ISRCTN18308962 https://doi.org/10.1186/ISRCTN18308962

Exploring the clinical and cost-effectiveness of the Circle of Security Intervention for mothers in perinatal mental health services

Submission date
13/01/2022

Recruitment status
No longer recruiting

Registration date
18/02/2022

Overall study status
Completed

Last Edited
02/07/2025

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

One in five women experience mental health difficulties in pregnancy or in the first year after giving birth (often called the perinatal period). Around 7% of women in the perinatal period experience complex and severe mental health difficulties (such as bipolar disorder, complex post-traumatic stress disorder) and receive specialist support from NHS community perinatal mental health services. Research tells us that if women experiencing these kinds of mental health difficulties are not able to get treatment, their symptoms are unlikely to get better on their own and for some women it can make it difficult to parent their new baby. In England, untreated perinatal mental health difficulties costs over £8 billion each year. Perinatal mental health services provide a range of support for new mothers with mental health difficulties, but there are still gaps in the research about what interventions and therapies work for which mothers. Two of these gaps are in group therapy approaches and parent-infant bonding therapies that are adapted to the needs of women with complex and severe mental health problems One therapy that is showing some promise in filling these gaps outside of the perinatal period is the Circle of Security-Parenting Intervention. Circle of Security-Parenting is a parent-infant bonding, group intervention developed in America that is delivered over 10 weekly sessions. Circle of Security-Parenting is designed to help parents understand more about their young children and their emotions, as well as manage their own difficult emotions and how they may affect their relationship with their child. The group environment also encourages peer support. A number of previous research studies have explored whether Circle of Security-Parenting works to improve parenting quality and mental health. These studies show that mothers find it a helpful approach and that it does improve their mental health and relationship with their child. However, these research studies have been poor quality and there has never been a research trial in England or in perinatal mental health services. Researchers are therefore aiming to address this gap by doing the first large study to test whether Circle of Security-Parenting works for women using perinatal mental health services in improving their mental health symptoms and the quality of their bond with their babies. It addresses an area of key concern to women, families and the NHS and is an opportunity to reduce the burden of its long-term effects. If shown to be effective the intervention could be delivered widely across the NHS in perinatal mental health services. The aim of this study is to find out whether Circle of Security-

Parenting is more effective than usual care in improving symptoms of maternal mental health difficulties and mother-infant bonding for mothers in perinatal mental health services.

Who can participate?
Women or birthing parents, at least 18 years of age with a child aged 0 – 12 months, who are accessing an NHS perinatal mental health service in one of the nine sites that are taking part in the study

What does the study involve?
Participants are divided into two groups at random to either receive Circle of Security-Parenting (COS-P) alongside usual care in their perinatal mental health service, or to receive their usual care only. The researchers will compare women's mental health symptoms and parent-infant bonding levels at the start of the study, 3 months later (when one group of the women will have received the COS-P group) and then 7 and 12 months after the women first joined the study. The researchers will also interview women to find out their views of receiving COS-P. There will be a recorded play and parenting task with their child to complete. The proposed research has also received feedback from a group of experts by experience who have used perinatal mental health services, to make sure it is adapted and relevant to the needs of women in the perinatal period with complex or severe mental health difficulties.

What are the possible benefits and risks of participating?
The participants will help the researchers to better understand whether Circle of Security-Parenting works for women in NHS perinatal mental health services. It will help them to shape the care provided to new mothers whilst under these services, as they adjust to their role within their new family. It will also help their Trust's and other perinatal mental health services across the country to ensure the care offered to all service users is as beneficial as possible.
The researchers do not expect that taking part in the study will put participants at any particular disadvantage. However, one of the elements of taking part involves participants completing questionnaires about their mental health and their relationship with their child, which may bring up difficult emotions or memories. Similarly, the intervention will involve discussions around their parenting and their experiences of being parented, which some may find challenging. The researchers have set in place safeguarding measures to make sure participants are supported throughout their time in the study. There will also be time commitments involved in taking part in both terms of completing the different questionnaires and the intervention.

Where is the study run from?
Anna Freud Centre (UK)

When is the study starting and how long is expected to run for?
March 2021 to February 2025

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
General study email: cosistudy@annafreud.org

Study website
https://fundingawards.nihr.ac.uk/award/NIHR131339

Contact information

Type(s)
Principal Investigator

Contact name
Dr Camilla Rosan

ORCID ID
https://orcid.org/0000-0002-0132-0618

Contact details
Anna Freud Centre
Kantor Centre of Excellence
4-8 Rodney Street
London
United Kingdom
N1 9JH
+44 (0)20 7794 2313
Camilla.rosan@annafreud.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303294

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50730, IRAS 303294, NIHR131339

Study information

Scientific Title
The COSI study: a multi-site randomised controlled trial (RCT) to explore the clinical and cost-effectiveness of the Circle of Security Intervention for mothers in perinatal mental health services

Acronym
COSI

Study objectives
Primary hypotheses:
As compared to participants receiving treatment as usual, participants receiving the 10-session Circle of Security – Parenting (COS-P) group intervention will show lower levels of maternal

mental health symptoms as measured by an average Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) score over the 3, 7, and 12-month follow up assessments. If an effect is found, the following are hypothesised to be mediators for the relationship between COS-P and lower levels of maternal mental health symptoms: maternal sensitivity (as measured by the National Institute of Child Health and Human Development [NICHD] Sensitivity Scales), emotion regulation (as measured by the Difficulties in Emotion Regulation Scale; DERS), and life changes (e.g., the start of social care for the family) and relationship status (as measured by the demographic questionnaire and Client Service Receipt Inventory [CSRI]).

Secondary hypotheses:
As compared to participants receiving Treatment as Usual, participants receiving the Circle of Security – Parenting group intervention will show the following changes in an average score over the 3, 7, and 12-month follow-ups:
1. Higher levels of emotional regulation skills, as measured by DERS
2. Lower levels of bonding difficulties, as measured by Postnatal Bonding Questionnaire (PBQ)
3. Lower levels of developmental problems for the child, as measured by Ages & Stages Questionnaires, Third Edition (ASQ-3)
4. Lower levels of emotional-social developmental problems for the child, as measured by Ages & Stages Questionnaires: Social-Emotional (ASQ-SE)
5. Higher levels of maternal parenting sensitivity, as measured by the NICHD Sensitivity Scales
6. Higher rates of secure attachments in the children, as measured by the Strange Situation at the 12-month follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2021, Surrey REC (Health Research Authority, 3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8144; surrey.rec@hra.nhs.uk), REC ref: 21/LO/0723

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Perinatal mental health

Interventions

This study is a multi-centre randomised controlled trial, in which members of the study team that conduct outcome assessments with participants will be blind to participant allocation and women are randomised to either:
1. COS-P plus Treatment as Usual (TAU) in perinatal mental health services (PMHS) – the 'intervention' is delivered in groups size 4-6.
2. TAU in a PMHS – the 'control'. Treatment in a PMHS is defined by a national service specification. Women will be recruited to the trial at a ratio of 2:1 (one participant in the control group for every two participants in the intervention group). The trial sites within the study will be community PMHS in nine NHS Trusts across England.

Participant recruitment
There will be two groups of participants involved in this study: women accessing PMHS (secondary care mental health services), and the NHS staff members working at these services. This section will address both of these participant groups separately:

PMHS participants:
Participants will be recruited from PMHS at nine trial sites across England. Trial recruitment will take place in 8 x 4-week recruitment blocks that will be equally spaced across the 24-month recruitment period. During these recruitment blocks, PMHS staff will approach women about the trial during standard screening meetings. PMHS staff will refer potential participants to the research team if eligible and if prospective participants have provided verbal consent to be contacted by a member of the research team to discuss the trial further. The research team will invite eligible participants to participate in the full study, provide information regarding the trial and obtain informed written consent. Participants will be randomly allocated to either the intervention or control arm of the study.

NHS staff members:
NHS staff members will be recruited to the study via their service, either by nomination or putting themselves forward. They will receive training and support to deliver the COS-P groups within the trial. At 3-months follow-up, staff members participating in the trial and their clinical supervisors will be invited by research staff at the University of Huddersfield to join a focus group regarding their experiences of COS-P. Informed consent will be obtained digitally prior to the beginning of the focus group.

PMHS participants:
Screening:
Participants will be asked to complete two screening measures during their routine screening appointment at their trial site: Clinical Outcomes in Routine Evaluation – 10 (CORE-10) and Postpartum Bonding Questionnaire (PBQ). Women that score 1.1 or more as their average score on the CORE-10 plus 12 or more on the general factor of the PBQ will be given basic information about the study and asked to provide verbal consent to be contacted by a member of the research team. A member of the research team will follow up with these women and invite them to participate in the full study. Informed consent will be obtained during the initial assessment visit.

Baseline:
Within a maximum of 4 weeks of receiving consent, participants will be contacted by a member of the research team for an initial assessment visit (baseline). We anticipate that this initial assessment will take approximately two hours in total, yet this time is inclusive of time taken for

participants to complete various scales online without the presence of a Research Assistant (unless requested). Participants will complete questionnaires online regarding their self-report psychological distress; emotion regulation; perceived social support; mother-infant bond and infant development as well as overall health and demographic information. Participants will also be invited to an assessment visit with a Research Assistant to participate in an observational measure of maternal sensitivity. Assessment visits can be conducted virtually or in-person dependent on participant preference and current COVID-19 restrictions.

Intervention:
Participants in the intervention arm of the trial will receive the Circle of Security – Parenting (COS-P) intervention. This is a series of 10 sessions, delivered weekly across a 10-week period, that will each last between 90-120 minutes. Each group will consist of 4-6 parents and will be predominantly delivered virtually by a trained and supervised NHS health professional working in specialist community PMHS. Wherever possible, the first session will be delivered in a face-to-face format and the remaining sessions will be delivered remotely, although where possible, PMHS are encouraged to run at least one additional session in a face-to-face format. Each session involves viewing and discussing a series of clips of mother-infant interactions and reflections from previous COS-P participants regarding their own parenting from COS-P. The topics in the 10-session series centre around concepts of attachment; responding to children's affective states; reflecting on caregiving struggles and noticing "mean", "weak" and "gone" parenting (terms associated with the COS-P intervention). All participants in the trial will continue to receive treatment as usual during this time.

Follow-up:
At 3, 7 and 12 months after baseline, all participants in both arms of the trial will be invited to complete the outcome measures collected at baseline (excluding demographic information). At 3 months, women in the intervention arm will also complete a short experience questionnaire developed for the trial to explore facilitators and barriers to taking part in COS-P and ascertaining interest in being involved in a follow-up interview. A selection of women from the intervention arm will be invited to take part in an additional interview about their experiences of COS-P. Wherever possible, the data collection visit will take place remotely online. Participant interviews will be conducted in-person (at the participant's home or on NHS premises) or remotely (by telephone or video call), according to participant preference and in line with COVID restrictions at the time.

At 12 months, all participants in both arms of the trial will complete the Strange Situation Procedure, which is a 40-minute observational task between mother and infant to assess attachment security. The Strange Situation will be completed in a lab and so participants will need to travel to this location to complete this task.

NHS Staff Members:
At the 3-month follow-up, staff members participating in the trial will be invited to take part in a focus group regarding their experiences of COS-P. The focus group will be audio/audio-visually recorded and we anticipate the focus group to last a maximum of 2 hours.

Intervention Type
Behavioural

Primary outcome measure
Maternal mental health symptoms measured using CORE-OM at baseline, 3 months, 7 months and 12 months follow up

Secondary outcome measures
1. Mother-infant relationship difficulties measured by the Postpartum Bonding Questionnaire (PBQ) at baseline, 3, 7, and 12 month follow up
2. Maternal emotion regulation ability measured by the DERS at baseline, 3, 7, and 12 month follow up
3. Global infant development in communication, motor and cognitive areas measured by the Ages and Stages Questionnaire-3 (ASQ-3) at baseline, 3, 7, and 12 month follow up
4. Infant development in social and emotional behaviours measured by the Socio-Emotional (ASQ-SE) at baseline, 3, 7, and 12 month follow up
5. Observed maternal sensitivity assessed by coding of video recordings of mother-child interactions in accordance to the National Institute of Child Health and Human Development (NICHD scales) at baseline, 3, 7, and 12 month follow up
6. Child attachment security assessed by coding of video recordings of the Strange Situation Procedure (SSP) at 12 months follow up
7. Mother-child co-regulation of emotion measured with heart rate monitors worn during the SSP which are used for State Space Grids coding at 12 months follow up
8. Quality of life used for economic evaluation measured by the EuroQol- 5 Dimension (EQ-5D-5L) at baseline, 3, 7, and 12 month follow up
9. Health service usage, accommodation and living situation, income, employment and benefits measured using the Client Service Receipt Inventory (CSRI) at baseline, 3, 7, and 12 month follow up
10. Maternal maltreatment history measured by Childhood Trauma Questionnaire-Short Form (CTQ-SF) at baseline
11. Adverse events and serious adverse events (e.g., eye strain from online measures, start of social care involvement for the family) reported via a short questionnaire at 3, 7 and 12 months follow up

Overall study start date
01/03/2021

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Women and other birthing parents who:
1. Are accessing a community perinatal mental health services (PMHS) from one of the 9 recruiting sites
2. Have a child aged 0-12 months with no severe illness or developmental disorder
3. Score 1.1 or more as their average score on the CORE-10 or 1 or more as their average score on the CORE-OM
4. Score 12 or more on the general factor of the Postnatal Bonding Questionnaire (PBQ) or 26 or more on their total PBQ score
5. Are aged at least 18 years and are willing and able to give informed consent
6. Are able to attend groups without being under the influence of substances

NHS staff members who:
1. Are currently working in one of the PMHS involved in the trial

Participant type(s)

Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 369; UK Sample Size: 369

Key exclusion criteria
Women and other birthing parents who:
1. Do not meet the inclusion criteria
2. Do not have a minimum of conversational English
3. Have received COS-P previously
4. Are experiencing active psychosis

NHS staff:
1. NHS staff members who do not meet the inclusion criteria

Date of first enrolment
04/01/2022

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Prescot
United Kingdom
L34 1PJ

Study participating centre

Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
United Kingdom
NN15 7PW

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Trust Headquarters Redesmere
The Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1BQ

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Sponsor information

Organisation
Anna Freud Centre

Sponsor details
12 Maresfield Gardens
London
England
United Kingdom
NW3 5SU
+44 (0)20 7794 2313
info@annafreud.org

Sponsor type
Hospital/treatment centre

Website
http://www.annafreud.org/

ROR
https://ror.org/0497xq319

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131339

Results and Publications

Publication and dissemination plan
Publications and dissemination activities will include:
1. NIHR report
2. Final report for Health Research Authority within a year of the end of the study
3. Presentations at national and international conferences to audiences of health professionals, policymakers and researchers relevant to the field of public mental health, perinatal and infant mental health, maternity care, and psychological practice
4. Publishing open-access articles in high-impact peer-reviewed journals, as well as less-academic practitioner journals with high readerships
5. Writing policy briefings and reports, engaging the What Works Centres, and promoting through the All-Party Parliamentary Group on 1001 critical days
6. Providing continuous updates and presentations through local and national NHS England Perinatal Mental Health Strategic Clinical Network meetings
7. Working with the AFNCCF's communication team to develop an online presence on social media
8. Providing research summaries in newsletters and on websites e.g. through the Maternal Mental Health Alliance, Early Years Foundation.
9. Working with the Expert by Experience panel to present findings on support forums, parent events, and through high profile service user blogs and social media platforms
10. At the end of the study, participants will be able to request a copy of the results of the study from the investigator at that site. A summary of results will also be provided through other formats including animation, study newsletters, podcasts, and social media blogs

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available as de-identified data upon request from Peter Fonagy and Camilla Rosan (peter.fonagy@annafreud.org/camila.rosan@annafreud.org), beginning 12 months and ending 5 years after the primary publication and pre-planned secondary analysis following approval of a methodologically sound proposal and a signed data-sharing agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol		14/03	15/03		

article		/2023	/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article	interparental conflict between families who are, and are not, experiencing complex or severe mental health difficulties	30/06/2025	02/07/2025	Yes	No