Clinical effectiveness of the Circle of Security-Parenting group intervention for birthing parents in perinatal mental health services in England (COSI): a pragmatic, multicentre, assessor-masked, randomised controlled trial

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Summary

Background Perinatal mental health difficulties are common and, if untreated, are associated with long-term adverse child outcomes. Substantial evidence gaps exist in group-based and parent–infant interventions for perinatal mental health difficulties. Circle of Security-Parenting (COS-P) groups have shown preliminary efficacy, although previous studies were methodologically weak or not specific to relevant populations. This study aimed to evaluate whether the hybrid delivery of COS-P plus treatment-as-usual reduces psychopathology in birthing parents accessing National Health Service community perinatal mental health services, compared with treatment-as-usual alone.

Methods The study was a pragmatic, multicentre, parallel-arm, assessor-masked, randomised controlled trial, with an internal pilot. Participants were recruited from ten geographically spread National Health Service (NHS) Trusts across England, including in Cheshire, Merseyside, North and South Yorkshire, Cumbria, Northamptonshire, Devon, Sussex, and Hampshire. Sites were eligible if they had a specialist community perinatal mental health service and had clinical equipoise to delivering COS-P. Participants were eligible for inclusion if they were aged 18 years or older; receiving care from the participating community perinatal mental health service sites between January, 2021, and October, 2023; had clinical-level psychopathology (average Clinical Outcomes in Routine Evaluation–Outcome Measure [CORE–OM] ≥1·1); bonding difficulties (total Postpartum Bonding Questionnaire ≥12); and were the birthing parent of a child aged younger than 1 year. Participants currently experiencing active psychosis were excluded. Participants were randomly assigned (2:1) to COS-P plus treatment-as-usual or treatment-as-usual alone. Randomisation was stratified by recruitment site and cohort, with random allocation lists generated in advance. Investigators and assessors were masked. COS-P is an attachment-informed parenting group delivered in ten 90-min sessions, predominantly online. The primary outcome was psychopathology, assessed by the average CORE–OM score across all follow-up timepoints of 3 months, 7 months, and 12 months post-baseline. Analyses followed the intention-to-treat principle and sensitivity analyses were done using multiple imputation to account for missing data. People with lived experience were involved in the design, delivery, and dissemination of the trial. This study is registered as an International Standard Randomised Controlled Trial, ISRCTN18308962, and was completed in January, 2025.

Findings Between Jan 4, 2022, and Oct 26, 2023, 3171 individuals were screened for eligibility, 2785 were ineligible, and 371 were randomly assigned to a group (248 to the COS-P plus treatment-as-usual group and 123 to the treatment-as-usual group. All participants were assigned female at birth and were the birthing parent to the index child. 332 (89%) participants identified as women (including trans woman), five (1%) identified as non-binary, one (<1%) in another way, three (1%) preferred not to say, and 30 (8%) had missing gender identity data. The mean age of participants was 30·8 years (SD 5·4; range 19–44); 329 (89%) were of White ethnicity. The adjusted mean difference in psychopathology scores, averaged across the 3-month, 7-month, and 12-month follow-up points, was −1·41 (95% CI −5·11 to 2·28; p=0·45), indicating neither clinical nor statistical significance. No significant differences were identified in secondary outcomes. Commonly reported adverse events included increases in mental health difficulties or symptoms, affecting 16 participants (4%); self-harm or concerns about self-harm, affecting 11 (3%) participants; and eye strain following screen use for study activities, affecting 11 (3%) participants. Serious adverse events were reported by eight (2%) participants.

Interpretation COS-P plus treatment-as-usual did not demonstrate greater clinical effectiveness compared with treatment-as-usual alone when delivered in NHS community perinatal mental health services. Therefore, COS-P should not be recommended for inclusion in routine community perinatal mental health services care, as it does not provide any additional clinical benefit when added to the current treatment-as-usual available in improving parental psychopathology, parenting, or infant outcomes.

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Introduction

Mental health difficulties that develop, persist, or worsen during pregnancy and the first postnatal year are collectively termed perinatal mental health difficulties. Perinatal mental health difficulties are prevalent and can affect up to 27% of birthing parents (typically mothers) in high-income countries.[1,2] These difficulties are associated with notable adverse outcomes for birthing parents, infants, families, and society more broadly.[2,3] An economic analysis based on UK data estimated the cost of untreated perinatal mental health difficulties at £8·1 billion per birth cohort, with 72% of this cost being attributable to long-term child morbidity.[4] Although the relationship between perinatal mental health difficulties and adverse child developmental outcomes is multifaceted, existing research strongly implicates compromised parent–infant relationship quality as a key mediating factor when a birthing parent experiences mental health difficulties.[3,5]

Internationally, statutory service approaches to identifying and managing perinatal mental health difficulties vary considerably. In England, substantial government investment exceeding £500 million since 2016 has facilitated the development of comprehensive, multidisciplinary community perinatal mental health services across the country.[6,7] These services target approximately 10% of birthing parents experiencing the most severe and complex perinatal mental health difficulties, aiming to provide timely access to evidence-based interventions. However, current evidence regarding psychological interventions during the perinatal period remains mixed.[8,9] The most recent UK National Institute for Health and Care Excellence (NICE) guidelines for antenatal and postnatal mental health highlight several important clinical research gaps.[10] Specifically, there is a lack of robust evidence regarding interventions that: (1) are transdiagnostic, addressing multiple perinatal mental health difficulties simultaneously; (2) target both perinatal psychopathology symptoms and parent–infant

Research in context

Evidence before this study

The evidence reviewed before undertaking this trial was identified by systematically searching the electronic databases PubMed, PsycINFO, MEDLINE, Embase, and Cochrane Central, alongside screening reference lists from relevant journal articles and books. Searches were conducted from database inception up to Dec 31, 2021, using the search terms: "Circle of Security", "COS-P", "perinatal mental health", "parent-infant intervention", "bonding", "attachment", and related synonyms. Studies were included irrespective of publication language. Selection criteria encompassed studies evaluating Circle of Security-Parenting (COS-P) or comparable parent–infant group interventions within clinical or community settings targeting mental health or bonding outcomes. The existing literature identified indicates that COS-P has high acceptability with both parents and interveners and was considered to be a clinically helpful group approach for parents of children of various ages across several risk groups. Previous research reported improvements in parental psychopathology and parent–child relationship quality. However, these research studies were found to be of poor quality, demonstrating small sample sizes, reliance on self-report measures, and inadequate randomisation methods. Furthermore, there has never been a research trial in England or in a perinatal mental health service where birthing parents with severe and complex mental health difficulties are treated. No appropriate meta-analysis was feasible due to methodological heterogeneity.

Added value of this study

This study is the first robust, multicentre, randomised controlled trial evaluating the clinical effectiveness of COS-P specifically within National Health Service (NHS) community perinatal mental health services (ie, those providing specialist care to birthing parents, typically mothers, with moderate to severe or complex mental health difficulties). Its rigorous design, including a clearly defined population, masked outcome assessments, and long-term follow-up, directly addresses previously identified methodological shortcomings. The trial's findings substantially enhance understanding of COS-P within routine clinical practice in community perinatal mental health services, demonstrating no added benefit over standard care alone.

Implications of all the available evidence

The combined existing evidence and results from this trial suggest that COS-P does not confer additional clinical, relational, or child benefits compared with treatment-as-usual within NHS community perinatal mental health services. Consequently, COS-P, in the format tested here, should not be adopted into routine practice within these services. Importantly, findings of the cost-effectiveness and qualitative analyses will be published elsewhere, and these will include essential insights into parents' and practitioners' mixed experiences with the group; possible gains in other areas; and important considerations for delivering remote, group interventions in the context of complex mental health difficulties in the perinatal period. Future research should prioritise investigating alternative evidence-based interventions capable of effectively addressing perinatal psychopathology and parent–infant bonding difficulties within the context of community perinatal mental health difficulties.

relationship quality; and (3) can be effectively delivered in group settings. The present trial addresses these identified gaps; the rationale for targeting each will be discussed further.

Birthing parents entering perinatal mental health services frequently present with complex, comorbid mental health issues,[11] complicating clinical decisions about appropriate interventions. Current NICE guidance primarily recommends disorder-specific interventions,[10] such as high-intensity cognitive behavioural therapy for moderate-to-severe depression. However, accumulating evidence supports transdiagnostic approaches, proposing that various mental health issues represent different manifestations of a limited number of core underlying features.[12] One such core transdiagnostic feature consistently identified in research is emotion regulation difficulties.[13,14] This highlights the importance of developing and testing interventions targeting emotion regulation, particularly relevant during the postnatal period due to its substantial effect on both the birthing parent and infant.

A key developmental task during infancy involves acquiring skills for emotion regulation.[15] Parents play a crucial role in facilitating this skill, thereby supporting the brain development of the infant.[15] Birthing parents experiencing emotion regulation difficulties might struggle with reflective functioning—understanding their infant's thoughts and feelings—and are consequently at increased risk of bonding difficulties.[16] Research is therefore essential to evaluate interventions addressing transdiagnostic constructs such as emotion regulation, especially within community perinatal mental health services. To date, very few studies have examined treatments targeting both perinatal mental health difficulties and bonding issues, specifically for parents of infants younger than 12 months, who experience complex and severe perinatal mental health difficulties and are accessing community perinatal mental health services. Currently, within community perinatal mental health services, perinatal mental health difficulties and bonding issues are assessed and treated separately by distinct professional teams.[5] A unified intervention addressing both concerns could offer greater cost-effectiveness and improved acceptability for both parents and practitioners.

Group interventions might be particularly beneficial for new parents experiencing mental health difficulties. The supportive and validating environment created by shared group experiences can reduce feelings of isolation, facilitate open sharing of mental health and parenting challenges, and promote mutual learning.[17,18]

Circle of Security-Parenting (COS-P)[19] is a transdiagnostic, group-based psychological intervention showing preliminary efficacy in non-perinatal populations,[9] and it has already been adopted by psychologists within National Health Service (NHS) community perinatal mental health services. A 2016 meta-analysis identified ten eligible studies evaluating COS-P programmes; however, few were randomised controlled trials and none specifically targeted perinatal populations or parents with mental health difficulties.[9] Since that review, four additional trials conducted in Europe, Australia, and the USA have evaluated the effectiveness of COS-P.[20–23] Yet, these studies remain limited by small sample sizes, insufficient statistical power, and a lack of specificity to severe perinatal mental health difficulties. Additionally, the need for an England-specific evaluation was especially relevant, as international trials demonstrating intervention superiority often show diminished relative effectiveness when compared with NHS treatment-as-usual, which typically offers more comprehensive care compared with North American or European service provisions (eg, Family Nurse Partnership).[24,25]

Given the potential applicability of COS-P, the Circle of Security Intervention (COSI) trial aimed to evaluate the clinical effectiveness of COS-P for birthing parents experiencing moderate to severe perinatal mental health difficulties and bonding difficulties. Specifically, the trial examined whether COS-P plus treatment-as-usual was more effective than treatment-as-usual alone within NHS community perinatal mental health services in improving parental mental health, parent–infant bonding, parental emotion regulation, child development outcomes, parenting sensitivity, and child attachment.

Methods

Study design

The study was a pragmatic, multicentre, randomised, assessor-masked, parallel-arm controlled trial conducted across ten recruitment sites in England, following a published protocol.[26] Sites were eligible if they had a National Health Service (NHS) specialist community perinatal mental health service and had clinical equipoise to delivering COS-P. They were geographically spread across England, including in Cheshire, Merseyside, North and West Yorkshire, Cumbria, Northamptonshire, Devon, Sussex, and Hampshire to represent a mix of urban and rural locations, and include areas of high socio-economic deprivation. The specific sites involved in the study were: Cheshire and Wirral Partnership NHS Trust; Mersey Care NHS Foundation Trust (two sites in this Trust); Cumbria, Northumberland, Tyne & Wear NHS Trust; South West Yorkshire Partnership NHS Trust; Tees, Esk and Wear Valleys NHS Foundation Trust; Northamptonshire Healthcare NHS Foundation Trust; Sussex Partnership NHS Foundation Trust; Devon Partnership NHS Trust; Southern Health NHS Foundation Trust.

The trial is described as pragmatic to reflect its delivery in a real-life NHS setting, including mirroring the screening tools and outcome measures, the number, type and seniority of practitioners involved in psychological group delivery, and the mode of this delivery (ie, predominantly online) that are used in current

perinatal mental health services. This was to ensure the highest levels of generalisability of the results to contemporary clinical practice and reduce the translational gap of research to clinical implementation.

The trial included a nested internal pilot over the first 12 months of recruitment and delivery; assessing treatment fidelity, adherence, recruitment, retention, and the duration between randomisation and initiation of treatment. Progress on these metrics was monitored against pre-specified criteria by the funder, the trial steering committee, and the data monitoring and ethics committee and was linked to continuation of the trial following the 12-month pilot.[26] Favourable results across all internal pilot criteria led to the continuation of the trial and all data collected during the internal pilot were included in the final dataset. Recruitment sites were selected based on geographical diversity, research-naivety, and absence of existing COS-P provision to ensure clinical equipoise.

A racially and socially diverse group of people with lived experience of a range of perinatal mental health difficulties were involved in the study, led by the study's co-applicant and lived experience lead. They were convened in preparation for the grant application to co-develop all aspects of the study's research question, design, and delivery. This group was expanded to 12 members when funding was confirmed, delivering an embedded lived experience workstream, which included training at recruitment sites on trauma-informed inclusive recruitment, training research staff on person-centred, engagement skills for data collection visits, becoming peer researchers involved in qualitative data analysis, and co-producing and co-delivering all aspects of dissemination. Additionally, independent experts by experience were part of both the trial steering committee and the data monitoring and ethics committee. Ethical approval was obtained from NHS Surrey Research Ethics Committee (reference: 21/LO/0723). The statistical analysis plan is available in the appendix (pp 37–59). This study is a registered International Standard Randomised Controlled Trial, number ISRCTN18308962 (registered on Feb 18, 2022), and was completed in February, 2025.

See Online for appendix

Participants

Participants were birthing parents (typically mothers, but the trial was inclusive of all gender identities) receiving care from the participating community perinatal mental health service sites between January, 2021 and October, 2023. Eligibility criteria included clinical-level psychopathology, defined by an average Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE–OM) score of 1·1 or more,[27] and bonding difficulties indicated by a total Postpartum Bonding Questionnaire (PBQ) score of 12 or more.[28] Participants also had to be aged 18 years or older, capable of providing written informed consent, able to engage in the intervention sessions without being under the influence of substances, and parenting an infant younger than 1 year without severe illness or developmental disorders. An exclusion criterion of not having conversational levels of English was used initially, but this was later removed to widen access. To the best knowledge of the study team, no exclusions were made based on this criterion prior to it being removed. Individuals previously receiving COS-P or currently experiencing active psychosis were excluded. All participants provided written consent for study procedures. All special category data (eg, participant gender) were self-reported. The gender data collected were: woman (including trans woman); non-binary; identify in another way; and prefer not to say.

Participants received a £10 voucher for each completed assessment timepoint. Participant self-reported ethnicity data were: White (British, Irish, Other White Background); Black (Black British, Black Caribbean, Black African, Other Black Background); Mixed (White and Black Caribbean, White and Black African, White and Asian, Other Mixed Background); Asian (Asian British, Indian, Pakistani, Bangladeshi, Other Asian Background); Chinese or Other Ethnic Group; and Do not wish to specify. These data were then compared with ethnicity profiles of the wider group of parents under the care of each recruitment site. Both the trial steering committee and the data monitoring ethics committee monitored whether the inclusion of ethnic groups at each site reflected the local population. Additionally, experts with experience in the study team developed and delivered inclusive recruitment training to all recruitment sites and translations or interpreters were arranged and were paid when needed.

Randomisation and masking

Eligible, consenting participants were randomly assigned to either COS-P plus treatment-as-usual or treatment-as-usual alone using a web-based randomisation system integrated into REDCap, the study's electronic data capture system, with a 2:1 allocation ratio favouring COS-P plus treatment-as-usual. Randomisation was conducted in site-specific recruitment cohorts of up to nine individuals to facilitate timely group allocations and prevent study-induced treatment delays. Stratification was by recruitment site (ten sites in total) and cohort (up to seven participants per site), targeting COS-P groups of approximately between four and six participants. Randomisation lists for each stratum were generated in advance by the study statistician. Randomisation was executed by unmasked central study team members who subsequently informed intervention delivery staff and participants via email. Intervention providers, participants, site principal investigators, qualitative data collectors, statisticians, and those performing randomisation or fidelity assessments were not masked. However, data assessors (ie, those collecting quantitative data from participants) and observational coders (ie, those involved in coding the sensitivity scales and the strange situation

recordings) were masked to allocation. If unmasking occurred, follow-up assessments were reassigned to alternative masked data collectors.

Procedures

The COS-P intervention integrates psychoeducational, cognitive–behavioural, and psychodynamic theories and techniques. It consists of eight modules covering key topics, including foundational attachment principles; responding effectively to children's emotional states; addressing parenting difficulties; and recognising hostile, helpless, or neglectful caregiving behaviours. The contents of the ten weekly, 90-min intervention sessions were delivered by trained interveners as stated in the appendix (p 2). Parents were presented with video examples of parent–child interactions demonstrating the key topics and reflections from previous COS-P participants who have implemented intervention learnings. These materials were used to facilitate discussion about parents' own attachment and parenting experiences.

COS-P interveners were eligible if they were a psychological practitioner (clinical psychologist, cognitive behavioural therapist, or parent–infant psychotherapist) and had previous experience in facilitating psychological group work or parent–infant interventions. They were all newly trained in the COS-P intervention specifically for this trial, receiving the standard 24-h online training across the course of a week, supplemented by a 1·5-h workshop focused on perinatal adaptations, plus 20 h of coaching supervision, all provided by COS International, the intervention developers. Intervention fidelity was independently assessed by two raters using video recordings of group sessions. Two sessions from each recorded COS-P group were randomly selected for fidelity rating, with detailed findings reported separately. The intervention developers were not involved in study design, data collection, data analysis, data interpretation, or writing of the manuscript.

Delivery of the intervention, for cases in which it was possible, involved two face-to-face sessions (the initial session and one additional session) conducted in group rooms at the NHS Trust or at accessible local venues (such as libraries or a Family Hub), with remaining sessions delivered online via video call. Interpreters attended sessions as needed to support participants. Adherence was monitored through participant attendance at each COS-P session.

Treatment-as-usual at each recruitment site remained unchanged by participants' involvement in the trial and was consistent across study groups. Treatment-as-usual followed a national service specification, providing multidisciplinary, needs-based care, including mental health treatments (eg, psychiatric reviews, pharmacological interventions, or care coordination), parent–infant relational interventions (eg, baby massage), psychological therapies (eg, cognitive behavioural therapy), and psychosocial support (eg, occupational health services or peer support).[29] Reported treatment-as-usual procedures are detailed in the appendix (p 3).

Participants completed baseline questionnaires via an online form following consent and before randomisation, with alternative completion options (ie, telephone or paper forms) provided as necessary. Additionally, participants were offered an online video call to complete a recorded play task. Follow-up assessments occurred at 3 months, 7 months, and 12 months post-baseline. At the 12-month follow-up, participants and their infants were invited to attend a local in-person session to undertake the Strange Situation Procedure (SSP; a procedure to

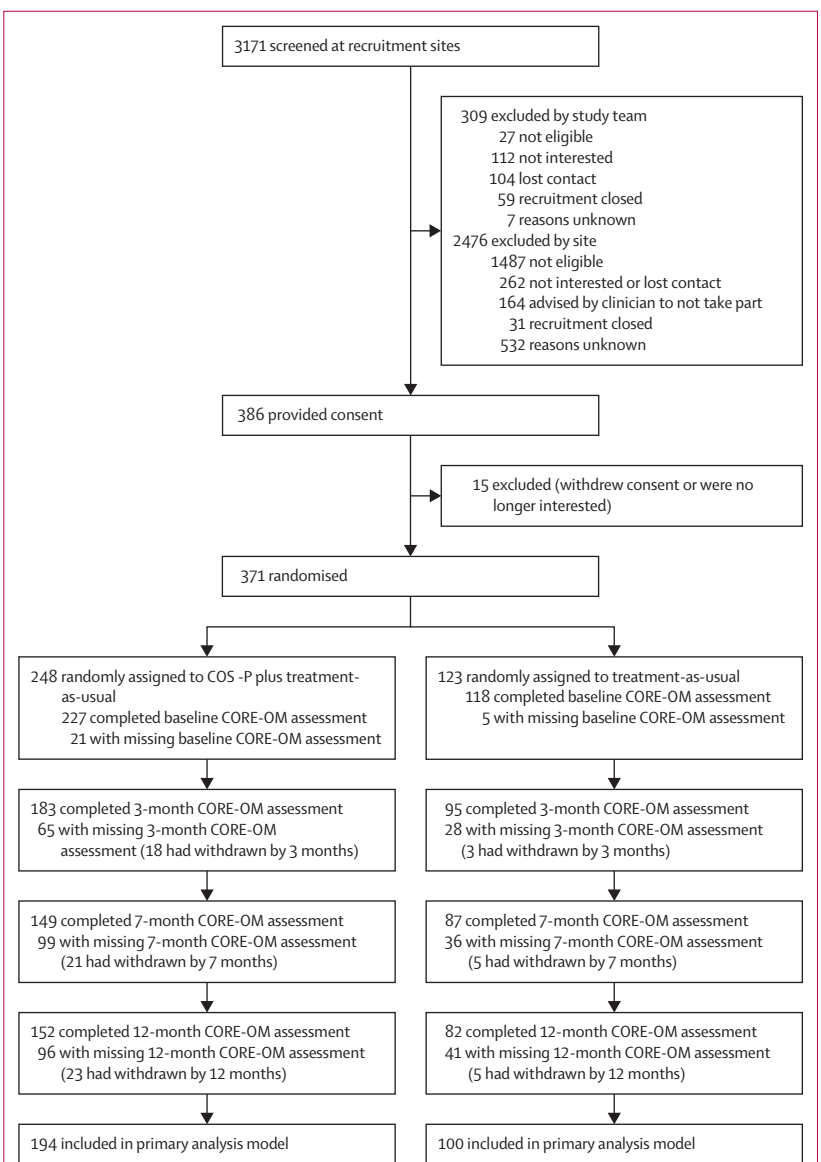

Figure 1: **Trial profile**
CORE–OM=Clinical Outcomes in Routine Evaluation–Outcome Measure. COS-P=Circle of Security-Parenting.

	COS-P plus treatment-as-usual (n=248)	Treatment-as-usual (n=123)	Total (N=371)
Age	30·7 (5·4)	31·1 (5·6)	30·8 (5·4)
Ethnicity			
White (British, Irish, Other White Background)	216 (87%)	113 (92%)	329 (89%)
Black or Black British	1 (<1%)	0	1 (<1%)
Mixed	6 (2%)	3 (2%)	9 (2%)
Asian or Asian British	2 (1%)	1 (1%)	3 (1%)
Other Ethnic Group	1 (<1%)	1 (1%)	2 (1%)
Missing	22 (9%)	5 (4%)	27 (7%)
Current living situation			
Living alone	21 (8%)	10 (8%)	31 (8%)
Living with partner	188 (76%)	96 (78%)	284 (77%)
Living with other relatives	13 (5%)	11 (9%)	24 (6%)
Living with others	4 (2%)	1 (1%)	5 (1%)
Prefer not to say	1 (<1%)	0	1 (<1%)
Missing	21 (8%)	5 (4%)	26 (7%)
Highest completed level of education			
Primary or less	4 (2%)	0	4 (1%)
Secondary	17 (7%)	9 (7%)	26 (7%)
Tertiary or further education	75 (30%)	36 (29%)	111 (30%)
Higher education	127 (51%)	70 (57%)	197 (53%)
Other general education	2 (1%)	2 (2%)	4 (1%)
Prefer not to say	1 (<1%)	0	1 (<1%)
Missing	22 (9%)	6 (5%)	28 (8%)
Been pregnant before			
Yes	148 (60%)	78 (63%)	226 (61%)
No	82 (33%)	39 (32%)	121 (33%)
Prefer not to say	3 (1%)	2 (2%)	5 (1%)
Missing	15 (6%)	4 (3%)	19 (5%)
Previous pregnancy loss			
Yes	109 (44%)	58 (47%)	167 (45%)
No	37 (15%)	17 (14%)	54 (15%)
Prefer not to say	2 (1%)	3 (2%)	5 (1%)
Missing	100 (40%)	45 (37%)	145 (39%)
Mental health difficulties leading to community perinatal mental health services referral			
Depression	204 (82%)	97 (79%)	301 (81%)
Anxiety	199 (80%)	101 (82%)	300 (81%)
Trauma	101 (41%)	42 (34%)	143 (39%)
Personality difficulties	36 (15%)	20 (16%)	56 (15%)
Obsessive compulsive disorder	32 (13%)	11 (9%)	43 (12%)
Psychosis	10 (4%)	2 (2%)	12 (3%)
Bipolar disorder	10 (4%)	5 (4%)	15 (4%)
Other	13 (5%)	7 (6%)	20 (5%)
Child age (in weeks)	21·4 (12·5)	21·5 (12·9)	21·4 (12·6)
Sex of child			
Female	113 (46%)	62 (50%)	175 (47%)
Male	121 (49%)	56 (46%)	177 (48%)
Missing	14 (6%)	5 (4%)	19 (5%)
Total CORE–OM score at baseline	63·7 (20·2)	62·7 (19·8)	63·3 (20)

Data are n (%) or mean (SD). CORE–OM=Clinical Outcomes in Routine Evaluation–Outcome Measure. COS-P=Circle of Security-Parenting.

Table 1: **Baseline characteristics**

assess an infant's attachment style by observing their reactions to a series of play tasks alongside separations and reunions with their parent and a stranger).[30]

Outcomes

Outcome measures were captured directly via the REDCap Electronic Data Capture system, completed online by participants using unique access codes or administered by the research team during direct communication with participants. The primary outcome was measured using the Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE–OM),[27] with the primary estimand corresponding to the difference in CORE–OM score between treatment groups averaged across all three follow-up timepoints (3 months, 7 months, and 12 months post-baseline). The average CORE–OM score was chosen as the primary metric as this was judged to represent a sustained and meaningful period over which to assess benefit, and the use of repeated analysis offers efficiencies allowing the trial to take advantage from a smaller sample size than a single endpoint analysis.[31] Secondary outcomes included the PBQ;[28] Difficulties in Emotion Regulation Scale (DERS);[32] Ages and Stages Questionnaire-3 (ASQ-3) and the socio-emotional version (ASQ-SE);[33,34] National Institute of Child Health and Human Development (NICHD) Sensitivity Scales to assess parental sensitivity to infants' needs in a timely and appropriate way;[35] SSP to assess infant attachment categorically as insecure and secure attachment and various attachment subtypes;[30] EQ-5D-5L to assess quality of life;[36] and Client Service Receipt Inventory to quantify service use.[37] For the CORE–OM, PBQ, and DERS, symptom severity and pathology increase with higher scores. For the NICHD scales, ASQ-3, ASQ-SE, and EQ-5D-5L symptom severity and pathology decreases with higher scores.

Each assessment timepoint included an adverse events questionnaire capturing physical (eg, eye strain) and social events (eg, deterioration of mental health, increased service involvement) and provided an opportunity for open-text reporting. Safety events spontaneously reported by participants or community perinatal mental health services staff were also recorded.

Choice of primary measure

The CORE–OM is a 34-item measure of psychological distress (appendix pp 4–5).[27,38] This measure of psychological distress was developed based on service user experience and the practice-based evidence movement, and it was strongly endorsed by our Expert by Experience panel, who met on four separate occasions in preparation for the funding application. A minimum clinically important difference of 5 was agreed and supported by this panel and was used as a basis on which to calculate the sample size. The CORE–OM is one of the most widely used outcome measures in secondary care mental health services in the UK and Europe, and as

such is familiar to service managers as well as local and national commissioners. Any detected changes on this scale will be highly compelling to key decision-making stakeholders, particularly in England, where the trial took place. The CORE–OM takes 5 min to complete, has high acceptability with a range of populations, and is translated into more than 30 languages. Its copyright is held by the Core System Trust (CST), which states that it is free to reproduce if not amended, use is not for profit, and copyright to the CST is acknowledged.

Statistical analysis

Descriptive analyses were presented using means and SDs to summarise continuous variables and proportions for categorical variables. Treatment effects estimated from models were reported as means with SEs and 95% CIs, with p values in instances where hypotheses were formally tested. The trial target sample size was set at 369 participants (246 in the intervention group and 123 in the treatment-as-usual group). A total of 312 observations were required to achieve 90% power at a 5% two-sided significance level, aiming to detect a clinically meaningful 5-point difference in the improvement of total CORE–OM scores between groups.[39] The sample size was increased by 10% to account for potential missing data and by an additional 5% to allow for clustering effects due to group sessions within the intervention group, resulting in the final sample size of 369.

The primary outcome was analysed using mixed-effects linear regression models incorporating fixed effects for intervention group, baseline CORE–OM score, infant sex, infant age, first-born status, and, due to their relatively low number, recruitment site. Random effects were included for individual participants and, within the intervention group, session cohorts, the latter to allow for possible variations in intervention delivery relating to the peer group and session facilitator. Within the treatment-as-usual group, each participant was treated as a singleton cohort. Model fit was assessed using residual plots. The primary analytical model assumed a consistent intervention effect across follow-up assessments at 3 months, 7 months, and 12 months, whereas a secondary model included interaction terms between timepoints and the intervention to explore potential temporal variations. The primary analysis included only non-missing observations. Sensitivity analyses were also done using: (1) multiple imputation to account for missing data; and (2) a Bayesian framework. Primary and secondary outcomes were analysed according to the intention-to-treat principle, including all randomly assigned participants who completed at least one follow-up assessment. A prespecified supplementary analysis using the Complier Average Causal Effect framework was also carried out to estimate the effect of the intervention in those who complied with the session programme. Safety analyses incorporated data from all randomly assigned participants. Statistical analyses were done with Stata (version 18.0; appendix pp 6–36). Detailed analytic plans are documented in the trial protocol[26] and the full statistical analysis plan in the appendix (pp 37–59).

The independent data monitoring and ethics committee provided oversight of participant safety throughout the trial. Meetings occurred regularly and were timed to precede trial steering committee meetings to ensure effective reporting and oversight.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

The COSI trial commenced recruitment on Jan 4, 2022, with the first participant randomly assigned on Feb 4, 2022. Of 3171 individuals screened, 2785 were ineligible,

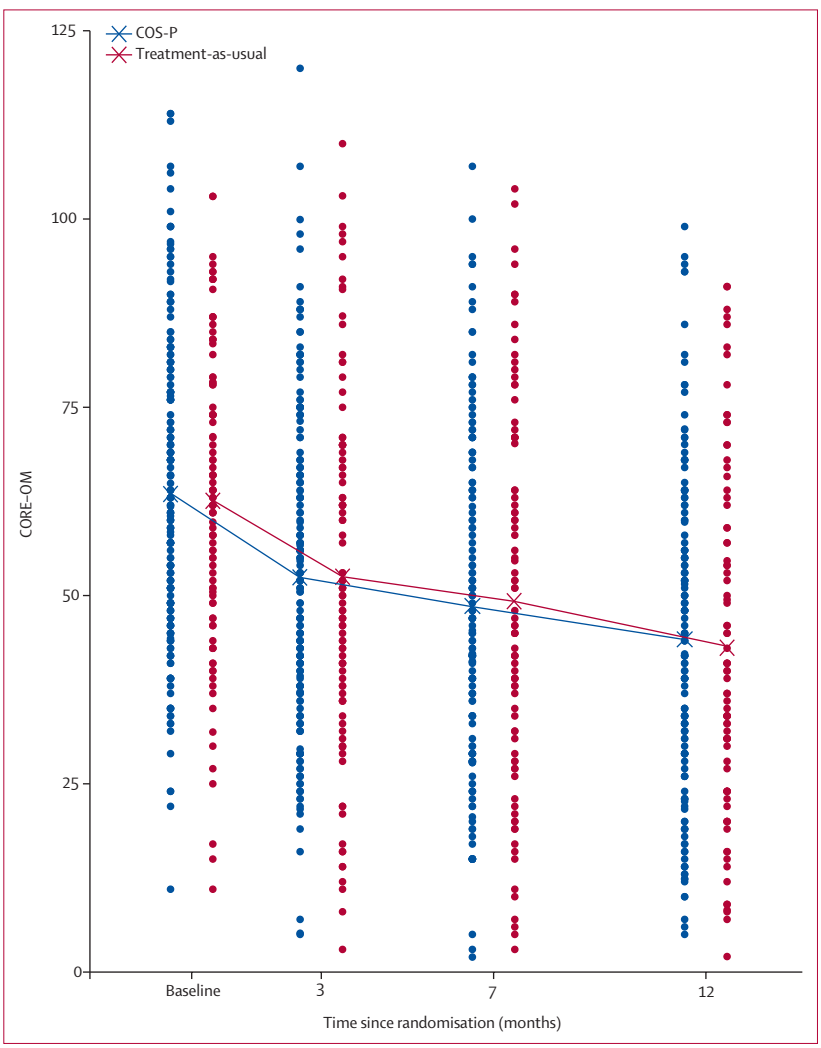

Figure 2: **Distribution of CORE-OM scores and mean score trend over time, by treatment group**
CORE–OM=Clinical Outcomes in Routine Evaluation–Outcome Measure. COS-P=Circle of Security-Parenting.

	Estimated mean difference	SE	95% CI	p value
CORE–OM				
Constant treatment effect model	–1·41	1·89	–5·11 to 2·28	0·45
Time-varying treatment effect model, 3 months	–1·34	2·28	–5·80 to 3·12	0·56
Time-varying treatment effect model, 7 months	–1·85	2·39	–6·54 to 2·84	0·44
Time-varying treatment effect model, 12 months	–1·22	2·42	–5·96 to 3·52	0·61
Time-varying treatment effect model, average across timepoints	–1·46	1·86	–5·10 to 2·18	0·43
PBQ				
3 months	–0·06	1·42	–2·83 to 2·72	0·97
7 months	–0·35	1·48	–3·24 to 2·55	0·82
12 months	1·43	1·52	–1·55 to 4·40	0·35
DERS				
3 months	–2·42	1·74	–5·83 to 0·98	0·16
7 months	–2·07	1·83	–5·64 to 1·51	0·26
12 months	1·26	1·87	–2·40 to 4·93	0·50
ASQ-3				
3 months	9·83	7·60	–5·07 to 24·72	0·20
7 months	–1·12	8·02	–16·82 to 14·59	0·89
12 months	–9·33	9·24	–27·45 to 8·78	0·31
ASQ-SE				
3 months	–1·95	2·77	–7·37 to 3·47	0·48
7 months	3·98	2·86	–1·62 to 9·57	0·16
12 months	2·89	3·11	–3·21 to 8·99	0·35
NICHD-3-Composite Scale				
3 months	0·24	0·24	–0·23 to 0·71	0·32
7 months	0·52	0·24	0·04 to 1·00	0·033
12 months	0·26	0·26	–0·24 to 0·76	0·31
NICHD-Dyadic Mutuality Subscale				
3 months	0·03	0·11	–0·19 to 0·24	0·80
7 months	0·09	0·11	–0·13 to 0·31	0·42
12 months	0·22	0·12	–0·01 to 0·45	0·061
SSP				
12 months	3·70	3·39	0·62 to 22·25	0·15

Lower scores are more favourable for PBQ, DERS, ASQ-SE, and CORE-OM; favourable negative effect estimate favours COS-P. Higher scores are more favourable for ASQ3 and NICHD sensitivity scores (composite and dyadic); positive effect estimate favours COS-P. Models include fixed effects for intervention group, site, baseline CORE-OM, infant sex, infant age, infant first born status, and random effects for participant and intervention session cohort. CORE–OM=Clinical Outcomes in Routine Evaluation–Outcome Measure. COS-P=Circle of Security-Parenting. PBQ=Postpartum Bonding Questionnaire. DERS=Difficulties in Emotion Regulation Scale. ASQ-3=Ages and Stages Questionnaire-3. ASQ-SE=Ages and Stages Questionnaire-socio-emotional version. NICHD=National Institute of Child Health and Human Development. SSP=Strange Situation Procedure.

Table 2: **Mixed effects logistic regression for primary and secondary outcomes**

and although 386 consented, 15 withdrew before randomisation. By Oct 26, 2023, a total of 371 participants had been randomly assigned to COS-P plus treatment-as-usual (n=248) or treatment-as-usual alone (n=123; figure 1). All participants were assigned female at birth, and were the birthing parent to the index child. 332 (89%) participants identified as women (including trans woman), five (1%) identified as non-binary, one (<1%) in another way, three (1%) preferred not to say, and 30 (8%) had missing gender identity data. The mean age across both groups was 30·8 years (SD 5·4; range 19–44), and 329 (89%) participants reported their ethnicity as White; nine (2%) were from a mixed ethnic background; three (1%) were Asian; one (<1%) was Black; two (1%) were from another ethnic background, and the remaining 27 (7%) had missing data on ethnicity (table 1). When split up per site, these proportions were representative of the population under the care of each recruitment site. Baseline assessments were completed by 345 (93%) of 371 participants, with follow-up completion rates of 278 (75%) at 3 months, 236 (64%) at 7 months, and 234 (63%) at 12 months. Participants attended a mean of 6·4 (median, 8) out of ten COS-P sessions. In total, 51 COS-P groups were delivered by 21 interveners.

Distributions and mean scores for the primary outcome measure across treatment groups and timepoints are presented in figure 2. Baseline CORE–OM scores were similar between groups (COS-P plus treatment-as-usual, mean 63·7 [SD 20·2]; treatment-as-usual, mean 62·7 [19·8]; table 1). By the 12-month follow-up, mean CORE–OM scores improved in both groups from moderate to mild severity (COS-P plus treatment-as-usual, mean 44·2 [SD 21]; treatment-as-usual, mean 43·3 [23]). The primary analysis indicated an adjusted mean difference averaged across the 3-month, 7-month, and 12-month follow-up points of –1·41 (95% CI –5·11 to 2·28; p=0·45; table 2), with no clinical or statistical significance between groups. Adjusted mean differences at individual timepoints were similarly no different between groups.

Secondary outcomes also showed no significant differences across groups for most measures across follow-up timepoints (table 2). For post-partum bonding, at 12 months, mean PBQ scores were comparable (COS-P plus treatment-as-usual, mean 20·2 [SD 13·3]; treatment-as-usual, mean 19·5 [13·4]), with an adjusted mean difference favouring treatment-as-usual of 1·43 (95% CI –1·55 to 4·40, p=0·35; table 2). Differences at 3 months and 7 months were minor and non-significant. For both groups, mean PBQ scores decreased from above the threshold for potential bonding disorders at baseline (≥26) to below this threshold at 12 months.[28]

Emotion regulation, measured by DERS scores, also showed no significant differences between groups. Adjusted differences slightly favoured COS-P plus treatment-as-usual at 3 months (–2·42 [95% CI –5·83 to 0·98]; p=0·16) and 7 months (–2·07 [–5·64 to 1·51]; p=0·26) but favoured treatment-as-usual at 12 months (1·26 [–2·40 to 4·93]; p=0·50; table 2). Child development outcomes assessed using ASQ-3, ASQ-SE, SSP, and NICHD Sensitivity Scales showed no meaningful differences between groups. However, the NICHD Sensitivity Composite Scale indicated a significant advantage for COS-P plus treatment-as-usual at 7 months (adjusted difference 0·52 [95% CI 0·04 to 1·00]; p=0·033), although significance was not

	Events			Participants		
	COS-P plus treatment-as-usual (n=99)	Treatment-as-usual (n=35)	Total (N=134)	COS-P plus treatment-as-usual (n=248)	Treatment-as-usual (n=123)	Total (N=371)
Severity						
Mild	67 (68%)	20 (57%)	87 (65%)	33 (13%)	13 (11%)	46 (12%)
Moderate	22 (22%)	8 (23%)	30 (22%)	13 (5%)	4 (3%)	17 (5%)
Severe	10 (10%)	7 (20%)	17 (13%)	6 (2%)	4 (3%)	10 (3%)
Serious						
Yes	9 (9%)	3 (9%)	12 (9%)	7 (3%)	1 (1%)	8 (2%)
No	90 (91%)	32 (91%)	122 (91%)	45 (18%)	20 (16%)	65 (18%)
Category						
Self-harm or concerns about self-harm	16 (16%)	3 (9%)	19 (14%)	9 (4%)	2 (2%)	11 (3%)
An increase in mental health difficulties or symptoms: outpatient	23 (23%)	0	23 (17%)	16 (6%)	0	16 (4%)
An increase in mental health difficulties or symptoms: inpatient	9 (9%)	6 (17%)	15 (11%)	5 (2%)	2 (2%)	7 (2%)
Social care involvement	6 (6%)	10 (29%)	16 (12%)	3 (1%)	7 (6%)	10 (3%)
Eye strain following screen use for study activities	17 (17%)	4 (11%)	21 (16%)	8 (3%)	3 (2%)	11 (3%)
Musculoskeletal or back pain following screen use for study activities	11 (11%)	7 (20%)	18 (13%)	2 (1%)	3 (2%)	5 (1%)
Headaches following screen use for study activities	14 (14%)	5 (14%)	19 (14%)	6 (2%)	4 (3%)	10 (3%)
Accidents involving the participant's infant during online data collection visits	1 (1%)	0	1 (1%)	1 (<1%)	0	1 (<1%)
Other	2 (2%)	0	2 (1%)	2 (1%)	0	2 (1%)
Related to study procedures						
Yes	53 (54%)	11 (31%)	64 (48%)	28 (11%)	6 (5%)	34 (9%)
No	43 (43%)	24 (69%)	67 (50%)	23 (9%)	15 (12%)	38 (10%)
Missing	3 (3%)	0	3 (2%)	1 (<1%)	0	1 (<1%)

Data are n (%). COS-P=Circle of Security-Parenting.

Table 3: **Adverse events by treatment group**

observed at other follow-up points (table 2). Mean scores for DERS, ASQ-3, ASQ-SE, and NICHD Sensitivity scales were similar across groups and timepoints. Notably, DERS scores remained above the clinical threshold (≥88)[40] at all timepoints for both groups.

A total of 134 adverse events were reported among 73 participants, representing 20% of participants (table 3). Of these, 12 events were classified as serious adverse events, with one of these determined to be related to the trial intervention. Serious adverse events were reported by eight (2%) participants. Seven serious adverse events, including one related to the intervention, were classed as increases in mental health difficulties requiring an inpatient stay; two were classed as self-harm or thoughts thereof; one was the involvement of social care; one was an unrelated surgical procedure; and one an instance of fever in the child. The most frequently reported non-serious adverse events included pre-specified categories that were of particular interest (ie, eye strain, headaches, and musculoskeletal pain associated with computer use during assessments, exacerbation of mental health symptoms, and increased involvement with social care services). In the COS-P plus treatment-as-usual group there were 99 adverse events reported by 52 (21%) participants, including nine serious adverse events reported by seven (3%) participants, compared with 35 adverse events reported by 21 (17%) participants in the treatment-as-usual group, including three serious adverse events reported by one (1%) participant. The most common adverse events in terms of the number of participants affected were increases in mental health difficulties and symptoms: 16 (4%); self-harm or concerns about self-harm: 11 (3%); and eye strain following screen use for study activities: 11 (3%). The most common serious adverse events were increases in mental health difficulties or symptoms in seven (2%) participants and self-harm or concerns about self-harm in two (1%) participants.

The complier average causal effect, estimating intervention effectiveness among adherent participants (defined as attending at least six of ten COS-P sessions), indicated an adjusted mean difference of –1·82 (95% CI –6·22 to 2·59), averaged across 3 months, 7 months, and 12 months. This difference favoured COS-P plus treatment-as-usual but was not significant (p=0·42). When adherence criteria were more stringent (attending all ten sessions), the estimated adjusted mean difference reached –6·49, a clinically meaningful magnitude, but it

remained non-significant (95% CI −22·22 to 9·43; p=0·42). Details of the complier average causal effect analysis are in the appendix (p 14).

Sensitivity analyses using multiple imputation methods to account for missing data, under a missing-at-random assumption, did not significantly alter the primary outcome findings. Exploratory subgroup analyses (pre-specified and post-hoc) assessed potential heterogeneity of intervention effects on the primary outcome. Although these analyses were exploratory and not powered for subgroup detection, significant effects were found in two subgroups: participants with a history of personality difficulties (n=44; adjusted mean difference −17·07 [95% CI −26·50 to −7·64]; p=0·0004) and participants with a history of bipolar disorder (n=12; adjusted mean difference −30·68 [−49·03 to −12·34]; p=0·0010). Detailed subgroup analysis results are provided in the appendix (p 16).

Discussion

The results of this study showed that when the COS-P plus treatment-as-usual intervention was delivered within NHS community perinatal mental health services in a predominantly online format, it was not significantly more effective than treatment-as-usual alone in reducing perinatal mental health difficulties over a 12-month follow-up period. Similarly, no significant effects were found for secondary outcomes related to parent–infant bonding, parental emotion regulation, child developmental outcomes, parenting sensitivity, or child attachment when comparing COS-P plus treatment-as-usual with treatment-as-usual alone. Notably, clinically meaningful improvements over time were observed in self-reported psychopathology (CORE–OM) and parent–infant bonding (PBQ) within both groups of the trial. These findings indicate the overall beneficial effects of standard care within NHS community perinatal mental health services, irrespective of the COS-P intervention.

Our findings for the primary outcome of parental psychopathology align with literature released since the start of the COSI trial, examining COS-P specifically in perinatal contexts. Two recent studies in Denmark also found no significant benefits of COS-P on parental mental health, parenting behaviours, or child outcomes in antenatal (N=78)[41] and postnatal samples (N=297).[42] Conversely, one smaller study involving 23 inpatient mothers with postnatal depression living in Hong Kong reported some beneficial effects on mental health and reflective functioning, although child outcomes and parenting behaviours remained unchanged.[43]

The p values for secondary outcomes shown in table 2 should be interpreted with caution, as we have made no adjustment for multiple testing. Nevertheless, the absence of significant effects from COS-P on secondary outcomes in the current study further contributes to the mixed findings reported across the existing research. A 2021 systematic review highlighted that the standard 8-week COS-P programme lacks robust evidence supporting improvements in attachment security, child behaviour, or emotion regulation among families facing multiple adversities, including mental health challenges.[44] However, the same review indicated potential benefits on parental stress, self-efficacy, and parenting skills, which were not measured in this current trial. Poulsen and colleagues[45] suggest that an intensive 20-week COS-P format might be required for high-risk parent and infant dyads who might benefit from more individualised approaches, such as video-feedback interventions. However, the clinical and cost-effectiveness of such intensive interventions specifically for families with perinatal mental health difficulties remains uncertain and warrants further exploration.

Consistent with the anticipated profile of a sample with moderate-to-severe or complex mental health needs, high levels of clinically relevant emotion regulation difficulties were evident at baseline. Contrary to expectations, these difficulties remained largely unchanged throughout the 12-month follow-up, despite participants receiving care from specialist community perinatal mental health services. This finding highlights the persistent nature of emotion regulation challenges and underscores the need for further investigation into more targeted or intensive therapeutic approaches for addressing these challenges within the context of perinatal mental health difficulties.

COS-P was originally developed by Circle of Security-International to target children from 4 months to 6 years; most previous published studies evaluating the programme were not perinatal-specific, and the children included were of preschool age.[9] As Circle of Security-International were invited to train perinatal practitioners in COS-P in the UK (and beyond), a specific perinatally adapted manual was developed by the programme's developers, which is what was tested in this trial. The mixed and non-significant outcomes of COS-P in the perinatal period found in this study and the aforementioned Danish studies[41,42] might indicate that the timing of intervention delivery relative to childbirth and infant developmental stage could significantly influence its effectiveness. Importantly, the acceptability findings of the COSI trial (Darwin Z, unpublished) indicated that some of the concepts taught in COS-P might be relatively hard to apply to newborn infants as opposed to school-aged children, such as recognising the child's socioemotional cues in live interactions. The absence of convincing beneficial effects of COS-P in the perinatal period might likewise be due to the fact that much of this period revolves around feeding, sleeping, and adjusting to changes in family life, which can be affected by mental health difficulties or bonding difficulties, leaving little time for the reflection and change required by parent–child programmes such as COS-P. This might be particularly challenging for those who are not parenting older children simultaneously, potentially making some

of the material about child development and child emotional needs at older ages too abstract.

The significant improvements observed among participants with histories of personality difficulties and bipolar disorder suggest that COS-P might be beneficial for specific clinical subgroups. Identifying and targeting such subgroups could facilitate more personalised or precision-based approaches within community perinatal mental health services, enabling better resource allocation and potentially enhancing clinical outcomes for those with distinct mental health profiles. Future research should investigate subgroup characteristics to inform tailored intervention strategies in perinatal mental health care. The persistent high levels of emotion regulation difficulties observed throughout the trial highlight a crucial therapeutic gap that was not adequately addressed by COS-P. Given these findings, it might be necessary to incorporate additional therapeutic components specifically designed to target emotion regulation, such as adaptations of dialectical behaviour therapy, mentalisation-based treatment, or other evidence-based interventions tailored explicitly for the perinatal context. Future studies should evaluate whether integrating these specialised treatments could provide more effective support for parents experiencing complex perinatal mental health difficulties. The limited evidence we observed in relation to attachment is of note, in view of the fact that COSI was originally designed as an attachment-focused intervention, aiming to promote sensitive caregiving and support parents to be a more effective secure base in relation to their child's needs for exploration and comfort. Our results are consistent with Cassidy and colleagues' study,[22] which also did not detect a benefit of COS-P for attachment security in a sample of socioeconomically disadvantaged mothers in the USA.

This study has several limitations that should be considered when interpreting the findings. First, the primarily online delivery format of COS-P might have influenced participant engagement and intervention fidelity, potentially limiting its effectiveness. The delivery format was driven by the pragmatic approach of the trial and the real-life delivery constraints of NHS perinatal mental health services, which deliver most of their psychological group programmes virtually (as is their onward strategy). Parents experiencing complex mental health needs, possibly in addition to psychosocial difficulties, might need more frequent in-person support than that offered in the trial's intervention, although research on this topic is lacking. However, we cannot assume that online delivery necessarily dilutes the effect of an intervention since a recent meta-analysis found that online parenting programmes demonstrated comparable effectiveness to face-to-face programmes in a range of outcomes, including parenting knowledge and behaviours, parental self-efficacy and stress, parent–child interaction quality, child behaviour problems, and parenting stress.[46] Importantly, the acceptability and engagement of group programmes might be positively affected by an online format for those unable to leave their house due to factors such as childcare and medical needs or anxiety around travelling, particularly with a baby. Second, adherence and attendance varied considerably, reflecting practical barriers such as severity of mental health symptoms, caregiving demands, and logistical challenges; lower adherence could have diluted observed intervention effects.[47] Thirdly, the study's inclusion criteria targeted birthing parents with moderate-to-severe perinatal mental health difficulties and bonding concerns, thus the findings might not generalise to populations with milder difficulties or different clinical presentations. Despite rigorous methodological design, outcomes relied heavily on self-reported measures, which are subject to potential bias,[48] and missing data remained an issue despite sensitivity analyses addressing this problem. Finally, although this was a pragmatic trial mimicking the real-life delivery of community perinatal mental health services, the acceptability findings (Darwin Z, unpublished) illustrated that the trial requirement to start COS-P delivery within 4 weeks from randomisation meant that there was little flexibility in the timing of COS-P relative to participants' other care and mental health status, or for practitioners to consider or influence group membership. Additionally, there was variance in whether participants were familiar with the facilitator; had addressed previous trauma through other therapies before starting COS-P; and whether support was offered before, alongside, and after the group intervention, which could have meant that some were better able to benefit from the intervention than others. Future research could address these limitations through incorporating more extensive face-to-face interaction, exploring optimal timing for intervention delivery, and further examining targeted, personalised therapeutic strategies.

In conclusion, the hybrid delivery of COS-P plus treatment-as-usual did not demonstrate greater clinical effectiveness compared with treatment-as-usual alone in NHS community perinatal mental health services. Therefore, the hybrid delivery of COS-P should not be recommended for inclusion in routine community perinatal mental health services care, as it does not provide any additional clinical benefit when added to the current treatment-as-usual available in improving parental psychopathology, parenting, or infant outcomes.

Contributors

CR, PFo, VC, SP, PFe, DB, EP, ZD, and LR conceptualised the study and acquired funding. VC and EW were responsible for the methodology and led the data analysis. HH did the study investigations such as recruitment and data collection. KA-vD, HH, and LR led on developing the participant-facing study resources and participant recruitment. VC, EW, KA-vD, LR, and HH created the tables and figures in the manuscript. KA-vD and DB were responsible for project administration. EW, CR, KA-vD, and PFo wrote the original draft of the manuscript. VC, SP, PFe, DB, EP, ZD, LR, JD, EW, and HH reviewed and edited the

manuscript. Trial data were accessed and verified by the chief investigators (CR and PFo) and all authors had full access to all the data in the study and accept responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

The anonymised quantitative datasets (eg, questionnaire data but not video recordings) generated during the current study will be available as de-identified data upon request from Peter Fonagy and Camilla Rosan (p.fonagy@ucl.ac.uk; camilla.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. The transcripts from the interviews and focus groups will not be made available because, although the names of places and people will have been removed, the combination of contextual information given by participants could compromise their anonymity if the transcripts were available in their entirety.

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