

About one in a hundred mothers develop severe mental illness after giving birth. Illnesses such as psychosis (a mental health problem that causes people to perceive or interpret things differently from those around them) or severe depression (low mood), can have a significant negative impact on the mother and her baby. These mothers are usually admitted to a Mother and Baby Unit (MBU). MBUs are psychiatric wards which aim to improve the mother's mental health and her relationship with her baby. At present, MBUs offer a range of different types of support but no structured therapy. MBU staff and mothers believe the recently developed parenting programme called Baby Triple P could be helpful. This programme aims to strengthen the relationship between mother and baby and their wellbeing by teaching mothers skills to cope and skills to look after their baby using a book that they can also share with their partners /family. So far, though, the programme's possible benefits in this NHS setting are not known. The aim of this study is to test whether it is possible to recruit, engage and retain mothers to take part in a study looking at the effectiveness of Baby Triple P in order to find out if a full-scale study would be possible.

Who can participate?

Women who have a child aged under one year old and are in the late stages of pregnancy, as well as permanent full-time or part-time members of the Mother and Baby Unit (MBU) staff team.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive usual treatment only, which varies from person to person depending on their needs. Those in the second group take part in Baby Triple P as well as receiving usual treatment. This involves taking part in eight sessions, delivered over 8-10 weeks. The first four sessions are individual and involve advice on parenting, bonding and mother-baby-interaction and relationship, partner and family support and brief psychological coping strategies. The second four are designed to be delivered over the telephone. The telephone sessions allow the participant to review progress and practice skills, thereby enhancing her parenting confidence/competence and overall

wellbeing. At the beginning of the study and after 8-10 weeks and six months, participants in both groups complete a range of questionnaires designed to measure their confidence and competence and mental wellbeing. MBU staff looking after them also complete questionnaires about each mother and baby's wellbeing.

What are the possible benefits and risks of participating?

Participants who take part in Baby Triple P may benefit from enjoying taking part in the sessions and having the opportunity afterwards to share their experiences of and thoughts about the programme. All participants in the study may find it interesting to complete questionnaires about their mood, wellbeing and relationship with their baby as well as having the opportunity to talk to a researcher on three occasions. Mothers who are not allocated to receive Baby Triple P will be offered a copy of the workbook upon completion of the study. All participants will be offered a Thank You in the form of a £30 voucher or cash at their final assessment. There is a small risk that completing questionnaires may cause some distress because they can cover difficult issues. Participants can refrain from answering any questions they are not comfortable answering, withdraw from the study at any point without giving a reason and discuss with the research team anything that they have concerns about.

Where is the study run from?

1. Andersen Ward Mother and Baby Unit, Wythenshawe Hospital (UK)
2. Chamomile Suite, The Barberry (UK)

When is the study starting and how long is it expected to run for?

September 2014 to April 2019

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

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Additional identifiers

Protocol serial number
31813

Study information

Scientific Title
Enhancing maternal and infant wellbeing: A feasibility study of the Baby Triple P Positive Parenting Programme for mothers with severe mental health difficulties

Acronym
IMaGINE

Study objectives
The aim of this study is to investigate whether it is would be feasible to conduct a full-scale trial looking at the effectiveness of the Baby Triple P intervention in mothers with severe mental health difficulties in a Mother and Baby Unit (MBU) setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester South Research Ethics Committee, 26/09/2016, ref: 16/NW/0510

Primary study design

Interventional

Study design

Randomised; Both; Design type: Treatment, Prevention, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Schizophrenia, schizotypal and delusional disorders

Interventions

Participants are randomised via a clinical trials unit telephone service using an allocation ratio of 1:1 and permuted blocks of size 4 and 6 to one of two groups.

Intervention group: Participants receive the Baby Triple P Positive Parenting Programme (Baby Triple P) plus treatment as usual (TAU). Baby Triple P consists of eight sessions (estimated to be delivered over 8-10 weeks) of which the first four sessions are delivered face-to-face on an individual basis. These sessions are designed to enhance the knowledge, skills and confidence of parents. Sessions cover advice on parenting, bonding and mother-baby-interaction and relationship, partner and family support and brief psychological coping strategies. The subsequent four sessions are designed to be delivered over the telephone, which is suitable for an inpatient setting when the women may be discharged or on home leave from the unit in preparation for discharge. The telephone sessions allow the participant to review progress and practice skills, thereby enhancing her parenting confidence/competence and overall wellbeing. The intervention has a flexible delivery format, which is suitable for mothers with severe mental health difficulties who care for babies.

Control group: Participants receive treatment as usual (TAU) only.

TAU, in line with all standard and individually prescribed clinical interventions as directed by the MBU clinical teams, will apply for both the intervention and control group. This will include case management using a care programme approach (CPA) from their allocated Mother and Baby Unit (MBU) psychiatric nurse, pharmacological interventions from psychiatry (where indicated) and non-parenting, brief psychological interventions (e.g. Cognitive Behaviour Therapy (CBT) for depression). Nursery nurses and MBU staff offer psychosocial interventions (e.g. Baby Massage or Video Interactive Guidance), which mothers can engage in, but these are not structured, manualised activities including parenting skills. The type and duration of standard care that mothers in both arms of the trial receive during the intervention phase will be recorded in order to examine what psychiatric, psychopharmacological psychosocial or psychological treatment mothers are offered and engaged in in order to test the feasibility of using TAU as a comparative arm for a future trial.

For all participants, follow up takes place at 8-10 weeks and 6 months post-baseline.

Intervention Type

Behavioural

Primary outcome(s)

Maternal confidence and competence is measured using the Maternal Efficacy Questionnaire at baseline and 8-10 weeks and 6 months post-baseline.

Key secondary outcome(s)

Self-Report Outcomes (completed by participants):

1. Maternal mood is measured using the Brief Depression Anxiety and Stress Scale at baseline and 8-10 weeks and 6 months
2. Mother-infant relationship is measured using the Postpartum Bonding Questionnaire at baseline and 8-10 weeks and 6 months
3. Quality of life is measured using the EQ-5D-5L at baseline and 8-10 weeks and 6 months
4. Mental illness symptom severity and distress is measured using the Brief Symptom Scale at baseline and 8-10 weeks and 6 months

Observer-Rated Outcomes (completed by MBU staff):

1. Mental illness symptoms are measured using the Brief Psychiatric Rating Scale at baseline and 8-10 weeks and 6 months
2. Mental illness symptom improvement from admission (to the MBU) to discharge is measured using the Clinical Global Impression Scales at baseline and 8-10 weeks and 6 months
4. Infant wellbeing is measured using the Louis Mother and Child Risk Observation (Louis MACRO) at baseline and 8-10 weeks and 6 months
5. Health outcomes are measured using Health of the Nation Outcome Scales (HoNOS) at baseline and 8-10 weeks and 6 months

Feasibility and Acceptability Outcomes:

1. Feasibility of recruitment will be measured through recording how participants found out about the study, recruitment rates, number of potential participants found eligible, initially approached by Mother and Baby Unit (MBU) staff, consented to be approached by the research team, and approached about the study by the research team, reasons for declining to be approached or take part in the study if known and percentage of eligible participants consented and their characteristics
2. Feasibility of randomisation will be assessed by recording number of refusals to be randomised
3. Engagement/retention in the study and to study procedures will be measured by recording the number of participants who withdraw and the time point at which they withdraw from the study. Reasons for leaving the study early will be recorded if known. The number of participants who complete outcome measures at each of the time points and the completeness of their data will be recorded.
4. Engagement/retention in the intervention will be measured by recording the percentage of intervention sessions delivered, duration and maternal self-reports of time spent between sessions on Baby Triple P as well as maternal use of the workbooks. Reasons for leaving the intervention early will be recorded if known.
5. Acceptability of the intervention and study design and procedures will be assessed post-intervention via a questionnaire (for acceptability of the intervention only) and semi-structured interviews with participants allocated to receive Baby Triple P plus Treatment as Usual ($n > 15$) and Mother and Baby Unit staff ($n \geq 15$).

Completion date

16/04/2019

Eligibility

Key inclusion criteria

Patient participants:

1. Aged 18 years or more
2. Have at least one infant aged birth to 12 months who they care for or are going to care for
3. Are in the third trimester of pregnancy and are expected to reside on the MBU following delivery
4. Are able to comprehend and understand English to provide consent to the study
5. Are able to provide written informed consent. Note: MBU staff routinely assesses their capacity

Staff participants:

1. Permanent full-time or part-time members of the Mother and Baby Unit (MBU) staff team
2. Have worked on the MBU for at least six months
3. Proficient in English to understand the study, provide written, informed consent and can take part in interviews

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

37

Key exclusion criteria

Patient participants:

1. Participants who do not have a sufficiently good working knowledge of English to provide written informed consent and understand and complete questionnaires. Use of interpreters is beyond the scope of this feasibility study, but could be built into a definitive trial. Note: If interpreters are involved in the routine care of a participant, then their inclusion can be considered.
2. Participants whose current symptoms seriously compromise their ability to concentrate on the assessments or intervention sessions. Examples include participants who experience persistent and loud auditory hallucinations that they clearly react to. Eligibility can be reassessed once a participant's acute symptoms subside.
3. Participants who show severe personality disorder traits including significant current self-harming behaviours (such as attempting suicide). Note: MBU staff assess these behaviours as part of routine practice alongside risk issues.
4. Participants whose infant will be removed from their care on a non-temporary basis
5. Participants whose discharge has been scheduled within 7 days from date of recruitment

Staff participants:

1. Nursing students or bank staff who work on the MBU on a temporary basis only.
2. Have less than six months experience of working on the MBU.

Date of first enrolment

28/11/2016

Date of final enrolment

30/04/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Andersen Ward Mother and Baby Unit

Laureate House

Wythenshawe Hospital

Southmoor Road

Baguley

Manchester

United Kingdom

M23 9LT

Study participating centre

The Barberry

Chamomile Suite

25 Vincent Drive

Edgbaston

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United Kingdom

B15 2FG

Sponsor information

Organisation

University of Manchester

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health 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

Individual participant data (IPD) sharing plan

The current 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?
Results article	protocol	16/05/2022	08/06/2022	Yes	No
Protocol article		10/09/2018	27/11/2020	Yes	No
HRA research summary			28/06/2023	No	No