PROTOCOL TITLE:

Feasibility of a psychoeducational group intervention to improve parental reflective functioning and bonding in prenatal depression

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Sponsor/s

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CONTENTS

Study Synopsis

Full Title	Feasibility of a psychoeducational group intervention to improve parental reflective functioning and bonding in prenatal depression
Short Title/Acronym	A prenatal bonding intervention for pregnant women with depression
Protocol Version number and Date	Version 1 05/05/2022
Study Duration	12 months
Study Design	Feasibility trial
Sponsor/Co-sponsors	South London & Maudsley NHS Foundation Trust and Institute of Psychiatry, Psychology & Neuroscience
Chief Investigator	Dr Fiona Challacombe
IRAS number	302132
Primary objective	To assess the acceptability and feasibility of a single-session psychoeducational group intervention, Baby CHAT, in women experiencing depression during pregnancy
Secondary objective (s)	To provide preliminary evidence for Baby CHAT's effect on parental reflective functioning and prenatal bonding. To further develop the intervention from participants' feedback and running of the group.
Number of Subject	N=24
Main Inclusion Criteria	Women aged ≥18 years who are pregnant, between 20- and 34-weeks' gestation, and currently experiencing depressive symptoms as identified by the Edinburgh Postnatal Depression Scale (EPDS). All participants must be resident in or accessing services in a London borough served by South London & Maudsley NHS Foundation Trust.
Statistical Methodology and Analysis	Quantitative feasibility and acceptability outcomes will be summarised descriptively. Qualitative data from the open-ended questions on the feedback form will be analysed using content analysis. Effect sizes for primary and secondary outcome measures will be calculated using Cohen's *d*.

Glossary of Terms and Abbreviations

AE	Adverse Event
AR	Adverse Reaction
ASR	Annual Safety Report
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
EC	European Commission
GAfREC	Governance Arrangements for NHS Research Ethics Committees
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trial Number
MA	Marketing Authorisation
MS	Member State
Main REC	Main Research Ethics Committee
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
Subject	An individual who takes part in a clinical trial
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee

1. Introduction

Depression is a significant public health problem in the United Kingdom and perinatal depression represents a particular concern. Prenatal or antenatal depression, that is, depression during pregnancy, is estimated to affect approximately 10-15% of pregnant women (Gavin et al., 2005). Meanwhile there is evidence that prevalence of prenatal depression may be increasing in the UK (Pearson et al., 2018). Depressive symptoms during pregnancy often persist into the postpartum period, where there is evidence that depression has a detrimental effect on the early mother-infant interaction (Field, 2011). Mothers may feel less confident in their role as a parent and show less sensitivity to infants' needs and behaviour, which can substantially interfere with optimal child development. Maternal depression in pregnancy has been associated with a range of adverse emotional, behavioural and cognitive outcomes during childhood (Stein et al., 2014).

NICE guidelines for treating prenatal depression depend on the severity of difficulties and include psychological treatment for depression and/or antidepressant medication, or a period of watchful waiting. However, evidence from studies with postnatal depression suggests that reducing mothers' depressive symptoms is insufficient to also improve the mother-infant relationship and mitigate the impact on child development (Forman et al., 2007; Tsivos et al., 2015). It is therefore important to consider mechanisms for the association between maternal depression and the mother-infant interaction, and how these may be targeted in interventions.

Prenatal bonding, or maternal-foetal attachment, describes the emotional connection a woman develops with her foetus during pregnancy (Salisbury et al., 2003). Prenatal bonding has been shown to predict postnatal maternal involvement and can identify women who may have difficulties with the mother-child interaction after birth (Siddiqui and Hägglöf, 2000). McFarland and colleagues (2011) found an association between a clinical diagnosis of major depressive disorder during pregnancy and significantly lower levels of maternal-foetal attachment during the second and third trimesters, consistent with the clinical picture that depression is associated with social difficulties across a range of relationships. In a recent study in at-risk groups of women, prenatal depressive symptoms were again associated with poorer maternal-foetal bonding (Røhder et al., 2020). Taken together, the mother-infant relationship appears to play an important role in the widespread negative impacts of perinatal depression. Bonding between mother and foetus before birth could therefore be an important target for treatment.

During pregnancy, mothers usually create a mental representation of their baby as a growing person, with their own social and emotional characteristics. The ability of a person to notice and describe feelings, thoughts and intentions underlying one's own and others' behaviour is known as mentalisation (Fonagy et al., 1991), operationalised in research as reflective functioning (RF). Parental RF is particularly important during a child's early years, when children are entirely dependent on their caregiver to meet their needs. Developing RF during the prenatal period may therefore enable expectant mothers to prepare for parenthood. Research by Smaling and colleagues (2016) demonstrated that high prenatal RF predicted quality of the mother-child interaction and ameliorated some of the negative consequences of perinatal risk factors (including psychiatric disorders) on parent-child interactions.

Evidence from the non-perinatal population suggests that psychological disorders, including depression, can affect a person's capacity for RF (Katznelson, 2014; Luyton et al., 2012; Fischer-Kern et al., 2013). Studies have not consistently supported this relationship in maternal depression (e.g. Cordes et al., 2017). However, in a recent study in an Iranian community

sample (Khoshroo & Seyed Mousavi, 2021), maternal depression was found to be associated with poorer parental RF, as well as with greater internalising and externalising problems in the mothers' children. Moreover, children of mothers with lower RF exhibited more internalising and externalising problems than children of mothers with higher RF. Therefore, despite the limited research on depression and RF in the prenatal period, interventions aimed at developing RF in pregnant women with depression have the potential to will ameliorate some of the negative consequences of depression and low parental RF for both mother and child.

A variety of parenting interventions have been developed to promote prenatal bonding, postnatal attachment or RF. These include ultrasound scans (e.g. deJong-Pleij et al., 2013), psychoeducational sessions (e.g. Family Minds; Bammens, Adkins & Badger, 2015), and psychotherapy (e.g. the Mothers and Toddlers Programme; Suchman et al., 2012). Formats of these interventions have varied, including one-to-one sessions and groups. However, many existing interventions are conducted post-birth, are time-consuming for participants, or costly to facilitate.

Therefore, a novel intervention, 'Baby CHAT', has been designed as a single-session group antenatal intervention, targeting both prenatal bonding and RF. The group incorporates 4D ultrasound footage of foetuses at 32 and 36 weeks of gestation showing imitation of mouth movements when hearing specific sounds, which indicates that foetuses react to stimulation and are preparing to interact socially before birth (Reissland et al., 2016). The clear, baby-like movements and facial expressions seen in 4D ultrasounds could aid attachment (Campbell, 2006), and creating a meaningful narrative while viewing an ultrasound scan has been associated with good maternal-foetal bonding (Roberts, 2012). Baby CHAT aims to develop parents' personal narratives and feelings of closeness with the baby by encouraging them to think about the social experience of their unborn baby and to engage socially with their baby before birth.

There is promising early evidence that Baby CHAT is acceptable to participants and has the potential to improve prenatal bonding and RF in a non-clinical sample of expecting parents (Cox et al., 2020). Given these encouraging findings, the present study aims to examine the acceptability and feasibility of this intervention with a sample of pregnant women with depression, who are more likely to experience difficulties with bonding and RF. As Baby CHAT is a novel intervention, the study will also examine the feasibility of conducting research with Baby CHAT with this population.

Terminology

In the interests of brevity, the term 'pregnant women' will be used in the rest of this protocol to refer to all pregnant/birthing people, including women, non-binary people and transgender men, who will all be eligible to participate in this study.

2 Study Objectives and Design

2.1. Study Objectives

The primary objective of the study is as follows:

- To assess the acceptability and feasibility of a single-session psychoeducational group intervention, Baby CHAT, in women experiencing mild-to-moderate depression during pregnancy

Further, secondary objectives, are:

- To provide preliminary evidence for Baby CHAT's effect on parental RF and prenatal bonding in pregnant women with depression
- To further develop the intervention from participants' feedback and running of the group

The study's primary end point is as follows:

- The study will be completed once Baby CHAT has been run enough times for 24 participants to attend and the last participant has completed their outcome questionnaires 1 month after attending the final group

2.2 Study Design & Flowchart

Baby CHAT is a novel intervention and, to our knowledge, has never been trialled with pregnant women with depression. Therefore, a feasibility design is appropriate to explore whether Baby CHAT is acceptable to participants, if they experience the intervention as helpful, and to understand whether it is possible to recruit for and complete research on Baby CHAT with this group. Feasibility studies vary in scope but include assessing how practical it is to deliver the intervention, what the demand for the intervention is and how participants respond to it (Bowen et al., 2009). The findings of feasibility studies can then inform subsequent, larger-scale trials on the efficacy of the intervention.

A single-arm repeated measures mixed-methods design will be utilised to provide rich feedback on the acceptability and feasibility of Baby CHAT. The aims of the quantitative arm of the study will be to gather descriptive statistics on the feasibility of the intervention, including uptake and retention of participants and whether the intervention can feasibly be delivered during the given time frame. Effect sizes will also be calculated to inform sample size calculations for a larger-scale clinical trial in the future.

The qualitative arm of the study will gain participants' feedback on the content and impact of the intervention, including their opinions on use of the 4D scan footage, level of adaptation for low mood and any suggested improvements. This qualitative data will provide rich information about participant's experiences of Baby CHAT, that will inform the next stage of the intervention's development.

2.3 Study Flowchart

	Screening	Baseline	Intervention	Post-intervention	1-month follow-up
Written informed consent	X				
Demographics	X				
EPDS	X			X	X
MAAS		X		X	X
P-PRFQ		X		X	X
Baby CHAT intervention			X		
Feedback form				X	
Adverse events				X	

3. Sample Size, Statistics, Selection and Withdrawal of Subjects

Sample size

This study is concerned with generating descriptive statistics to assess the feasibility of the proposed methods, rather than establishing effectiveness or generalisability of the intervention. There has been disagreement in the literature on appropriate sample sizes for feasibility studies, but sample sizes between 24 and 50 have been recommended (Lancaster, Dodd & Williamson, 2004; Sim & Lewis, 2012; Julious, 2005). To further aid decision-making regarding an appropriate sample size for the current project, sample sizes of similar studies in the field were also reviewed. These included N=24 in the treatment arm for the intervention Nurture and Play (Salo et al., 2019), and N=25 for a feasibility trial of the Beating the Blues Before Birth intervention (Milgrom et al., 2015).

In qualitative studies, there is often less rigour in the choice and justification of the sample sizes used (Marshall et al., 2013). Qualitative research often concerns developing a depth of understanding, and therefore data saturation, that is, the point at which including more participants no longer contributes additional perspectives, is often suggested as a guide for ending recruitment (Glaser & Strauss, 1967). However, this provides little guidance for estimating sample sizes prior to data collection. Determination of appropriate sample sizes in advance will depend on the context and scientific paradigm of the research (Boddy, 2016). This study involves a brief qualitative component designed to generate a breadth of feedback on the intervention. Meanwhile, it is feasible to ask all participants to provide qualitative feedback, using the questionnaire following completion of the intervention.

Taken together, a sample size of N=24 is estimated as appropriate for both the quantitative and qualitative components of the study. This is expected to be achievable based on current recruitment rates in a similar study with women with prenatal depression (the DAWN trial; Trevillion et al., 2020) and given that in 2020, around 925 babies were born in Southwark, Lambeth and Lewisham each month (Office for National Statistics, 2020).

Participant selection

An opportunity sample of participants will be recruited through their clinician or self-referral. This study will recruit participants from South London and Maudsley NHS Foundation Trust (SLaM) who are receiving care within the primary care Improving Access to Psychological Therapies (IAPT) services and secondary care perinatal services in Lambeth, Southwark, Lewisham and Croydon. The student researcher will have no prior relationship with the participants. The research team will share information with clinicians about Baby CHAT and the study procedures, so that they have a good understanding of the study before they are asked to give their patients information about the research. Clinicians will provide eligible clients with a flyer (see Appendix 2 for flyer) and, if a client is interested, will ask for verbal consent for the student researcher to contact them by phone (just name and phone number provided at this stage). To enable self-referral, posters will be placed in the waiting areas of relevant services. Posters will also be placed in maternity scanning clinics at King's College Hospital and St Thomas' Hospital, for participants to self-refer. The study will also be advertised through carefully selected online groups, social media channels and the King's College London research participation email circular.

Once a potential participant has self-referred or consented to be contacted via their clinician, the student researcher will contact them to check eligibility, introduce the project, provide the information sheet and to answer any questions. Participants will have sufficient time to consider whether they consent to take part. Participants will be offered £20 in reimbursement for taking part in the study.

Inclusion criteria

Participants eligible to take part in the project will be women aged ≥18 years who are pregnant, between 20- and 34-weeks' gestation, and currently experiencing depressive symptoms as identified by the EPDS. Those scoring >13 will be eligible to take part in the study. Both first-time and experienced parents will be eligible to participate.

Given the study involves the participation of potentially vulnerable individuals, all participants must be resident in or accessing services in a London borough served by SLaM, in order to facilitate access to local mental health services if needed.

Exclusion criteria

Women will be excluded if they are experiencing severe depression or current severe co-morbid diagnoses (e.g. psychosis), if they endorse 'yes, quite often' or 'sometimes' on question ten of the EPDS (in the past 7 days, 'the thought of harming myself has occurred to me'), or if they are unable to complete informed consent and the questionnaires in English. Participants must be able to sufficiently understand the psychoeducational materials and group discussions during the intervention, so that all participants experience a 'high feedback', interactive intervention.

There will be clear signposting to NHS and third sector organisations (including the general practitioner, midwifery team, local psychological therapies service, and other online resources) for all included and excluded participants, given that women interested in the study will be experiencing subjective low mood and may not be accessing treatment.

Withdrawal of subjects

Participants have the right to withdraw from the study at any time for any reason. If participants drop out during the study their data will be included in the analysis, unless they also withdraw consent for this. No further data will be collected from them. Their pseudonymised data will be destroyed after a period of 5 years following completion of the study, consistent with Clinical Trials Regulations and in line with the rest of the data collected in this study. Efforts will be made to report reasons for withdrawal. Withdrawn participants will not be replaced**.** Withdrawn participants will receive signposting information to local mental health and other support services, as outlined above (see Exclusion criteria).

Statistics

The following quantitative feasibility and acceptability outcomes will be collected: rates of eligible participants, uptake and retention of participants, scores on the feedback form, rates of missing data, and scores on the fidelity checklist (to monitor intervention delivery). For the qualitative arm of the study, participants will complete the open-ended questions on the feedback form. Descriptive data on participant demographic characteristics will also be collected.

The quantitative feasibility and acceptability outcomes outlined above will be summarised descriptively. Qualitative data from the open-ended questions on the feedback form will be analysed using content analysis.

Although this study is exploratory due to the novelty of the intervention, within feasibility research it is appropriate to set a priori thresholds for the main feasibility and acceptability outcomes. Feasibility thresholds will be as follows: 30 or more potential participants express interest in the study (participant uptake); 20 or more participants attend Baby CHAT (participant retention); and at least 70% of participants complete the study measures (missing data). The acceptability of Baby CHAT will be assessed by the feedback form, which consists mostly of open-ended questions. These will be analysed qualitatively and therefore no specific acceptability thresholds will be set.

Effect sizes for primary and secondary outcome measures will be calculated using Cohen's d. These effect sizes will inform the sample size calculations of future larger-scale studies on Baby CHAT.

Items on the outcome questionnaires will be designated as mandatory on the online survey portal, Qualtrics, to minimise missing data. Participants will be contacted to attempt to complete any missing items from other forms. Therefore, no statistical imputation methods will be required to correct for missing data.

Any deviations from the original statistical analysis plan will be reported in a protocol amendment.

4. Study procedures

Informed consent procedure

All interested participants, whether they self-referred to the study or consented to be contacted via their clinician, will have an initial contact with the research team to ask any questions about the project. Participants will be sent a full Participant Information Sheet by email to read and consider. The information in the Participant Information Sheet and opportunity for further discussion with the research team will allow detailed explanation of the aims, methods, anticipated benefits and potential harms of the study, as well as the participants' right to refuse involvement in the study and to withdraw consent at any time. The research team will ensure adequate time for each participant to consider their consent to take part. Individuals who agree to take part will then be asked to complete and return a signed consent form. All participants will receive a copy of their signed consent form.

Potential participants who either do not meet the eligibility criteria or decide not to consent will be provided with information signposting them to appropriate sources of psychological support, as outlined in previous sections (see Section 3, Exclusion criteria).

Risks/burdens

Ethical approval will be sought from an NHS REC via the Health Research Authority. The sample will be recruited from a potentially vulnerable population of women with depression during pregnancy and therefore several steps will be taken to reduce risk of distress and harm.

Anticipated ethical implications include increasing participants' feelings of guilt about their current behaviours or behaviours during a previous pregnancy. Baby CHAT is a psycho-educational, rather than therapeutic, intervention which focuses on ways to develop women's feelings of bonding towards their unborn baby. However, it is possible that some participants could experience distressing thoughts and feelings during the group; for example, if they feel they are not bonding well with their baby, not engaging in attachment-promoting behaviours, or are engaging in risky health behaviours such as drinking alcohol or smoking. Negative thoughts are a symptom of depression and therefore this is more likely with this group when compared to the general population.

Full informed consent will be gained from each participant, including adequate description of the intervention and the opportunity to further discuss the potential for distress. The group facilitator will be sensitive to the difficulties experienced by pregnant women with low mood and present the group content with a validating, non-blaming approach. Ground rules will be set at the start of each group to encourage participants to engage in their preferred coping strategies if they experience any distress during the group. Limits of confidentiality will also be outlined at the start of the group i.e. the need to discuss information with a third party if there are risk concerns.

The facilitator will monitor participants' reactions, contributions and emotional state throughout the group. The clinician will facilitate a sensitive and validating environment if a participant experiences a low level of distress during the group. If required, the facilitator will sensitively raise any concerns about emotional wellbeing with the participant after the group in private and attempt to resolve this in collaboration with the participant. If appropriate, consent will be sought to inform their midwife of their distress. If a participant leaves the online meeting in distress, the facilitator will attempt to contact them after the group to debrief. A more senior member of the research team will be available for supervision during the times that Baby CHAT is running. See Appendix 3 for the distress pathway.

Participants will be able to contact the research team following the group for a debrief. All participants will be signposted to further information and support, including their general practitioner, midwife, local psychological therapies service, and other online resources. Information on participants' experiences of the intervention will be collected via the feedback form to support detection of adverse events.

If there is a potential safeguarding concern at any point during the study and the research team believes there may be imminent risk to the participant or another person, appropriate action will be taken (see Appendix 4 for the study safeguarding pathway). Safeguarding issues may arise during the main group, for example, if a participant mentions something concerning about themselves, their unborn baby or someone else. If this occurs, a facilitator will attempt to contact the participant after the group to gain further information and remind them of the limits of confidentiality. Risk concerns will be escalated to an appropriate member of the research team or the participant's clinical team if applicable. Some participants will already be under the care of a mental health team, while some pregnant women with a history of mental health problems may be well-known to their midwife and have more frequent contacts with the midwifery team throughout their pregnancy. If there is felt to be an imminent and serious risk to the participant or someone else, crisis or emergency services will be contacted.

Screening procedure

Following informed consent, the depression screening measure (the EPDS) will be conducted. Participants will be informed in a timely and sensitive manner whether they have met the criteria

to be included in the study. Participants who consent but do not score above the threshold on the screening questionnaire will be signposted to appropriate sources of support (as above, see Exclusion criteria).

Study schedule

Following inclusion in the study (i.e. having completed informed consent and scored over the screening threshold), participants will be asked to complete the baseline set of outcome questionnaires via Qualtrics (Time 1). Once completed, the participant will be booked into an upcoming session of the Baby CHAT group.

Participants will attend an online Baby CHAT group at a time that is convenient for them. Up to eight women will be invited to each group, to facilitate optimal group dynamics and engagement with the group content. See below for further details of the intervention.

After attending Baby CHAT, participants will be asked to complete the post-intervention outcome questionnaires and feedback form within 48 hours of the group (Time 2). One month later, participants will be contacted to complete the final follow-up questionnaires (Time 3).

Measures

The primary clinical outcome will be prenatal bonding as measured using the Maternal Antenatal Attachment Scale (MAAS). Secondary clinical outcomes of RF and depressive symptomology will be measured using the Prenatal Parental Reflective Functioning Questionnaire (P-PRFQ) and the Edinburgh Postnatal Depression Scale (EPDS). Feedback forms, containing both qualitative and quantitative components, will also be administered after participants have attended Baby CHAT in order to gather feedback on experience of the intervention (including group format, content and perceived usefulness).

Edinburgh Postnatal Depression Scale
The EPDS (Cox, Holden & Sagovsky, 1987) is a 10-item self-report measure used to identify depression in women during the perinatal period. The scale was initially developed to screen for postnatal depression but has also been validated for use in antenatal populations (Murray & Cox, 1990). Women are asked to rate on a 4-point scale how much they have experienced symptoms over the last week. Total scores are calculated, with higher scores indicating more severe symptoms, and a score of 13 or greater indicating likely depressive illness. The final item on the scale “the thought of harming myself has occurred to me” indicates the presence of thoughts of self-harm or suicide. The EPDS has been shown to have satisfactory sensitivity and specificity (Cox, Holden & Sagovsky, 1987; Gibson et al., 2009).

Maternal Antenatal Attachment Scale
The MAAS (Condon, 1993) is a self-report questionnaire for expectant mothers, designed to assess the maternal-foetal attachment during pregnancy. The scale consists of 19 items on a 5-point Likert scale assessing women’s attitudes, feelings and behaviours towards their foetus. Most items evaluate experiences over the last two weeks, as well as imagined feelings towards the baby when they are born. An overall attachment score is calculated, as well as two subscale scores for ‘quality of attachment’ and ‘time spent in attachment mode (or intensity of preoccupation)’, for example, time spent thinking about the baby. Higher scores indicate stronger maternal-foetal attachment. The MAAS has been shown to have good construct validity (Condon & Corkindale, 1997), internal consistency and split-half reliability (Condon, 1993).

Prenatal Parental Reflective Functioning Questionnaire
The P-PRFQ (Pajulo et al., 2015) is a 14-item self-report questionnaire assessing expectant parents' abilities to think of their foetus as a separate individual with a developing temperament, personality and needs. The scale can be used during the second and third trimester of pregnancy. The 14-item measure asks expectant parents to rate several statements on a 7-point Likert scale, with higher total scores indicating higher prenatal RF. The P-PRFQ has good construct validity and showed strong concurrent validity with an established interview of prenatal parental RF (Pajulo et al., 2015), and therefore shows promising use in both clinical and research settings as a brief, cost-effective measure of prenatal parental RF.

Baby CHAT Feedback Form
The feedback questionnaire (Appendix 5) was developed as part of the initial trial on Baby CHAT with the general population (Cox et al., 2020). The form has been adapted for the purpose of this study and contains eight items, consisting of eight open-ended questions, two of which additionally have closed question components. The feedback form aims to gather participants' views on their experience of the group in order to develop it for future use, including what they liked about Baby CHAT, how helpful they found the inclusion of the 4D scan footage and anything they felt could have improved the group.

A brief, follow-up feedback form was developed for the purposes of this study's longitudinal component (Appendix 6). The form consists of four open-ended questions, one of which also contains a closed question component. The items aim to evaluate participants' experiences of the impact of the intervention over time, including anything they felt could improve the longitudinal impact and whether they have noticed any subjective changes in their mood.

Intervention

Baby CHAT is an approximately 90-minute group intervention to be delivered during pregnancy. The group is comprised of psychoeducational material about a baby's social development after birth and while the baby is growing in the womb. Attendees are encouraged to think about when an infant's social development begins and consider whether this occurs before or after birth. Participants are then shown a video clip of Reissland et al.'s (2016) study showing 4D ultrasound images of foetuses mouthing in response to sounds that are presented to them outside the womb. Reissland's research suggests that babies' social development may begin to occur as early as 32 weeks. During Baby CHAT, parents are encouraged to reflect on this information in the context of their own baby's development, including their likes and dislikes, routine and personality. The final section of the group involves generating ideas for social activities that parents can try with their baby prior to birth, such as singing to, massaging or reading to their baby. At the end, participants are asked to think about a positive take-home message from the session and, if they feel comfortable, to share this with the group. A Baby CHAT handout will be provided for participants to work through during the group and to refer to at home. See Appendix 7 for the full session plan.

No significant changes will be made to the Baby CHAT group content for the purposes of this study. Baby CHAT was designed as a standalone session, that could be used as an add-on to existing treatments, and therefore does not target symptoms of depression specifically. However, the nature of the group discussions may naturally differ given that all participants will be experiencing depression during their pregnancy. Group facilitators will present the Baby CHAT content in a sensitive and non-blaming manner, validating participants' experiences. The facilitators will also sensitively facilitate discussions during the group around the group content, for example, anticipated difficulties engaging in new activities while experiencing depression.

While Baby CHAT was originally designed to be delivered face-to-face, in this study all sessions will be held virtually using video conferencing software. This will facilitate participants' access to the group and enable greater safety relating to the risk of Covid-19. Groups will be offered at a mixture of times, including weekdays and evenings.

End of study definition

The study will be considered completed once participants of the last Baby CHAT group have completed 1-month follow-up questionnaires. The REC will be informed once the study has ended.

6. Assessment of Safety

Adverse event reporting will take place following the intervention via the Baby CHAT feedback form. Participants will be asked if they experienced any negative effects from attending the group. These will be recorded and reported in the Annual Progress Report and copied to the sponsor.

SAEs are defined in this study as any adverse event which: results in death; is life-threatening; requires hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability or incapacity; or consists of a congenital anomaly or birth defect. SAEs are not anticipated to occur due to any of the study procedures. However, it is expected that SAEs may occur during the study for other reasons. Hospitalisation, likely due to complications with participants' pregnancies, will be considered an unrelated but expected SAE. Where SAEs are made known to the research team, these will be documented. Suspected unexpected serious adverse reactions (SUSARs) will be reported to the REC within 15 days of the Chief Investigator becoming aware.

See Appendix 1 for further information on adverse event reporting in non-CTIMP (Clinical Trial of an Investigational Medicinal Product) research.

7. Study oversight arrangements

The joint Research & Development Office for the Institute of Psychiatry, Psychology & Neuroscience and South London and Maudsley NHS Foundation Trust will sponsor this study and provide advice when required.

8. Ethics & Regulatory Approvals

The study protocol and all other documentation will be submitted to the NHS Health Research Authority (HRA) REC.

9. Data Handling

Confidentiality

Participant's names, demographics, details of their pregnancy and past pregnancies, and contact details will be collected. Access to this information will be limited to the Chief Investigator and Co-Investigators named in this protocol. No participant-identifiable information

will be transferred outside of King's College London and South London and Maudsley NHS Foundation trust, nor outside of the EU. Participants have the right to revoke their authorisation for the use of their identifiable information. In the write-up and publication of this research, all participants will be anonymised.

Case Report Form

The Case Report Form (CRF) will record the following for each participant: unique participant identifier, confirmation of consent, demographics, eligibility criteria checklist, screening questionnaire, study procedure dates, follow-up outcome dates, any study interventional delays, AEs log, SAE form, withdrawal from study form (if applicable) and trial completion form. The Co-Investigators named in this protocol will be responsible for the completion of the CRF at the point of participant registration to the study and after each trial procedure. The CRF will be stored electronically on a secure computer network and archived after study completion as outlined below.

Record Retention and Archiving

Participants' details and consent forms will be stored electronically on a secure computer network. A unique participant ID number will be assigned to each participant, which can only be decoded by a member of the research team. This data will be password protected for additional security. Participant information collected via Qualtrics (demographics, details of pregnancy, outcome questionnaires and feedback form) will be password protected and only accessible to the research team.

Upon completion of the study, participants will be given the option to receive a report summarising the outcome of the project. In this instance, participants will be asked to agree for researchers to retain their contact details to contact them to disseminate the study findings. Researchers will not access the contact information for those who do not consent to be contacted. All identifiable information will be stored in a password-protected file on a secure computer network and destroyed at the point of dissemination.

Following completion of the study, pseudonymised data will be destroyed after a period of 5 years, in line with Clinical Trial Regulations and to allow for publication of study findings. The Chief Investigator will act as custodian of the data and keep a fully anonymised dataset in a secure location indefinitely.

If a participant wishes to withdraw from the study, the research team will ask how they would like any information provided so far to be dealt with and whether they consent to it still being used in the study analysis.

Compliance

The Chief Investigator will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including but not limited to the UK policy framework for health and social care research, Trust and Research Office policies and procedures and any subsequent amendments.

10. Finance and Publication Policy

Financial considerations

A research budget of up to £1000 is provided for the conduct of this study by the Doctorate in Clinical Psychology at the Institute of Psychiatry, Psychology & Neuroscience, King's College London.

Publication

This project will be disseminated to staff and trainees completing the Doctorate in Clinical Psychology at the Institute of Psychiatry, Psychology & Neuroscience, King's College London. Write-up of the findings will be submitted to the course team as part of a doctoral thesis and will also be submitted to a peer-reviewed journal for publication.

An overall findings report will be provided for participants and participating mental health and maternity services.

The study will be registered on the following public database: www.clinicaltrials.gov

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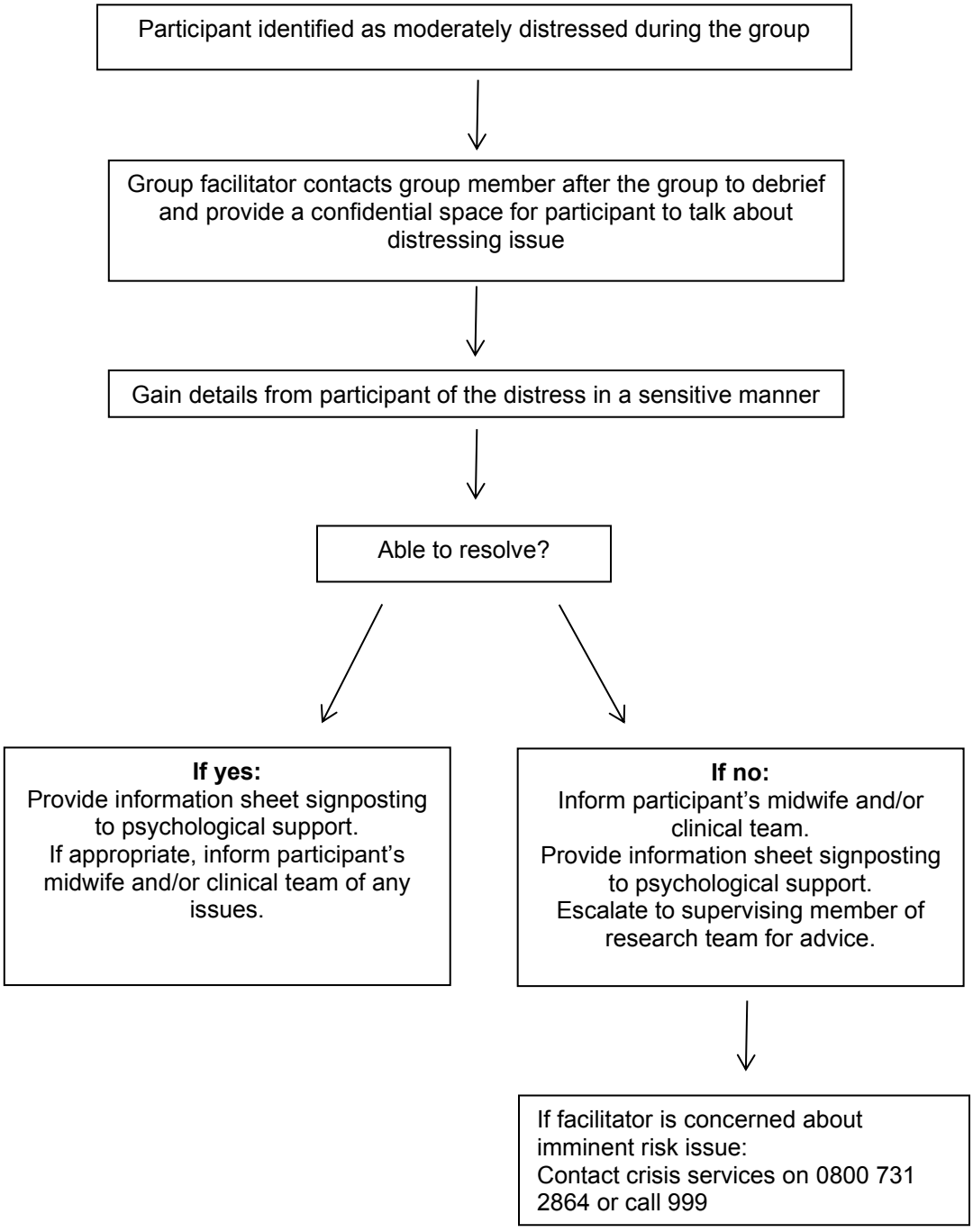
Appendix 1 – Information with regards to Safety Reporting in Non-CTIMP Research

	Who	When	How	To Whom
SAE	Chief Investigator	Within 15 days of CI becoming aware of the event	SAE Report form for Non-CTIMPs, available from NRES website.	Main REC with a copy to the sponsor
Urgent Safety Measures	Chief Investigator	Immediately Within 3 days	By phone Notice in writing setting out reasons for the urgent safety measures and the plan for future action.	Main REC Main REC with a copy sent to the sponsor. The MREC will acknowledge this within 30 days of receipt.
Progress Reports	Chief Investigator	Annually (starting 12 months after the date of favourable opinion)	Annual Progress Report Form (non-CTIMPs) available from the NRES website	Main REC with a copy to the sponsor
Declaration of the conclusion or early termination of the study	Chief Investigator	Within 90 days (conclusion) Within 15 days (early termination) *The end of study should be defined in the protocol*	End of Study Declaration form available from the NRES website	Main REC with a copy to the sponsor
Summary of final Report	Chief Investigator	Within one year of conclusion of the Research	No Standard Format However, the following Information should be included:- Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to subjects	Main REC with a copy to be sent to the sponsor

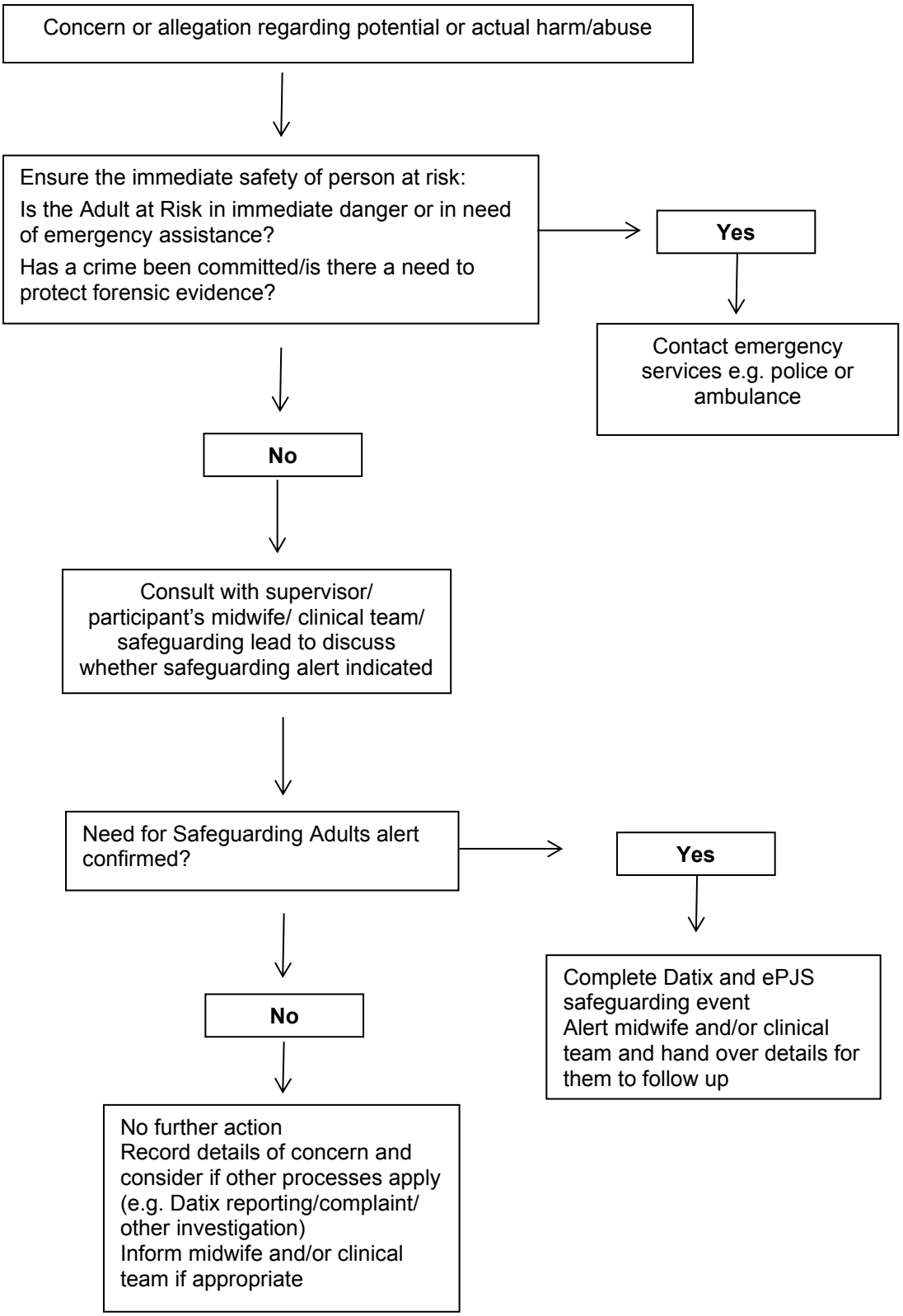
Appendix 2 – Study Poster

Appendix 3 – Distress Pathway

Group facilitators will remain vigilant to signs of emotional distress in participants during the group. The content and methods of Baby CHAT allow for sensitive and validating group conversations regarding participants' emotional reactions during the group and therefore low levels of distress can be managed sensitively within the group setting.



Appendix 4 – Safeguarding pathway



Appendix 5 – Feedback Form

Participant ID: ……..

Baby CHAT Group Feedback

Thank you for coming to Baby CHAT.

We would really like your feedback on Baby CHAT. Please let us know anything that you enjoyed as well as anything you think we could do to improve Baby CHAT.

Your feedback will add to our Baby CHAT research. We would like to include your feedback in our report about Baby CHAT. When we do this, we make sure that the feedback is completely anonymous so no one will know who has written the comments.

Date you attended Baby CHAT: …….

1. **Did you think the timing of the group in your pregnancy was (please circle):**

   Too early About right Too late

Please explain your answer: ……
……..
……..
……..
……..

2. **Was the length of the group (please circle):**

   Too long About right Too short

Please explain your answer: ……
……..
……..
……..
……..

3. **What did you enjoy about the group?**

……..
……..
……..
……..
……..

4. **What information did you find most useful from the group? Why?**

……
……
……
……

5. **Is there anything we can do to improve Baby CHAT?**

……..
……..
……..
……..
……..

6. **Was the group relevant to people with low mood? Why/why not?**

……..
……..
……..
……..
……..

7. **What did you think about the 4D scan video footage? Did this give you any ideas about how your own baby is developing?**

……..
……..
……..
……..
……..

8. **Do you have any other comments or feedback on the group?**

……..
……..
……..
……..
……..

Thank you for taking the time to complete this questionnaire.

Appendix 6 – Feedback Form – Follow-Up

Participant ID: ……..

Baby CHAT Group Feedback – Follow-Up

We would really like your feedback on whether Baby CHAT has been helpful over the weeks since you attended. Please let us know anything that you have noticed or remembered over the last few weeks.

Your feedback will add to our Baby CHAT research. We would like to include your feedback in our report about Baby CHAT. When we do this, we make sure that the feedback is completely anonymous so no one will know who has written the comments.

Date you attended Baby CHAT: …….

1. **How much have you thought about Baby CHAT since attending (please circle):**

   A lot Sometimes Rarely/never

Please explain your answer: ……
……..
……..
……..

2. **What have been the lasting impacts of Baby CHAT, if any:**

……..
……..
……..
……..

3. **Do you think attending Baby CHAT has helped your mood? Why/why not?**

……
……
……
……

4. **Do you have any other comments or suggestions about the impact of Baby CHAT over time? Is there anything else that might be helpful?**

……..
……..
……..
……..

Thank you for taking the time to complete this questionnaire.

Appendix 7 – Baby CHAT Session Plan

1. (10 mins) Welcome

- Group facilitators introduce themselves and welcome to Baby CHAT, overview of Baby CHAT
- Confidentiality explained as well as limits to confidentiality (i.e. if we hear something that is of concern over group members safety or the safety of someone they know this would be shared with a third party – most likely their midwife and/or safeguarding lead).
- Ask every member of the group to write down on a post-it something they are looking forward to about meeting their baby.
- Ask every member of the group to say their name and if they feel comfortable share aloud what they wrote on their post-it.

2. (10 mins) Social and Unique baby (page 2 handout)

- Show pictures/videos of babies after birth - Trying to get people thinking about the uniqueness of babies and their developing social skills after they are born
  e.g. video clip of Megan an 8-week old baby shown interacting first with her father, then with her mother. The video clip shows that an 8-week old baby is capable of reciprocal interaction with parents – when parents speak in high pitched tone, Megan kicks legs and makes noises (e.g. squealing with delight, laughing and babbling). Also shows Megan able to follow her mother with her head as her mother moves from side to side in front of her.
- ***All babies develop at slightly different times so this will not be the same for all babies***
- Discussion in pairs – what do people already know about a baby's social development and personality after birth? (Think about pictures/video clip/babies they know – try and think just after birth to about 6 months)
- Use flip chart paper/interactive white board to ask the group to feedback some of things they have been discussing. Feedback to group – flip chart paper/interactive whiteboard

  The aim of this discussion is to get people thinking about baby's:
  Personality
  Temperament
  Getting needs met
  Smiling
  Babbling
  Crying – the purpose of this
  Recognition- Moving head towards sounds/voice of mother/father
  Preferences
  Attention
  Concentration
  Awareness/baby cycles
  Learning

  Prompts for discussion if needed – draw attention to developmental timeline on page 2 of handout

  Question for the group: When do you think this development of personality/social skills develops? Does it just happen as soon as the baby is born? Brief ideas about when this begin to occur i.e. before or after birth

3. (10 mins) Your own baby (page 3/4 handout)

- What have you learnt about your baby so far? (work through work sheet in pack)
- Temperament and personality

4. (10 mins) New research in this area – would you like to see some new images of babies being social in the womb?

- Social responsiveness of baby in womb - Show Video clip from Nadja's research
- Suggests that babies are developing their social skills while they are waiting to be born - not only are they getting physically ready for life after birth but they are developing the necessary social skills that they need to survive and interact with their caregivers.
- Getting ready for when they meet you!

- **What do you think your baby is doing in the womb?** (**page 5 handout**)

5. (15 mins) Implications of this for your pregnancy

- How can you make the most of this new information? What would help your baby to begin to develop social skills before they are born? **(pages 5-12 handout)**
- ***Important to emphasise to parents that there are no right or wrong answers when interacting with baby***
- So… what activities can you do?
- ***Important that these activities are sensitively stimulating i.e. finding a volume of music that is right for parent and baby*** **(page 6-12 handout)**

  Think about baby's temperament/personality/routine
  Pet name
  Singing
  Talking
  Reading
  Playing music
  Massage
  Relax/Mindfulness

- Work through at least one example
  e.g. Give mindfulness meditation practice (on page 10 of handout)

- Plan when/where/how parents will have a go at one or more of these activities **(page 12 handout)**

6. (5mins) Ending – Ask everyone to write on a post-it something positive they will take away from the session about their baby's development.

Aim- to reinforce key messages and hopefully leave parents with positive feelings at the end of the group.