

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

<b>Submission date</b> 13/01/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/02/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 20/10/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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](mailto:cosistudy@annafreud.org)

## Contact information

Type(s)

Principal investigator

**Contact name**

Dr Camilla Rosan

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

303294

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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 controlled trial

#### **Primary study design**

Interventional

#### **Study type(s)**

Treatment

#### **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(s)**

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

### **Key secondary outcome(s)**

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

**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)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

### 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

### 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](mailto:peter.fonagy@annafreud.org)/[camila.rosan@annafreud.org](mailto: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?
<a href="#">Results article</a>	interparental conflict between families who are, and are not, experiencing complex or severe mental health difficulties	30/06/2025	02/07/2025	Yes	No
<a href="#">Results</a>	Primary results	07/10	20/10		

<a href="#">article</a>		/2025	/2025	Yes	No
<a href="#">Protocol</a>		14/03	15/03	Yes	No
<a href="#">article</a>		/2023	/2023		
<a href="#">HRA</a>			28/06	No	No
<a href="#">research</a>			/2023		
<a href="#">summary</a>					
<a href="#">Study</a>	Study website	11/11	11/11	No	Yes
<a href="#">website</a>		/2025	/2025		