ISRCTN12765736 https://doi.org/10.1186/ISRCTN12765736

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

Registration date
02/02/2017

Overall study status
Completed

Last Edited
08/06/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 wellbing. MBU taff looking after them also complete questionnaires about each mother and baby's wellbing.

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?
1. Dr Kim Cartwright (public)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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 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 interventino 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 ≥ 15).

Overall study start date
01/09/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

Planned Sample Size: 75; UK Sample Size: 75

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
England

United Kingdom

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
Birmingham
United Kingdom
B15 2FG

Sponsor information

Organisation
University of Manchester

Sponsor details
FMHS Research Office
3.53 Simon Building
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M13 9PI

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Throughout the life of the study, a dedicated website will provide information for and invite comments from participants (please note this is still in the process of being set up), stakeholders including academics, clinicians, local authorities and commissioners, NHS trust managers, perinatal organisations, as well as MBU staff and participating mothers, their families and the public about the on-going research and its progress and findings.

A range of dissemination methods at a local, national and international level. All reports will be presented following the CONSORT guidelines. Regular progress newsletters will be sent to participants (if they wish to receive this kind of information) throughout the study and in the final months, in collaboration with service users, the study team aims to:
1. Publish scientific papers in peer-reviewed, academic, open-access journals for the professional academic and clinical community
2. Distribute reports to local and national perinatal mental health organisations (e.g., the Maternal Mental Health Alliance)
3. Offer summaries to all participating mothers to inform them of the outputs and their valued contribution
4. Work with the University of Manchester and relevant Trust press office, radio/TV stations and community groups so that mothers and their families (and the wider public) can understand the study's potential benefits.

The Triple P organisation (www.triple.net) plays a central role in dissemination, because of its extensive international network of practitioners, policy makers and researchers in countries around the world. Plans to also disseminate findings at their annual international Helping Families Change Conference, as well as other relevant conferences (e.g., The World Congress of Infant Mental Health, the Marcé Society, etc.) attended by healthcare professionals and policy-makers linked to general perinatal and MBU-specific work (e.g., the MBU Perinatal Network organised by the Royal College of Psychiatrists, The Division of Clinical Psychology Faculty of Perinatal Psychology, etc.).

Finally, in collaboration with our service user consultants, a 'Dissemination Event' will be held to inform stakeholder discussions with services and service users and their families, which will decide how to proceed with the future definitive RCT.

Intention to publish date
16/04/2020

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