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Perinatal emotional skills groups for women with borderline personality disorder

Submission date
30/05/2022

Recruitment status
No longer recruiting

Registration date
01/06/2022

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with a diagnosis of Borderline Personality Disorder (BPD) sometimes have stormy relationships, and experience distressing changes in mood, as well as urges to harm themselves. Pregnancy, childbirth and becoming a parent are therefore particularly challenging experiences for women with BPD. Currently, we do not know the best way to help women with BPD during pregnancy and in the year after childbirth - a time that is referred to as the perinatal period. Emotional skills groups can help people to learn new skills in managing their feelings and relationships and these groups can relieve some of the symptoms of BPD. Members of our team have adapted emotional skills groups for women with BPD during the perinatal period. They involve twelve group sessions that are flexibly delivered and cover a range of topics about feelings and emotions, becoming a mother and the relationship with the baby. We know that perinatal emotional skills groups are popular with women with BPD, but we have not examined whether the groups provide an effective treatment. A clinical trial would help us to find this out. A clinical trial is a research project where we compare two or more treatments or therapies. Trials are important because they help us to find out whether a new treatment or therapy is better, or more effective, than what is currently provided as standard care.
We are a group of clinicians, service users and researchers who want to find out whether a trial can be used to examine the effectiveness of perinatal emotional skills groups for women with BPD. In this study, we will offer perinatal emotional skills groups as an addition to standard care to half of the women, and the other women will be offered standard perinatal mental health care. Women will be invited to take part from South-West England and London. Women who have used perinatal mental health services helped to plan this study and they will help us to ensure that we adopt the best and most sensitive methods for the future trial. They will also help us to share our findings with other members of the public.

Who can participate?
Women over the age of 18 years and are likely to have a diagnosis of BPD. They must also either be pregnant or have given birth within the last 12 months.

What does the study involve?
The study involves four stages:
1. Screening for participation in the study. In a telephone call or online video call, a researcher

will assess potential participants to see whether they are eligible to take part in the study. The researcher will complete some short checklists with the person, to confirm whether they have symptoms of borderline personality disorder. They will also check whether the person is willing and able to attend Emotional Skills Groups if assigned to these as part of the study.
2. Baseline assessment before randomisation. This assessment will take place by online video call. The researcher will explain the study in more detail and obtain the person's consent in writing. The researcher will then help the participant to complete several online questionnaires. The questionnaires will include questions about borderline personality disorder symptoms, and about any psychological distress, self-harming behaviours or parenting stress that the participant may be experiencing. If the participant is assigned to an Emotional Skills Group as part of the study, the researcher will explain this in more detail and will show them how to access the therapy groups online.
3. Emotional Skills Groups. The participant may be assigned to an Emotional Skills Group as part of the study. If they are not assigned to one of these groups, they will receive standard perinatal mental health care. The Emotional Skills Groups consist of two preparatory sessions (each lasting up to 90 minutes), followed by 12 weekly group therapy sessions, each lasting about 2 hours. The therapy sessions will take place online. They will focus on learning emotional skills and the groups will be run by a clinical psychologist, working with another qualified perinatal clinician. There will be up to six women in each group.
4. Follow-up assessments. 2 months and 4 months after being randomised, the participant will take part in a follow-up assessment. At the 4-month follow-up the researchers will also examine the participant's health records and those of the baby.

What are the possible benefits and risks of participating?
Patients randomised to ESGs will benefit from gaining new emotional regulation skills during their participation in the groups. Participants in the study may also gain a sense of value and well-being from making a contribution to new research into their condition.
Individuals with Borderline Personality Disorder typically lack emotional regulation skills and may have episodes of distress and/or suicidal thoughts. ESGs are designed to ameliorate their distress. The process of learning emotional regulation skills may be a stressful experience for some people. However, clinical work during the intervention will be delivered by trained and experienced mental health practitioners, under regular clinical supervision. Participants will be free to take breaks during the emotional skills groups if needed.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
March 2021 to May 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Prof. Paul Moran, paul.moran@bristol.ac.uk
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Contact information

Type(s)
Principal investigator

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
303255

Central Portfolio Management System (CPMS)
51168

Protocol serial number
3

Study information

Scientific Title
A feasibility randomised controlled trial with an embedded qualitative evaluation of perinatal emotional skills groups for women with borderline personality disorder.

Acronym
EASE

Study objectives
The aim of this study is to investigate whether it is feasible and acceptable to undertake a trial of the effectiveness and cost-effectiveness of perinatal emotional skills groups (ESGs) for women with borderline personality disorder (BPD) (in addition to standard care) compared with standard perinatal mental health care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, Camden & Kings Cross Research Ethics Committee (Camden & Kings Cross Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8068; camdenandkingscross.rec@hra.nhs.uk), ref: 21/LO/0833

Primary study design
Interventional

Study design
Two-arm parallel-group randomized controlled trial with a nested qualitative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
Randomisation will be via a secure online randomisation system, at an individual level, stratified by centre. Those in the active arm of the trial will be offered perinatal ESGs in addition to standard perinatal mental health care, while those in the control arm will continue to receive standard perinatal mental health.

Perinatal ESGs comprise two individual preparatory sessions, followed by 12 group sessions. The individual sessions will last up to 90 minutes and subsequent group sessions last up to 2 hours. Participants receiving ESGs will also continue to be cared for as usual by their perinatal mental health team. Groups usually treat up to six women and the groups are organised into four modules on emotion regulation, distress tolerance, mindfulness and interpersonal effectiveness. These modules are focused on the acquisition of emotional skills and each session is supplemented with “Keeping Baby in Mind” teaching skills relevant to becoming a parent of a new child; these skills can be taught and practiced both prenatally, as well as postnatally. The groups will be run by a clinical psychologist working with a trained nurse or other qualified perinatal clinician.

The comparator treatment will be standard perinatal mental health care, delivered on an individual basis, in accordance with current NICE and Royal College of Psychiatry guidelines. It should consist of an assessment, a written care plan and weekly reviews with a care coordinator. All study participants allocated to receive the comparator treatment will complete all the study assessments. Information on standard care will be gathered at the follow-up assessment, 4 months post-randomisation.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility of recruitment:
1. Appropriateness of eligibility criteria, as measured by the number of those referred to the trial over the study period who meet the eligibility criteria
2. Success of recruitment, as measured by the number of eligible patients who consent to participate in the trial over the study period, and the number of patients who decline to participate (including reasons for non-participation)
3. Retention rates, as measured by the number of participants who consent to participate that remain in the trial by the 4-month follow-up

Feasibility of measures:
1. Baseline measures: the number/proportion of participants with complete baseline data over the study period
2. Follow-up measures: the number/proportion of participants with complete follow-up data at the 4-month follow-up

Feasibility of the intervention as measured by
1. The number/proportion of participants attending all 12 sessions of treatment during the treatment phase of the study
2. The number/proportion of participants attending at least 9 sessions of treatment during the treatment phase of the study

Key secondary outcome(s)
1. Symptoms of borderline personality disorder measured using the Zanarini Rating Scale for Borderline Personality Disorder Self-Report Scale (ZAN-BPD), at 2 and 4 months post-randomization
2. Symptoms of psychological distress measured using the ten-item Clinical Outcomes in Routine Evaluation (CORE-10) at 2 and 4 months post-randomization.
3. Health-related quality of life measured using the EQ-5D-5L at 4 months post-randomization.
4. Mental wellbeing measured using the Short Warwick Edinburgh Wellbeing Scale (SWEMWBS) at 2 and 4 months post-randomization
5. Social functioning measured using the Work and Social Adjustment Scale (WSAS), at 2 and 4 months post-randomization
6. Parenting stress measured using the Parental Stress Scale at 2 and 4 months post-randomization
7. Self-harming behaviour over the past week measured using a single question: “Have you [in the past week] deliberately taken an overdose (e.g., of pills or other medication) or tried to harm yourself in some other way (such as cut yourself)?”. This will be assessed at 2 and 4 months post-randomization.

8. Resource use will be measured by maternal self-report at 4 months post-randomisation
9. Data about the baby's growth (weight and height) and vaccination status will be sourced from Personal Child Health Records at 4-months post-randomisation

Completion date
31/05/2024

Eligibility

Key inclusion criteria
Participants will meet the following inclusion criteria:
1. At least 18 years old
2. Likely to have a diagnosis of borderline personality disorder
3. Either pregnant (from week 15 gestation onwards) or are within 12 months of having a live birth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
48

Key exclusion criteria
Women will be excluded if:
1. They have a current clinical diagnosis of a co-existing organic, psychotic mental disorder or substance use dependence syndrome
2. They have cognitive or language difficulties that would preclude subjects providing informed consent or compromise participation in study procedures
3. They pose an acute risk to their baby, as assessed by clinicians
4. They require admission to a mother and baby unit
5. They are unable to speak English with sufficient fluency to participate in study procedures

Date of first enrolment
01/09/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
South London & Maudsley NHS Trust Hq
9th Floor
The Tower Building
11 York Road
London
United Kingdom
SE1 7NX

Study participating centre
Callington Road Hospital
Marmalade Lane
Bristol
United Kingdom
BS4 5BJ

Study participating centre
New Road Branch Surgery
32 New Road
Chippenham
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SN15 1HP

Study participating centre
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Monks Orchard Rd

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BR3 3BX

Study participating centre
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/12/2024	17/01/2025	Yes	No
Protocol article		23/09/2022	28/09/2022	Yes	No
HRA research summary			28/06/2023	No	No