Greater Manchester Mental Health
NHS Foundation Trust

Specialist Perinatal Community Mental Health Team Research
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This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE TRIAL

Cognitive Behavioural Group Therapy treatment via a Video Communications Platform for Perinatal Anxiety and Depression: A Case Series

SHORT TRIAL TITLE / ACRONYM

Telecommunication CBGT treatment for Perinatal depression and anxiety.

PROTOCOL VERSION NUMBER AND DATE

Protocol Version 1.6

RESEARCH REFERENCE NUMBERS

IRAS Number:	272394
EudraCT Number:	Not applicable
ISRCTN Number / Clinical trials.gov Number:	ISRCTN Registry application submitted
SPONSORS Number:	X516s
FUNDERS Number:	Not applicable

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:
.....
......./...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Date: 21/02/21

Signature:
.....

Name: (please print):

Aaron McMeekin

KEY TRIAL CONTACTS

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Key Protocol Contributors	Dr Will Davis Dr Helen Kennerley Dr Joanna Omylinska-Thurston

i. LIST of CONTENTS

ii. TRIAL SUMMARY

Trial Title	Cognitive Behavioural Group Therapy treatment via a Video Communications Platform for Perinatal Anxiety and Depression: A Case Series	
Internal ref. no. (or short title)	Telecommunication CBGT treatment for Perinatal depression and anxiety.	
Trial Design	Case Series	
Trial Participants	This is a Case Series researching a group of women with common characteristics i.e. within the perinatal period, fulfilling diagnostic criteria of ICD 10 categories F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression). Those who are asked to take part will be 18 years or older and be clients of the GMMH Perinatal Service. By the nature of this service clients will be in their reproductive years and therefore an inclusion age group of 18-50 will be used.	
Planned Sample Size	Ten (minimum six)	
Treatment duration	Ten sessions (one per week for ten weeks)	
Follow up duration	One follow up session eight weeks following the last session	
Planned Trial Period	01/03/21 – 30/02/22	
	Objectives	Outcome Measures
Primary	This research aims to explore the efficacy of Cognitive Behavioural Group Therapy (CBGT) via a Video Communications Platform (Microsoft TEAMS) as a means to reduce maternal anxiety and low mood during the perinatal period.	Prior to each session clients will complete the following outcome measures. The Edinburgh Postnatal Depression Scale (Cox, Holden and Sagovsky, 1987), the GAD-7 anxiety scale (Spitzer, Kroenke, Williams and Löwe, 2006) and the Core 10 short measure (Barkham et al., 2013). A CORE-OM will be completed prior to the first session and following the final session. Data from these will be collated for the purpose of the research. A Likert Scale Questionnaire (5 questions) with an option for free text will be asked at the follow-up session.
Secondary	Not applicable	

iii. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Funded by Chief Investigator	Not applicable

iv. ROLE OF TRIAL SPONSOR AND FUNDER

The sponsor for this study is the Greater Manchester Mental Health NHS Foundation Trust. Sponsor takes the responsibility for oversight and management of the study. Trial design, conduct, data analysis and interpretation and manuscript writing are the responsibility of the Chief Investigator. Dissemination of the results of the study will be the responsibility of the Chief Investigator under educational supervision by the sponsor. Mothers who are pregnant or have a child under 12 months old will contribute regarding the outcomes of the study and will receive study results.

v. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The research study has a Chief investigator (Dr Aaron McMeekin), clinical supervisor (Dr Joanna Omylinska-Thurston), university supervisor (Dr Helen Kennerly) and one co facilitator Dr Will Davis). For data relating directly to the research study the Chief Investigator (Dr Aaron McMeekin) will have access to this. Clients will be consented for this.

The co-facilitator (Dr Will Davis) will be present during the CBGT sessions. Dr Davis will be part of any CBT discussion and disclosure of information that occurs. However Dr Davis will not have access to patient records (and will not be expected to require this access). Furthermore Dr Davis will not be involved in the write up of the research project, that is the responsibility of the Chief investigator. Anonymised data may be shared between Dr McMeekin and Dr Davis via secure, password protected email. This will be for the purpose of facilitating the group and planning each CBT session. No files containing identifying patient details will be transferred electronically between Dr McMeekin and Dr Davis.

Anonymised findings may be discussed in the course of supervision between the Chief investigator (Dr Aaron McMeekin), clinical supervisor (Dr Joanna Omylinska-Thurston) and university supervisor (Dr Helen Kennerly).

The Chief investigator undertakes seminars and supervision with the University of Oxford regarding academic progress. As part of routine monitoring of the study both a clinical supervisor (Dr Joanna Omylinska Thurston) and an educational supervisor (Helen Kennerley) are in place.

The co-facilitator (Dr Will Davis) receives supervision from the Chief Investigator. Dr Davis will also receive independent higher psychiatry training supervision from his trust clinical and educational

supervisor. Dr Davis will not share any research patient identifiable information with his trust clinical or education supervisors.

The Chief investigator is also required to submit progress reports to the University outlining the research.

This research project is being undertaken in an NHS Trust, Greater Manchester Mental Health NHS Foundation Trust. The Chief investigator will liaise and cooperate with the GMMH research office.

This is a pilot study and there is no study steering group.

vi. Protocol contributors

The Chief investigator has consulted with the psychological leads for GMMH Perinatal Service (Dr Kirsty Pratt and Dr James McManus) the perinatal psychiatric consultants for cluster 2 (Dr Ipsy Mukherjee) and cluster 3 (Dr Laura Murphy), the lead medical consultant for GMMH Perinatal services (Dr Sarah Jones) and the lead for perinatal services in Manchester (Ms Carla Mobear).

Service Users in the Greater Manchester Mental Health NHS Foundation Trust Perinatal Service have requested alternative treatments to medication. Feedback from an earlier 'Cognitive Behavioural Therapy orientated Perinatal Group' service evaluation reported the group as beneficial for those who attended regularly. Mothers stated they would recommend the group to a friend. A focus on difficulties specific to motherhood was highlighted as a particularly helpful aspect of such a Perinatal CBT group.

vii. KEY WORDS: Perinatal; Cognitive Behavioural Group Therapy; Depression; Anxiety; Alternative to Medication; Shared Maternal Experiences

viii. TRIAL FLOW CHART

Activity	Start			In Progress			Complete												
		Duration	Feb 21	Mar 21	Apr 21	May 21	June 21	July 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 22	Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22
Obtain IRIS approval																			
Obtain ISRCTN registration																			
Recruit Participants																			
CBT Group and follow up																			
Write up and submission																			
Publication																			

1 BACKGROUND

The perinatal period (from conception to one year postnatal) is a time of significant change with an increased risk of depression and anxiety for the mother. Untreated these conditions can have detrimental outcomes for mother and baby resulting in increased physical, mental and economic costs with resultant morbidity and even mortality. Untreated Perinatal mental health carries an economic and social cost to society of 8.1billion per one year cohort of UK births (Centre for Mental Health, 2014).

During pregnancy and 3 months postpartum, there is a risk approximately 19% of the maternal population may experience a depressive episode with 7% facing a major depressive episode (Gavin et al., 2005). Maternal anxiety has been found to be more common than depression during pregnancy and equally common postpartum. Anxiety related disorders may not be given due importance or specific approaches (Brockington, Macdonald and Wainscott, 2006). Mortality is a serious concern within the perinatal period associated specifically with postpartum depression (Sit, Rothschild and Wisner, 2006). Maternal suicide is the fifth most common cause of a women's death during pregnancy or in the 6 weeks following pregnancy. It is the leading cause of death over the first perinatal year (Knight et al., 2018).

The Five Year Forward View (Mental Health Taskforce Strategy, 2016) set out to increase access to specialist perinatal mental health services by 2021. The aim was for 30,000 more women each year receiving evidence-based treatment, closer to their home, when they require it. This has now been supplemented by the NHS Long Term Plan (The NHS Long Term Plan, 2019) with an additional commitment to increased access to evidence-based psychological support including digital options.

It is important for a service to provide effective evidence based treatment, easily accessible to the client, at a time and place of their choosing. This can be facilitated by digital means.

Pregnant clients may be reluctant to take medication, voicing concerns about baby or side effects. Psychological approaches are available as alternatives, however the evidence base for these is smaller than treatments for general adult mental health disorders. Research into the effectiveness of Cognitive Behavioural Therapy (CBT) on perinatal mental health issues is increasing, however there is limited data on Cognitive Behavioural Group Therapy (CBGT) for treating perinatal anxiety and depression.

In 2020 – 21 mental health services have been affected by the COVID-19 pandemic. For perinatal women this has resulted in fewer face to face contacts, difficulties accessing services, with increased social and monetary stress.

This research aims to explore the efficacy of Cognitive Behavioural Group Therapy (CBGT) via a Video Communications Platform (Microsoft TEAMS) as a means to reduce maternal anxiety and improve low mood during the perinatal period.

This is a Case Series studying a group of women with common characteristics i.e. within the perinatal period, fulfilling diagnostic criteria of ICD 10 categories F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

Participants will be recruited from the Greater Manchester Mental Health NHS Foundation Trust Perinatal CMHT service. The CBGT will incorporate ten sessions with one follow up session. The group will be led by the Chief Investigator (a trained CBT therapist and consultant perinatal psychiatrist) and a psychiatric higher trainee with CBT experience.

The research is a part of a MSC programme in Cognitive Behavioural Therapy at the University of Oxford.

2 RATIONALE

This research is proposed to answer the important question of whether effective, therapeutic, non-pharmacological Cognitive Behavioural Group Therapy can be delivered to women in the perinatal period via video communication. We have noted perinatal Anxiety and Depression are major health

problems for mothers, their children, partners, families, and society (Cuijpers, Brännmark and van Straten, 2008). The evidence base for the proposed type of treatment is small, the expectation is this research can add valuable data.

This research proposal is especially relevant at the current time in view of the worldwide pandemic and the resultant restrictions on social interaction, face to face therapy and reduced access to psychological services (Chen et al., 2020). For women in the perinatal period this has resulted in fewer face to face contacts, difficulties accessing therapy services, increased anxiety and depression, increased social and monetary stress.

Pharmacological options are available but use of medication remains a complex and often intimidating area for prescriber and mother, with changing evidence taken from moderate to low quality studies (Henshaw, Cox and Barton, 2017). Mothers may be reluctant to take medication (Walton et al., 2014) with understandable concerns regarding medication in pregnancy, medication in breastmilk or side effects of medication when trying to look after a baby (over sedation or lethargy).

Psychological approaches are a viable alternative, however the evidence base for their effectiveness in the perinatal period is smaller than the evidence base for the general adult population (Maguire, Clark and Wootton, 2018). Research into the effect use of Cognitive Behavioural Therapy (CBT) for these perinatal mental health issues is increasing. Cognitive Behavioural Therapy has been demonstrated to be effective in treating postpartum depression (Appleby et al., 1997). For CBT treatment of perinatal anxiety the evidence base is smaller and more conflicting. Maguire, Clark and Wootton (2018) found CBT an effective treatment for Perinatal Anxiety consistent with the use of CBT for anxiety in the general population. However a review by Nillni et al (2018) found treatment studies of CBT for perinatal anxiety and trauma related disorders to be limited.

The evidence base for using Cognitive Behavioural Group Therapy when treating perinatal depression and anxiety is modest. A 2010 systematic review (Stevenson et al., 2010) assessing CBGT for postnatal depression found only six studies met the inclusion criteria for quantitative review. The authors highlighted a lack of Random Control Trial evidence of CBGT as treatment for postnatal depression as a limitation. This review found three studies indicated group psychoeducation incorporating CBT as effective, however the inconsistent and low quality nature of these studies limited proposing CBGT as a service provision.

For treatment of perinatal anxiety a 2016 study compared CBGT with interactive lectures for reducing anxiety during pregnancy (Salehi, Pourasghar, Khalilian and Shahhosseini, 2016). CBGT was found to be more effective in reducing anxiety than interactive lectures, but the difference was not significant. Regarding anxiety in childbirth a 2020 paper demonstrated GCBT useful for pregnant women with tokophobia (Ghavami, Ghanbari Hashem Abad, Saffarian and Khakpour, 2020).

The evidence base for CBGT via Video Communication in the Perinatal period is very small. However a 2017 quantitative survey of pregnant women found the majority would consider some form of computer-based therapy for mental health treatment during pregnancy (Hantsoo et al., 2017). Video telehealth therapy (patient engaging with a therapist via a web camera) was the most common considered. Computer assisted Cognitive Behavioural Therapy has been found to show a response for pregnant women (Kim et al., 2014) but this is based on computer software rather than a group video communication approach.

The treatment intervention for this research study is Cognitive Behavioural Group Therapy (CBGT). Group sessions will follow an adaptation of models outlined in:

Söchting, I., 2014. Cognitive Behavioral Group Therapy: Challenges And Opportunities

Wenzel, A. and Kleiman, K., 2015. Cognitive Behavioral Therapy For Perinatal Distress.

Green, S., Frey, B., Donegan, E. and McCabe, R., 2019. Cognitive behavioral therapy for anxiety and depression during pregnancy and beyond.

Additional utilisation of relevant journal articles and texts will also be adapted and referenced as required.

This research is a Case Series and there are no controls nor comparator groups.

Clients will not be under any pressure to participate in the research. They will be made aware they can withdrawal from the research at any point. Involvement, or non-involvement with the research will in no way affect their treatment and care plan within the perinatal CMHT.

2.1 Assessment and management of risk

A request to participate in research is common in the NHS. Clients have a choice to participate or to decline to participate. Clients are able to withdraw from the research at any point.

Suitable clients will be decided on the basis of inclusion and exclusion criteria.

CBT has a research base for treating anxiety and depression in the perinatal period. Research into Group Cognitive Behavioural Group Therapy has not been designed to make clients' worse in their mental health. CBGT is intended to be a positive, affirming and collaborative experience for the client. An aim of CBGT is to promote the client's own means of challenging negative cognitions and gain support from other mothers who may share similar experiences and strategies.

However therapy can raise difficult issues for clients and there will be a robust risk assessment and relapse plan in place for all clients in the group. If an unmet clinic need is uncovered or distress experienced the lead researcher is an experienced perinatal consultant psychiatrist and the co-facilitator a higher trainee in psychiatry. Clients will have the opportunity to discuss aspects of their mental health with one or both professionals. A risk strategy will be in place to ensure clients have a pathway of support. Professionals and client will follow GMMH risk management protocol (this is to contact the client's own care co-ordinator, contact client's own psychiatrist, contact relevant perinatal cluster duty line, contact GMMH crisis line, refer to Home Based Treatment Team or consider admission to Mother and Baby unit as appropriate).

If a client finds the research or therapy unsatisfactory, they will be given information regarding the Trust's PALS (Patient Advice Liaison Service) if they wish to discuss or complain about any aspect of the service received. This will not affect their ongoing care or future referrals.

Unforeseen factors external to the research can occur. Clients may experience changes to their mental state as a result (for example) changes to their social circumstances or family life. If this occurs the client will have the opportunity to discuss this with the group facilitators. Information and signposting will also be provided to the client's own cluster Perinatal team, care plan / standard care psychiatrist and the client will be made aware of appropriate perinatal and GMMH crisis lines.

Clients are free to withdraw from the research at any point if they feel it is not benefiting their mental health. Withdrawing from the research will not affect ongoing care or future referrals to other treatments or therapies in any way.

The lead researcher and facilitator will also seek support in supervision if any issues become apparent during the research that affect the researchers' mental health. The facilitator has quarterly supervision with an experienced consultant psychiatrist (separate to the research). The lead researcher also has regular supervision with a Chartered Counselling Psychologist, a Consultant Psychologist within Oxford Cognitive Therapy and the University of Oxford college supervision process.

This trial is categorised as:

- Type A = No higher than the risk of standard medical care

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS; RESEARCH QUESTION/AIM(S)

This research aims to explore the efficacy of Cognitive Behavioural Group Therapy (CBGT) via a Video Communications Platform (Microsoft TEAMS) as a means to reduce maternal anxiety and improve low mood during the perinatal period (conception to one year postnatal).

3.1 Primary objectives

Eligible Participants: Women with common characteristics i.e. within the perinatal period, fulfilling diagnostic criteria of ICD 10 categories F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

Outcome Measures: Edinburgh Postnatal Depression Scale (EPDS); GAD-7 Anxiety Scale; Core 10 short will be completed at each session. CORE-OM will be completed prior to the first session and following the final session.

3.2 Secondary objectives

A Likert Scale Questionnaire (five questions) with an option for free text, will be asked at the final session. This will allow feedback on the group.

3.3 Outcome measures/endpoints

3.3.1 Primary endpoint/outcome

Primary Outcome

The primary outcome are changes in outcome measure scales over the course of the CBGT group. The aim would be a reduction in scores of the EPDS, GAD-7, CORE-10 and CORE-OM for each participant.

3.3.2 Secondary endpoints/outcomes

Secondary Outcome

The Likert Scale Questionnaire will allow feedback by the participants on the group.

3.3.3 Exploratory endpoints/outcomes

Not applicable

3.3.4 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To monitor the change in outcome measure scales over the course of the Cognitive Behavioural Group Therapy.	Edinburgh Postnatal Depression Scale, GAD-7 anxiety scale and CORE-10 scale CORE-OM scale	The scales will be scored at each CBGT session and the follow up session. The CORE-OM scale will be scored at the first and final session.
Secondary Objectives To allow participants to give basic feedback on the group	A Likert scale (with free text availability) asking five questions.	Completed at the follow up session

4 TRIAL DESIGN

4.1 Study Design: Case Series

This is a Case Series studying a group of women with common characteristics i.e. within the perinatal period, fulfilling diagnostic criteria of ICD 10 categories F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

5 TRIAL SETTING

This is a single centre trial. Clients will be recruited by professionals (care coordinators, social workers, psychiatrists, community psychiatric nurses, psychologists) currently working with them in Clusters 2 and 3 of the Greater Manchester Mental Health NHS Foundation Trust (GMMH) Perinatal Service. Patients will therefore be recruited from secondary care.

6 PARTICIPANT ELIGIBILITY CRITERIA

The trial population will be women under the care of the GMMH Perinatal Service, within the perinatal period, fulfilling diagnostic criteria of ICD 10 categories F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

6.1 Inclusion criteria

Those who are asked to take part will be 18 years or older and be clients of the GMMH Perinatal Service. By the nature of this service clients will be in their reproductive years and therefore an inclusion age group of 18-50 will be used.

Clients will have diagnoses recorded by the perinatal service in the ICD 10 categories of F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

All women recruited will be under the care of a Greater Manchester Mental Health NHS Foundation Trust (GMMH) Perinatal team and will be identified by Perinatal professionals. GMMH has three perinatal teams based on geographical areas of Greater Manchester (cluster 1, 2 and 3). The author is a professional working in cluster 3 (North East Manchester) and therefore participants will be recruited from clusters 1 and 2 (South, Central and West Manchester) to ensure there are a separation of roles and no conflict of interest.

Clients will require access to a laptop, smartphone or tablet computer to enable the video based group therapy can take place.

6.2 Exclusion criteria

Clients who are severely psychologically distressed and unable to undertake therapy.

Clients will not be included if they have a condition which would make undertaking group CBT difficult for themselves or others. These difficulties would include pervasive psychotic experiences, severe difficulties in emotional regulation, difficulties with dissociation or difficulties in comprehension.

Clients who are at active risk of (or carrying out) self-harm to themselves. Clients who are at active risk of harm to others or their child.

Clients who are excessively misusing or dependent on alcohol or illicit substances.

Clients who have ongoing physical issues that would make it very difficult or uncomfortable to attend a CBT group.

Clients who cannot commit to CBGT will not be included at the initial assessment, however once a client is involved there will be a degree of flexibility permitted considering the challenging demands of looking after a child and the ongoing COVID-19 pandemic.

The researcher will follow ethical protocols to protect the confidentiality of clients' participation and personal data. However, confidentiality may have to be breached if there are concerns about harm to self, others or child and any escalation will follow normal clinical risk GMMH trust protocol.

7 TRIAL PROCEDURES

7.1 Recruitment

Suitable clients will be identified within the GMMH Perinatal Service. The GMMH Perinatal Service comprises three 'clusters' covering the area of Greater Manchester. The Chief investigator (Dr McMeekin) works in cluster 3 and to prevent any conflict of interest clients will not be recruited from that cluster.

Recruitment can occur at any point during a client's involvement with the GMMH perinatal service.

Perinatal professionals will use inclusion / exclusion criteria in deciding whom to approach and will ask the client if they have an interest in the study.

Suitable clients who express an interest will be asked by the professional within their cluster if they would like to know more about the research and will be given a Client Invitation Letter. If they decline they will not be asked about, or involved in, any further parts of the research study.

Clients who read the invitation letter and express an interest will be asked if their details can be passed on to the lead researcher for further contact regarding the nature of the study. They will be asked if they would like to be initially contacted by telephone or by email. All clients who express an interest will be sent a Participants' Information Sheet (PIS) outlining the study by email or postal mail. Clients who agree to be contacted by telephone will also have the option to reply via email or by paper slip. Clients who do not wish their details to be passed on to the lead researcher will not be contacted again regarding the study.

Contact with the lead researcher will allow a detailed explanation about the research and the opportunity for the client to ask further questions or clarify the PIS. Clients will be asked if they wish to participate in Cognitive Behavioural Group Therapy (CBGT). They will be aware they can withdraw at any time without any penalty or change to their ongoing involvement with the GMMH Perinatal Service.

A time frame and expected starting date will be discussed with the clients. Clients will be given as much time as they need (minimum 24 hours, maximum 7 days) to consider participation in the research. Clients will have options of replying by email, by post, by telephone or asking the lead researcher to ring them after a set time of their choosing. They can also use these contact points for further clarification or to ask questions.

Clients will not be under any pressure to participate in the research. They will be made aware they can withdrawal from the research at any point. They will be made aware that involvement, or non-involvement with the research will in no way affect their treatment and care plan within the perinatal CMHT. There will be no need for the researcher to have personal data until the patient has agreed to the contact from the researcher.

If a client agrees to participation in the research they will meet with the lead researcher. The client will be asked to sign a written consent form. The client will be under no obligation to sign this and is free to leave the process at this stage. The client will then undertake a clinical assessment with the lead interviewer. This will compose a psychiatric history to confirm their diagnosis. This will also allow inclusion and exclusion criteria to be reviewed. A risk assessment will take place.

7.1.1 Participant identification

Clients will be identified by perinatal professionals (care co-ordinators, community mental health nurses, social workers, specialist mental health midwives, psychiatrists and psychologists) working in Cluster 1 (Central and South Manchester, Trafford and Stockport) and Cluster 2 (Salford, Bury, Bolton and Wigan). Lead perinatal professionals from Cluster 1 and Cluster 2 have been consulted about the research study and are supportive of the project and this approach. The research proposal has been consulted with the psychological leads for GMMH Perinatal Services (Dr Kirsty Pratt and Dr James

McManus) the Perinatal consultants for Cluster 2 and Cluster 1 respectively (Dr Ipsy Mukherjee and Dr Laura Murphy) and the Perinatal lead for the GMMH service (Dr Sarah Jones).

7.1.2 Screening

Participants will be clients in a secondary care service, the GMMH Perinatal Service.

Clients will have diagnoses recorded by the perinatal service in the ICD 10 categories of F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression).

7.1.3 Payment

No payments are made or allocated in this research study.

7.2 Consent

If a client agrees to participation in the research they will meet with the lead researcher via either video conference or telephone link. If necessary this appointment can take place physically face to face however this is dependent on pandemic rules and GMMH trust pandemic guidance. The client will be asked to sign a written consent form. The client will be under no obligation to sign this and is free to leave the process at this stage.

Consent will be obtained by the chief investigator at the assessment meeting to allow access to identifiable personal information (relevant to the research) within the client's PARIS (trust electronic) records.

Consent will also be sought if relevant professionals need to be consulted for relevant information (for example social workers, health visitors, obstetricians or specialist midwives if required).

7.2.1 General Practitioner informed

When a client agrees to participate in the project and gives consent the Chief Investigator will send a letter to their General Practitioner informing them of this.

7.3 Baseline data

The following data will be recorded for clients.

Maternal and Pregnancy Related Variables: Age (within an age range for example 30-34, 35-39), their ethnicity, total previous pregnancies, medication, mental health diagnosis, physical health status

Infant Variables: pregnancy / postnatal status

The client will undertake a clinical assessment with the Chief investigator. This will compose a psychiatric history to confirm their diagnosis. This will also allow inclusion and exclusion criteria to be reviewed. A risk assessment will take place.

7.4 Research Intervention

When ten clients (minimum six) complete this process a convenient time and start date will be arranged to commence the therapy sessions. Each therapy session will have a duration of two hours and take place at approximately at the same time each week for ten weeks. There will be a follow up session at eight weeks.

Each session will be led by two professionals with experience of CBT therapy. The Chief Investigator (an experienced consultant perinatal psychiatrist with a postgraduate qualification in CBT) and a higher trainee psychiatrist (this signifies a trainee who has completed a minimum of 3 years core psychiatry

training involving 'short' and 'long' cases in psychotherapy and achieved successful membership of the Royal College of Psychiatrists requiring examination in various therapeutic techniques including CBT).

The treatment intervention for this research study is Cognitive Behavioural Group Therapy (CBGT). Group sessions will follow an adaptation of models outlined in:

Söchting, I., 2014. Cognitive Behavioral Group Therapy: Challenges And Opportunities

Wenzel, A. and Kleiman, K., 2015. Cognitive Behavioral Therapy For Perinatal Distress.

Green, S., Frey, B., Donegan, E. and McCabe, R., 2019. Cognitive behavioral therapy for anxiety and depression during pregnancy and beyond.

Additional utilisation of relevant journal articles and texts will also be adapted and referenced as required.

The group is a transdiagnostic group, meaning it includes different diagnoses: depression, anxiety syndromes and postnatal depression. Therefore reference will be made to McEvoy and Nathan, 2007 Effectiveness of cognitive behavior therapy for diagnostically heterogeneous groups: A benchmarking study and Hamilton et al., 2012 Exploring the Effectiveness of a Mixed-Diagnosis Group Cognitive Behavioral Therapy Intervention Across Diverse Populations.

Each session will use CBT techniques. A complete Session outline is available in the Interview Schedule.

The follow up session will review progress or setbacks made to that point, give encouragement and reinforce therapeutic techniques used. It will also aim to troubleshoot any problems with CBT techniques learnt.

CBGT sessions will be understood to take place in clients' homes in a quiet room for the two hour period. Babies will be encouraged to attend as evidence indicates the presence of infants is a key factor for the woman experiencing positive change (Væver, 2015). The presence of an infant will also help to normalise the experience for all the women in the group. There will be a scheduled break at 60 mins and unscheduled breaks will be expected and accommodated (for example the need to change a nappy). Breastfeeding is also encouraged and there is the option to turn her camera off during that period for more privacy.

7.5 Research intervention Outcome Measures

Prior to each session clients will complete the following outcome measures.

- The Edinburgh Postnatal Depression Scale (Cox, Holden and Sagovsky, 1987),
- GAD-7 anxiety scale (Spitzer, Kroenke, Williams and Löwe, 2006)
- Core 10 short measure (Barkham et al., 2013).

These scales will be sent by either email or physical post to the clients to allow them to complete them.

A CORE-OM will be completed prior to the first session and following the final session, again sent by email or physical post. Data from these will be collated for the purpose of the research.

7.6 Follow-up assessments

Following the ten session group therapy, the group will have one follow up session eight weeks later. This will allow a review and reflection on Cognitive Behavioral Techniques undertaken over the ten week course. Clarifications and questions can also be answered within this session.

All clients will remain under with the Perinatal Service for the duration of the research. On conclusion of the research clients will either remain with their perinatal treatment plan, be signposted to relevant

perinatal support services, have the option for further therapy, or return to Primary Care. This decision will not be influenced by the research study. This decision will be made as a collaborative choice between client and their GMMH perinatal professional / Multi-Disciplinary Meeting.

7.7 Qualitative assessments

This trial is primarily Quantitative.

A Likert Scale Questionnaire (5 questions) with an option for free text will be asked at the 8 week follow-up session. The scale is as follows:

Strongly Agree Agree Neither Agree Nor Disagree Disagree Strongly Disagree

The questions are as follows

1. The Cognitive Behavioural Therapy Group met my expectations
2. I would be willing to bring my baby to a Cognitive Behavioural Therapy Group
3. Cognitive Behavioural Group therapy is appropriate for mothers like me
4. The Cognitive Behavioural Therapy Group allowed me to build networks with other mothers
5. I would recommend Cognitive Behavioural Therapy Group to another client

7.8 Withdrawal criteria

If a client experiences a severe relapse in their mental health and is unable to continue with the trial they will be withdrawn.

If a client develops new symptoms of severe mental illness outside the remit of F32-33 (depression), F40-41 (anxiety) or F53 (Mental and Behavioural disorders associated with the puerperium, including postnatal depression). This can include (but is not exclusive to) Psychosis, Mania, Substance Misuse or Physical Self Harm.

If a client experiences difficulties in their physical or pregnancy health that mean they are unable to participate in the trial they will be withdrawn.

If a participant's baby or child becomes unwell requiring ongoing medical support this will take priority and the client will withdraw from the trial.

If a participant places another participant (or their child / family) at risk they will be withdrawn from the trial. This can include (but is not exclusive to) physical harm, mental distress, safeguarding concerns.

Clients are free to withdraw from the research at any point if they feel it is not benefiting their mental health. Withdrawing from the research will not affect ongoing care or future referrals to other treatments or therapies in any way.

If there is a dropout rate of greater than 75% of the CBGT group the trial will be ceased.

7.9 End of trial

The sponsor will notify the MHRA of the end of a clinical trial within 90 days of its completion. The completion date is scheduled for February 2021.

8 STATISTICS AND DATA ANALYSIS

This is a Case Series. No statistical review necessary as only frequencies and associations will be assessed – details of statistical input not required.

9 DATA MANAGEMENT

9.1 Data handling and record keeping

Participants are already patients of the GMMH Perinatal Community Mental Health Team service. Their personal details and clinical records are recorded on the trust electronic database PARIS.

A paragraph summary of each client's session will be uploaded to PARIS by the Chief investigator covering participant's attendance at the group, the headline theme of CBGT conducted during the session and a brief risk assessment.

Any electronic information sent via NHS.net email will either be uploaded to the client's PARIS notes if clinically relevant or recorded on the Chief investigator's secure GMMH 'Surface' trust laptop for the purpose of the research study. Once this is done the email will be deleted from the nhs.net email server.

Any physical paper information sent via post will either be scanned and uploaded to the client's PARIS notes if clinically relevant or scanned and recorded on the Chief investigator's secure GMMH 'Surface' trust laptop for the purpose of the research study. Once this is done the physical correspondence will be shredded.

Each CBGT session will be recorded via Microsoft Teams on the research lead's GMMH secure trust laptop. This information will not be moved or transferred from that computer. It will not be stored on any hard drive apart from the Chief investigator's secure trust laptop. It will not be stored on an external drive or cloud storage service.

Research information obtained during sessions will be recorded in a password protected document on the Chief Investigator's secure trust computer.

The research data and write up will be stored on the Chief Investigator's GMMH secure trust laptop. This is password encrypted, with password resets required on a 45 day basis. If the incorrect password is repeated the computer locks both the hardware and user's account.

This laptop will be kept in two locations. Locked securely at the Chief investigator's place of work (locked in a filing cabinet to which only the Chief investigator has access, the filing cabinet is in the consultant's locked office, to which only the Chief investigator and his secretary has access). Locked securely at the Chief investigator's home address in a filing cabinet to which only the Chief investigator has access.

Once the information is anonymised and the research write up commenced a backup copy of the research will be kept on a GMMH trust approved AES 256-BIT encrypted flash drive. This is required in case of a breakdown of the Chief investigator's trust laptop. This flash drive will be kept at the Chief investigator's home in a locked drawer to which only he has access.

9.2 Access to Data

The client's trust professional(s) will already have access to client records (via the GMMH trust electronic system - 'PARIS') for the purpose of CMHT perinatal treatment and care. The client's professional(s) will refer to these for the initial purpose of exclusion / exclusion criteria.

At the assessment interview access to client records (via the GMMH trust electronic system – 'PARIS') will be requested by the Chief investigator for the purpose of undertaking the clinical assessment and confirming inclusion / exclusion criteria. Clients will be asked for consent regarding this request.

Personal addresses and contact details will be viewed on PARIS to allow Participant Information Sheets (PIS) to be sent to clients; to contact clients for interviews; to write to thank clients for their participation; to send details of the findings to clients who elect to receive them. This information will not be viewed on PARIS unless required for these purposes. PIS and consent forms will be sent via email (www.nhs.net) or via post.

Only the Chief investigator (Dr Aaron McMeekin) will have access to this data relating directly to the research study only. Clients will be asked for consent for this.

The co-facilitator (Dr Will Davis) will be present during the CBGT sessions. Therefore he will be part of any CBT discussion and disclosure of information that occurs. However Dr Davis will not have access to patient records on PARIS (and will not be expected to require this access). Furthermore Dr Davis will not be involved in the write up of the research project, that is the responsibility of the Chief investigator. Anonymised data may be shared between Dr McMeekin and Dr Davis via secure, password protected email. This will be for the purpose of facilitating the group and planning each CBT session. No files containing identifying patient details will be transferred electronically between Dr McMeekin and Dr Davis.

Anonymised findings may be discussed in the course of supervision between the Chief investigator (Dr Aaron McMeekin), clinical supervisor (Dr Joanna Omylinska-Thurston) and university supervisor (Dr Helen Kennerly).

9.3 Archiving

Data relating to the research study will be kept in accordance with GMMH Standard Operating Procedure (RDSOP21 – Retention of Data, Off-site Archiving and Destroying of Documents). Electronic archiving will be undertaken for a retention period of 5 years from completion of study or submission of final report.

If a client contributes information clinically relevant to their perinatal care, this will be recorded on the GMMH electronic trust record 'PARIS'. The lead author will complete a paragraph summary of each client's session and upload this to PARIS. This will cover participant's attendance at the group, the headline theme of that CBGT session and a brief risk assessment. Once uploaded this information will remain on PARIS as part of the participant's clinical record.

10 ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Research Ethics Committee (REC) review& reports

Prior to the start of the trial a favourable opinion will be sought from NHS REC and HRA for the trial protocol, consent letters and relevant documents.

10.2 Peer review

The protocol will be reviewed by an independent reviewer, who has the knowledge in the field and is familiar with the analysis described in the study.

10.3 Public and Patient Involvement

Mothers in the Greater Manchester Mental Health NHS Foundation Trust Perinatal Service have requested alternative treatments to medication. Feedback from an earlier service evaluation of a Cognitive Behavioural Therapy orientated Perinatal Group found mothers reported the group as beneficial for those who attended regularly. Mothers stated they would recommend the group to a friend.

A focus on difficulties specific to motherhood was highlighted as a particularly helpful aspect of such a Perinatal CBT group.

10.4 Regulatory Compliance

The trial will not commence until a Favourable REC opinion.

10.5 Protocol compliance

Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials and must not be used e.g. it is not acceptable to enrol a participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

10.6 Data protection and patient confidentiality

To ensure any identifying material is excluded each participant will be allocated a pseudonym and an anonymous number when they enter the study. Any quotes will be subsequently attached to this number or pseudonym when recorded as part of the study rather than the participant's name.

The pseudonym will have no identifying demographic or direct clinical information. This link between pseudonym and client will be stored on the Chief investigator's encrypted trust laptop.

Access to personally identifying study data will be restricted to the Chief investigator.

Anonymised data may be shared between Dr McMeekin and Dr Davis (higher trainee in psychiatry) via secure, password protected email. This will be for the purpose of facilitating the group and planning each CBT session. No files containing identifying patient details will be transferred electronically.

Anonymised findings may be discussed in the course of supervision between the Chief investigator (Dr Aaron McMeekin), clinical supervisor (Dr Joanna Omylinska-Thurston) and university supervisor (Dr Helen Kennerly).

A database will be created to store clinical information (e.g. number of CBT sessions, goal for therapy, details of treatment, cognitions, helpful factors of CBGT) which will be linked to clients' pseudonyms / number. The database will be securely stored in a password protected document on the Chief investigator's secure trust computer and trust approved AES 256-BIT encrypted flash drive.

Data relating to the research study will be kept in accordance with GMMH Standard Operating Procedure (RDSOP21 – Retention of Data, Off-site Archiving and Destroying of Documents). Electronic archiving will be undertaken for a retention period of 5 years from completion of study or submission of final report.

If a client contributes information clinically relevant to their perinatal care, this will be recorded on the GMMH electronic trust record 'PARIS'. Furthermore, as outlined, the Chief investigator will complete a paragraph summary of each client's session and upload this to PARIS. This will cover participant's attendance at the group, the headline theme of that CBGT session and a brief risk assessment. Once uploaded this information will remain on PARIS as part of the participant's clinical record.

The Chief investigator will be the data custodian.

10.7 Financial and other competing interests for the Chief investigator, PIs at each site and committee members for the overall trial management

There are no ownership interests, commercial ties or noncommercial potential conflicts.

Participants are identified from Cluster 1 and Cluster 2 GMMH Perinatal services. They will not be identified from cluster 3 perinatal services (Dr McMeekin's cluster) to prevent any clinical conflict of interest.

10.8 Indemnity

The Chief investigator and the co-facilitator are members of a medical indemnity society. This society can provide assistance and advice for ethical or legal problems that might arise from the study for its members (Dr McMeekin and Dr Davis).

10.9 Amendments

The Chief Investigator will submit a valid notice of amendment to the REC for consideration if a substantial amendment to the REC application or the supporting documents is made.

The Chief Investigator will discuss any proposed amendments in clinical and educational supervision. There will be a collaborative decision on whether an amendment is substantial or insubstantial.

Any amendments will be communicated in writing.

Amendments will be tracked by reference to protocol versions with any amendment generating a new version of the protocol.

10.10 Post trial care

Following the ten session group therapy, the group will have one follow up session eight weeks later. This will allow a review and reflection on Cognitive Behavioural Techniques undertaken over the ten week course. Clarifications and questions can also be answered within this session.
All clients will remain under with the Perinatal Service for the duration of the research. On conclusion of the research clients will either remain with their perinatal treatment plan, be signposted to relevant perinatal support services, have the option for further therapy, or return to Primary Care. This will not be influenced by the research study. This decision will be made as a collaborative choice between client and their GMMH perinatal professional / Multi-Disciplinary Meeting.

10.11 Access to the final trial dataset

The Chief investigator and will have access to the full datasets. Each participant will be allocated a pseudonym and an anonymous number when they enter the study. Access to personally identifying study data will be restricted to the Chief investigator.

Anonymised findings may be discussed in the course of supervision between the Chief investigator (Dr Aaron McMeekin), clinical supervisor (Dr Joanna Omylinska-Thurston) and university supervisor (Dr Helen Kennerly).

11 SAFETY REPORTING

11.1 Adverse Events Definitions

Adverse Event (AE)	Any untoward medical or psychological occurrence in a participant receiving psychological therapy or other trial intervention and which does not necessarily have a causal relationship with this intervention. An adverse event can therefore be any unfavourable and

	unintended sign, symptom, or disease in any subject in a trial (including those in an untreated control group), whether or not considered related to the investigational psychological therapy/intervention.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • results in suicidal thoughts Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Adverse Reaction (AR)	All untoward and unintended responses to an investigational psychological therapy or other intervention. All adverse events judged by either the reporting investigator or the sponsor as having a reasonable causal relationship (e.g. definitely, probably or possibly related) to a psychological therapy/intervention qualify as adverse reactions.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the trial treatments, based on the information provided.
Unexpected Adverse Reaction	An adverse reaction, the nature or severity of which is not consistent with the effects or consequences of the psychological therapy/intervention being investigated.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction, the nature and severity of which is not consistent with information in the MHRA approved Reference Safety Information

Note: To avoid confusion or misunderstanding of the difference between the terms “serious” and “severe”, the following note of clarification is provided

“Severe” is often used to describe intensity of a specific event, which may be of relatively minor medical significance.

“Seriousness” is the regulatory definition supplied is Serious Adverse Reaction.

The following grading criteria is used for the purpose of this protocol:

Mild: asymptomatic or mild symptoms, diagnostic observations only, no intervention indicated. Not interfering with everyday activities/functioning.

Moderate: an event that is sufficiently discomforting to interfere with normal everyday activities. Minimal, local or non-invasive intervention indicated.

Severe: an event that prevents normal everyday activities. Medically significant but not immediately life-threatening. Hospital or prolongation of hospitalisation indicated.

11.2 Assessment of Causality

The relationship of each reportable adverse event to the trial medication must be determined by a medically qualified individual according to the following definitions:

Unrelated – Where an event is not considered to be related to the IMP / intervention

Possibly Related – although a relationship to the IMP / intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship make other explanations possible.

Probably Related – the temporal relationship and absence of a more likely explanation suggest the event could be related to the IMP / intervention

Definitely Related – the known effects of the IMP, its therapeutic class or based on challenge testing suggests that the IMP / intervention is the most likely cause.

11.3 Procedure for Recording and Reporting Adverse Events

Cognitive Behavioural Therapy and Cognitive Behavioural Group Therapy are well established therapeutic interventions for anxiety and depression with a particularly good safety basis. However adverse reactions and events can occur (for example suicidal thoughts after exposure, dissociation, destabilisation, emergence of new feelings, strains in existing relationships, non-adherence to therapy structure). The severity of any of any occurring events will be assessed on the above ‘Mild’ / ‘Moderate’ / ‘Severe’ scale. If ‘Mild’ they are not required to be reported. If moderate or severe the procedure is followed as outlined in GMMH RDSOP41 Recording and Reporting Adverse Events for non-CTIMPs. All Adverse Events considered related to the trial as judged by a medically qualified investigator will be followed either until resolution, or the event is considered stable.

It will be left to the Investigator’s clinical judgment to decide whether or not an AE is of sufficient severity to require the participant’s removal from treatment. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable AE. If either of these occurs, the participant will be followed-up and be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable.

12 DISSEMINIATION POLICY

12.1 Dissemination policy

The Chief investigator and the sponsor owns the data arising from the study.

On completion of the study, a Final Study Report will be prepared.

The study data will aim to be published in a relevant peer reviewed journal.

Once the data is analysed and the write up completed, participants are welcome to receive findings.

If the study is published in a journal, participants will also have the opportunity to receive a copy of the published paper.

12.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be based on the international committee of medical journal editors authorship criteria.

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13. APPENDICIES

13.1 Appendix 1 – Required Documentation

Curriculum vitae of Chief investigator

13.1 Appendix 2 – Proposed Schedule

Activity	Start			In Progress			Complete											
		Duration	Feb 21	Mar 21	Apr 21	May 21	June 21	July 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 22	Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22
Obtain IRIS approval																			
Obtain ISRCTN registration																			
Recruit Participants																			
CBT Group and follow up																			
Write up and submission																			
Publication																			

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1	14/03/21	McMeekin	
1.2	1.2	30/03/21	McMeekin	
1.3	1.3	16/05/21	McMeekin	
1.4	1.4	09/08/21	McMeekin	
1.5	1.5	10/08/21	McMeekin	Addition sponsor number