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Perinatal emotional skill s groups for women and birthing parents with borderline personality disorder

Submission date
05/02/2026

Recruitment status
Recruiting

Registration date
30/03/2026

Overall study status
Ongoing

Last Edited
10/06/2026

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
People with a diagnosis of borderline personality disorder (BPD) often have difficult relationships, experience distressing changes in mood and are at increased risk of self-harm and suicide.
Pregnancy, childbirth and becoming a parent are known as the 'perinatal period'. During this period, the bond that forms with a baby is very important and can affect the health and later development of the baby. This period can be particularly stressful for women and birthing parents with BPD, but we do not know the best way to help people with BPD during the perinatal period.
People with BPD have advised us that they would have valued more help during this very important period of their lives.
The aim is to determine the efficacy of perinatal emotional skills groups (ESGs) (in addition to Current NHS care) for women and birthing parents with BPD.

Who can participate?
Women and birthing parents aged 18 or over who are currently pregnant (from 12 weeks' gestation onwards) or who have given birth within the past 12 months can take part in the study. Participants will need internet access, at least conversational-level English, and to meet the DSM-5 criteria for borderline personality disorder.

What does the study involve?
Individuals who decide to take part in the PROSPER study will be randomly put into one of two groups.
Group 1 will receive NHS current perinatal mental health care; this currently consists of assessments, care planning, and reviews delivered by staff working in perinatal community mental health teams.

Group 2 will attend ESGs for 3 months. This involves attending 12 online sessions (each lasting about 2 hours) covering a range of topics, including feelings about becoming a parent and their relationship with the baby. They will also receive current NHS perinatal mental health care.

Babies are welcome to be present during the sessions; there is no expectation that parents need to arrange childcare.

A researcher will contact the participants three times during the first 3 months. Participants will also be contacted by the researcher at 4, 8 and 12 months. During each call, the researcher will go through several questionnaires about participants' mental health and well-being. They will also ask about any complications participants have had since their last call. At 12 months, the researcher will also ask them for some information about their baby's health. Each video call with the researcher will last for 30-60 minutes.

With participants' consent, the study team would like to video-record a portion of the 12-month video call they have with the researcher, so that we can look at their interactions with their baby. They will ask if participants agree to this during their 8-month follow-up call with the researcher (the call before the 12-month follow-up call); if they agree, they will ask them to sign a consent form.

Some participants will also be invited to have a conversation (research 'interview') to understand their views on being in the study and their treatment experiences since starting the study.

What are the possible benefits and risks of participating?
Benefits: There is no guarantee that the study will benefit participants' health directly; however, it will guide the study team in finding the best way to help people who are perinatal with BPD in future.
All appointments for the study can be done remotely, so there is no expectation for participants to travel to see us for this study.

Risks: Participants will be asked to spend time completing questionnaires across the year, which will focus on their mental health and wellbeing.

If they are put into Group 2, during the Emotional Skills Groups, they will be asked to think about and discuss their feelings about becoming a parent and their relationship with the baby. These discussions will sometimes touch on sensitive matters relating to emotions and relationships. The sessions will be conducted by a clinical psychologist, working with other trained and experienced perinatal health professionals, and the well-being and safety of all those taking part will be closely monitored by an independent group of experts throughout the study.

During the optional interview, participants may be asked about their experiences of the support they received for the symptoms of BPD and during pregnancy. For some people, this may cause distress. The research team will try to ensure that participants are comfortable. They can pause or stop the interview at any time with no obligation to continue.

Where is the study run from?
This study is sponsored by the University of Bristol; the Bristol Trials Centre (at the University of Bristol) is responsible for managing the study.

When is the study starting and how long is it expected to run for?
The study began in June 2025, with participant recruitment expected to start in June 2026. The study is expected to run until late 2028.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation (EME), UK.

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

Contact information

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Public

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Integrated Research Application System (IRAS)
341566

Central Portfolio Management System (CPMS)
61444

National Institute for Health and Care Research (NIHR)
167051

Study information

Scientific Title
A randomised controlled trial evaluating the efficacy and mechanisms of online PeRinatal emOtional skillS groups compared to treatment as usual for women and birthing parents with borderline Personality disordER (PROSPER).

Acronym
PROSPER

Study objectives
Principal objective: To determine whether online emotional skills group (ESG) sessions, in addition to standard NHS perinatal mental health care, can help to relieve symptoms of BPD in women and birthing parents who have borderline personality disorder, in comparison to standard NHS perinatal mental health care only.

Secondary objectives: To determine whether ESG sessions reduce psychological distress and/or improve wellbeing, social functioning, health-related quality of life, postpartum bonding and caregiving.
To determine whether ESG sessions affect the health of participants' babies. To test whether ESG sessions work by improving the regulation of emotions, tolerance of distress, mindfulness and/or the understanding of others.
To explore participants' and their therapists' views and experiences of perinatal ESG sessions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/03/2026, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; preston.rec@hra.nhs.uk), ref: 26/NW/0022

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Reproductive Health and Childbirth, Primary sub-specialty: General Obstetrics (antenatal and postnatal care, perinatal mental health); Health Category: Mental health, Reproductive health and childbirth; Disease/Condition: Mood [affective] disorders, Persons encountering health services in circumstances related to reproduction

Interventions

Women and birthing parents, aged 18 years or over, meeting DSM-5 diagnostic criteria for BPD will be recruited. They will be allocated to receive emotional skills group (ESG) sessions plus standard perinatal mental health care, or standard perinatal mental health care alone, in a 1:1 ratio. Randomisation will be stratified by centre and minimised by perinatal stage and severity of BPD symptoms. The internal pilot, run across 3 sites, will establish whether sufficient numbers of eligible patients can be recruited, engage with their allocated treatment and whether sufficient primary outcome data can be obtained to robustly answer the trial questions. If the progression criteria are met, the main trial recruitment period will start at (at least) 7 sites. If the main trial proceeds, patients from the internal pilot will be included in the final analysis. All participants will be followed up for 1 year following the final randomisation within each cohort.

Within each recruitment centre, potentially eligible patients will be identified from the existing caseload by the PI (or delegated member of the clinical team) for screening into the study. The PI (or delegated member of the clinical team) will introduce the study to potentially eligible patients during an in-person or remote consultation and will establish whether the patient agrees to being contacted by a member of the local research team. The PI (or delegated member of the team) will provide the patient with a copy of the participant information using a layered approach, and it will be explained that, if they agree to be contacted by a member of the local research team, then the first step involves participating in a screening interview to assess their eligibility to enter the trial. During the approach at the initial consultation, the PI (or delegated member of the clinical team) will record the relevant clinical eligibility checks on a screening CRF if the patient agrees to be contacted by the local research team, or if the patient does not wish to be contacted. Where possible, reason(s) for non-participation will be stated.

A member of the local research team will arrange a time to schedule a call with the participant to explain the study in more detail, answer any questions and complete the rest of the screening assessment if the patient is interested in participating. This will include confirming the presence or absence of DSM-5 symptoms of BPD by administering the McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD). The member of the local research team will inform the patient during the screening interview whether they are eligible for the study or not.

Following eligibility being confirmed, if the patient would like to take part and has time to proceed, informed consent will be obtained during the initial screening call. If the patient does not have time during this first call, the member of the local research team will schedule a further call with the patient, where informed consent will be obtained. Consent will also be sought for details of the participant to be shared with the qualitative researcher so that they can be approached about taking part in an interview. Patients who are willing to participate in the trial will be asked to provide informed, written consent, either electronically (e-consent) or on paper.

The baseline assessment will proceed once informed consent has been obtained. If the participant has time and it is convenient for them, the baseline assessment will take place immediately after informed consent has been obtained. If this is not convenient for the

participant, a further call will be arranged in order to complete the baseline assessment with the participant. The assessment will take place online. The assessments include the Zanarini Rating Scale for Borderline Personality Disorder-Self Report (ZAN-BPD-SR), alongside measures of psychological distress (CORE-10), mental well-being (SWEMWBS), infant bonding (PBQ), social function (WSAS) and quality of life (EQ-5D-5L). The participant will complete the questionnaires verbally with the researcher and the researcher will enter the data directly into the REDCap database. Screensharing may be utilised to show the questionnaires, so that participants have time to read and digest the questions. At baseline, participants will be asked to provide socio-demographic details and additional information will be gathered on indicators of socio-economic status. Birth outcomes will be collected from the participant (e.g. birth weight, mode of delivery and whether the baby was transferred to a neonatal unit); these will be collected later if the participant has not yet given birth at the time of joining the study.

After informed consent has been provided by the participant and the baseline assessment has been completed, participants will be randomised by the local research team using REDCap. Individuals will be allocated, on a 1:1 ratio, to online perinatal ESGs (in addition to usual care (UC)) or UC alone. There may be a short delay until treatment begins to allow for a sufficient number of participants to be recruited to online ESGs.

Participants randomised to perinatal ESGs will attend up to two individual, preparatory sessions (60 minutes per session), followed by 12 online group intervention sessions (2 hours per session). The individual preparatory sessions involve having an opportunity to meet the facilitators and ask any questions, as well as establishing specific, individually tailored goals for the group intervention. The optimum number of participants in each group is 6-8. The ESG sessions will be audio-recorded in order to monitor how well the sessions are being delivered. Participants will be informed in the participant information leaflet that ESG sessions will be audio-recorded and will provide consent to the recording.

The comparator treatment will be usual perinatal mental health care, delivered on an individual basis, in accordance with current NICE (National Institute for Health and Care Excellence) guidelines. Usual care (UC) will be delivered by staff working in perinatal community mental health teams and will comprise assessment, care planning, and reviews. UC does not routinely include access to perinatal ESGs. However, as part of UC, during a crisis, patients may be referred to a mental health crisis team, and arrangements may also be made for inpatient treatment if it is not possible to safely manage them in the community. Staff will also be able to refer participants in both groups to psychological treatments during their study participation, except psychological treatments that are focused on personality or personality disorder symptoms, because such treatments are closely related to the intervention (ESG sessions). The rationale for this is that the overarching aim of the study is to test the efficacy of ESGs. The frequency and nature of service contact and treatment associated with UC will be captured in both trial arms directly from participants.

Follow-up frequencies will be calculated based on the randomisation date of the last recruited participant within each cohort. All follow-up assessments, at 4,8 and 12 months post-randomisation, will be done remotely by video call (or telephone, if preferred) with a member of the local research team. These calls will each last 30-60 minutes; participants will be asked questions about their mental health and any adverse events they have experienced since the previous assessment. At 12 months, sensitivity will be assessed via a video-recording of a portion of the call; this is so that researchers can assess the participant's interactions with their baby. The assessment is performed using the National Institute of Child Health and Human Development Sensitivity Scale (NICHD). This is optional, and participants will be asked via a consent form at the 8-month follow-up assessment whether they agree to a section of the 12-

month follow-up video call being recorded for this purpose. If the participant agrees, at the beginning of the 12-month follow-up call, the local research team will again ask the participant if it is acceptable to record. The following secondary infant outcomes will also be collected at 12 months post-randomisation: weight, height and vaccination status, which will be self-reported by the participant using the Personal Child Health Record (PCHR), i.e. 'Red Book' and referrals to safeguarding services, which will be self-reported by the participant.

The embedded mechanistic study will determine how any reductions in BPD severity are mediated; this will be assessed via various questionnaires in all participants during weeks 1, 6 and 12 of treatment (1st, 6th and 12th ESG sessions or the equivalent timepoint in the UC group). Questionnaires administered will be as follows: Difficulties in Emotion Regulation Scale (DERS), Distress Tolerance Scale (DTS), Mindful Attention Awareness Scale (MAAS) and the Brief Symptom Inventory (BSI) interpersonal sensitivity subscale. Additional mechanistic assessments will be carried out in only those randomised to perinatal ESGs during weeks 1, 6 and 12 of treatment measurements. Some participants will also be invited to take part in the embedded qualitative study, participants will be asked to provide verbal consent to being interviewed and these interviews will be audio-recorded. We will examine the views and experiences of both the intervention and the trial with a sample of participants, therapists and their supervisors. Interviews with ESG participants, supervisors and therapists at 4 months will examine group dynamics and the therapeutic alliance with group facilitators, and how the groups may impact the domains of emotional regulation, distress tolerance, mindfulness and interpersonal sensitivity. We will also explore patient and staff perspectives about the emerging relationship with the baby. Usual care participants will be interviewed to examine their experiences and compare them with those of intervention arm participants. We anticipate interviewing up to 30 participants, 14 therapists and 7 supervisors. Each interview will take up to one hour.

A Study Within A Trial is also embedded. Given that the PROSPER trial will exclude people with Limited English Proficiency (LEP) due to the current set-up and delivery of the ESG online sessions, the aim of the SWAT is to explore the feasibility of adapting the perinatal ESG group intervention for people with symptoms of BPD who have LEP, and whether it can be tailored for people from different ethnic groups. We will use a mixed-methodology approach to address these objectives. Using detailed screening data, we will collect ethnicity and language data (where available) to explore the need for possible adapted perinatal ESGs. Qualitative methods will then be used to explore the views of perinatal people, therapists and supervisors on barriers and facilitators of setting up adapted perinatal ESG groups for people from ethnic minority groups with LEP.

Individual, semi-structured interviews with the therapists and supervisors will be combined within the main qualitative realist evaluation to reduce both participant and researcher burden. Patients excluded from the trial, as deemed 'required an interpreter to facilitate clinical engagement will be approached and provided with the Summary and Main SWAT PIL. With permission via verbal consent, contact details will be passed on to the research team to arrange an interview. Participants who agree to be contacted will be approached by the GCP-trained researcher who will explain more about the interview, answer any questions, and, if they agree, arrange a convenient time via their preferred method to conduct the interview. An interpreter will be provided for interviews taking place with patients approached to take part in PROSPER who were excluded due to LEP. Interviews will be up to 60 minutes. A maximum of 20 therapists and supervisors at sites and up to 15 perinatal people from ethnic minority groups will be interviewed.

Intervention Type
Behavioural

Primary outcome(s)
1. The global BPD symptom severity measured using the total score on the Zanarini Rating Scale for Borderline Personality Disorder-Self Report (ZAN-BPD-SR) at 4 months post-randomisation (end of intervention delivery)

2. Emotional regulation, distress tolerance, mindfulness and interpersonal sensitivity, measured using the Difficulties in Emotion Regulation Scale, Distress Tolerance Scale, Mindful Attention Awareness Scale and the Brief Symptom Inventory interpersonal sensitivity subscale, respectively, at 4 months post-randomisation

Key secondary outcome(s)
1. Psychological distress, wellbeing, social functioning, health-related quality of life and postpartum bonding measured using CORE-10, SWEMWBS, WSAS, EQ-5D-5L & PBQ at 4 months post-randomisation

2. Global BPD symptom severity, and psychological distress, wellbeing, social functioning, health-related quality of life and postpartum bonding, measured using ZAN-BPD-SR, and CORE-10, SWEMWBS, WSAS, EQ-5D-5L & PBQ, respectively, at at 8- and 12-months post-randomisation

3. Sensitivity measured using the NICHD assessment at 12-months post-randomisation

4. Infant weight, height, vaccination status & referrals to safeguarding services measured using self reporting by the participant including use of the Personal Child Health Record (PCHR) at 12-months post-randomisation

5. Treatment adherence, therapeutic alliance, and group cohesion measured using attendance of ESG sessions, Working Alliance Inventory – Short Revised and the Group Climate Questionnaire-Short (GQS-S) at 4-months post-randomisation

Completion date
31/08/2028

Eligibility

Key inclusion criteria
Participants may enter the study if ALL of the following apply:
1. Women and birthing parents aged 18 years or over who are pregnant (from week 12 gestation onwards) or within 12 months of having a live birth
2. Meet DSM-5 criteria for borderline personality disorder
3. Have internet access
4. Does not require an interpreter to facilitate clinical engagement
5. Provided informed consent for audio-recording of the ESG sessions (if allocated to the ESG group)

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
51 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Participants may not enter the study if ANY of the following apply:
1. Those with psychosis, bipolar disorder or substance dependence
2. Those who pose a high risk to their baby or themselves
3. Those requiring admission to a psychiatric hospital
4. Those who are already receiving psychological treatment that is focused on personality or personality disorder symptoms

Date of first enrolment
10/06/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds and York Partnership NHS Foundation Trust
St. Marys House
St. Marys Road
Leeds
England
LS7 3JX

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Kings Drive
Prescot

England
L34 1PJ

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

Study participating centre
West London NHS Trust
1 Armstrong Way
Southall
England
UB2 4SD

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
England
SO40 2RZ

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
England
AL10 8YE

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
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BR3 3BX

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

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?
Study website			26/03/2026	No	No