Greater Manchester Mental Health
NHS Foundation Trust

Specialist Perinatal Community Mental Health Team Research
Aaron McMeekin
Consultant Perinatal Psychiatrist
CBT master's Student at the University of Oxford.
aaron.mcmeekin@gmmh.nhs.uk
11th Floor
Hexagon Tower
Crumpsall Vale
Manchester
M9 8GQ
Tel 0161 271 0319

PARTICIPANT INFORMATION LEAFLET

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

VERSION NUMBER	1.7
IRAS NUMBER	272394
CHIEF INVESTIGATOR'S NAME:	Aaron McMeekin
CHIEF INVESTIGATOR'S TITLE:	CBT Therapist, Consultant Perinatal Psychiatrist
TELEPHONE NUMBER:	01612710319 / 01612710188
CONTACT ADDRESS:	Greater Manchester Mental Health NHS Foundation Trust Hexagon Tower, Crumpsall Vale, Manchester, M9 8GQ

INTRODUCTION

Dear _____

You are invited to take part in a research study undertaken with, and sponsored by, Greater Manchester Mental Health NHS Foundation Trust Perinatal Service (GMMH). Thank you for considering taking part in this treatment.

Before you decide whether to take part in the study, please read the information below. This will allow you to understand why the research is being done and what your involvement might be. If you wish, please discuss this information with family, friends or your health care professional. Take the time to read the information carefully and do not feel rushed to make any decision.

This leaflet will allow you to clearly understand any risks and benefits about taking part in this study, to make a decision that is right for you. This process is known as 'Informed Consent'. Please ask questions if you are unsure of anything in this leaflet.

There is no obligation to take part in this study. If you decide not to take part, it will not affect your medical care. Once the study has started you are free to change your mind and opt out at any point.

If you choose to take part in the study, the treatment will be carried out at no cost to you financially.

WHAT IS THIS RESEARCH STUDY ABOUT?

We know that pregnancy and the period after delivery is a time of significant change for women and their families. A mum can experience a variety of emotions and challenges. Some mums are at greater risk of mental health issues including depression and anxiety.

Talking (psychological) treatments are available for mums, but there is not a lot of evidence for this. There is even less evidence for the use of group talking treatments for mums. The COVID-19 pandemic has made it more complicated for mums to access mental health services. Mums can find it challenging to attend appointments, getting on public transport is more difficult and there are worries about social distancing.

To help develop a therapy for mums, we have created a group using Cognitive Behavioural Therapy (CBT) as a treatment for mothers with anxiety or depression. This will take place on a video platform (Microsoft Teams) with a group of six to ten women. Mums can take part in the group in the privacy of their own homes. Babies are encouraged to attend.

WHO IS ORGANISING THE STUDY?

The lead researcher is Aaron McMeekin who is a Consultant Perinatal Psychiatrist at Greater Manchester Mental Health NHS Foundation Trust (GMMH). Aaron has qualifications and an interest in Cognitive Behavioural Therapy (CBT). This research is being sponsored by GMMH and Aaron is also studying a Master of Science programme in CBT at the University of Oxford.

Aaron McMeekin will run the group with the assistance of a higher trainee in psychiatry, Will Davis, who also has an interest in CBT.

WHY AM I BEING ASKED TO TAKE PART?

You are being asked because a health professional in your perinatal community mental health team (for example your care co-ordinator or psychiatrist or specialist midwife) thinks you may benefit from Cognitive Behavioural Group Therapy. They consider this may help with periods of anxiety or low mood. They feel you may benefit from treatment in a group with women who have had similar experiences.

HOW WILL THE STUDY BE CARRIED OUT?

The study will involve participants, like you, who are already clients in the GMMH Perinatal Service. The group is proposed to begin in the summer / Autumn of 2021.

We aim to recruit between six to ten women to take part in the group.

Taking part in the CBT group will not affect your normal treatment in your Perinatal Team.

WHAT HAPPENS NEXT AND IF I DECIDE TO TAKE PART ON THE STUDY

You have as much time as you need over the next seven days to decide if you would like to take part in this study. Please use that time to read the information in this sheet carefully. You are welcome to contact the lead researcher to ask any questions you require on the phone numbers above.

If you wish to participate in the study, you can either choose to make contact with the researcher on the contact details given, or they can contact you. Aaron will answer any questions you may have about taking part in the study.

We will ask you sign a written consent form. The consent form will be sent out to you in the post or by email. You can sign this and hand it into the clinic or to the researcher. Or can scan and email it back. We will also ask your consent for the lead researcher to access your GMMH electronic record for information that is relevant to the research and to allow contact information to be obtained.

We will organise a meeting with the lead researcher Aaron. This can be either face to face or via video link. This meeting gives you another chance to ask further questions. Aaron will undertake a clinical assessment to confirm your suitability for the group therapy and a risk assessment. Aaron will discuss a time frame for the therapy and the expected starting date.

Aaron will write to your General Practitioner informing them you are taking part in the therapy.

When the group begins you will attend 10 sessions of Cognitive Behavioural Group Therapy (one per week). There will be one final follow up session 8 weeks after the end of the 10 sessions. This will allow a reflection and 'top up' for the group.

Each session will be via video link on Microsoft TEAMS. If you are in the period after delivery, we encourage you to bring your baby. Each group session will be approximately 2 hours long with breaks to allow you to get a refreshment. If your baby is with you there is flexibility to allow you to change baby, comfort baby or breastfeed / bottle-feed. The amount of privacy you need to do any of these things will be accommodated.

As this is a research project, we will ask you to complete questionnaire scores at each appointment. These will be in the form of short scales to let us know how you are feeling and tell us about any anxiety or low mood you might have. At the final follow up session we will also ask five general questions about the research study and your thoughts on the study. All this information will be anonymised and analysed for a research dissertation.

After each session Aaron will place a paragraph summary in your GMMH 'PARIS' electronic record. This will state you attended, the number of the session, the headline theme of the session and a brief risk assessment. Once uploaded this information will remain on PARIS as part of your clinical record.

During the research you will be able to continue your normal treatment programme through your GMMH Perinatal team.

The expected participation time should be approximately four to five months. This includes the initial time you have to consider taking part in the research, the 10 sessions of therapy and then the follow up session after 8 weeks.

WHAT ARE THE POSSIBLE DISADVANTAGES, SIDE EFFECTS, RISKS, AND/OR DISCOMFORTS OF UNDERTAKING THE STUDY?

We can reassure you that participating in research is common in the NHS and hugely valuable. The majority of people who participate in research find the process helpful, fulfilling, and in many cases fun and enjoyable. We hope that will be the case with this group.

However, for some people, taking part in a talking therapy can result in exploring upsetting thoughts from the present, or memories from the past. If this occurs, please be reassured this can happen in normal therapy. Aaron the lead researcher is an experienced perinatal consultant psychiatrist and the co-facilitator, Will, a higher trainee in psychiatry. You will have the opportunity to discuss these issues with one or both professionals. Aaron and Will, will ensure a help strategy is in place and will discuss different options with you to make sure you feel supported.

For some clients when completing their questionnaire scores, this might bring into focus worries about their mental health and how it impacts their day to day functioning. Please be reassured there will be opportunities to discuss these scores with Aaron and Will after each session.

We are aware that unforeseen events, outside of the research, can occur. For example social, physical health or housing circumstances might change. If an unforeseen situation occurs, please discuss this (if you wish) with the group facilitators. We will try to accommodate any change in the group, offer signposting for support and also alert your own Perinatal team (if you wish) to obtain further support.

A big issue for any mum is the safety of their baby. If any concerns become known (regarding any participant in the group) of a safety issue regarding another mum or baby, then confidentiality may need to be broken and appropriate mental health or social services involved. Please be reassured this will aim to be done in cooperation with the person as a supportive measure. Be reassured both your safety and your baby's safety is our priority.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

Cognitive Behavioural Group Therapy is intended to be a positive experience. We hope therapy will not only reduce distress (and help you feel better), but also give you tools to carry on feeling better with your child.

We hope the group is an opportunity to gain support from other mothers who have shared similar experiences. This may lead to the building of a support network, where you can champion each other.

Our intention is that video therapy will allow you to take part in a place of your choosing. We anticipate this will have a number of benefits. You will be in a comfortable environment. You will be able to social distance. If you bring your baby you will have familiar toys and changing materials at hand. We hope this will reduce costs (public or private transport) and make it practically easier to bring your baby to the group (as you won't have to travel the distance to the clinic).

By taking part in this study you will be helping mums as your feedback will give us an idea if this treatment might be suitable for others.

WHAT IF SOMETHING GOES WRONG WHEN I'M TAKING PART IN THE STUDY?

Aaron the lead researcher is an experienced perinatal consultant psychiatrist and Will (the co-facilitator) a higher trainee in psychiatry. They will ensure you have an opportunity to discuss any concerns and plan a pathway of support. This might include talking to your GMMH perinatal team or giving you relevant information on who to contact. Will and Aaron will ensure there is appropriate follow up contact to check how you are feeling.

The group therapy takes place via video link. If something goes wrong (or you wish to discuss a concern) there will be opportunity for a private video call either following the session or at a convenient time.

VIDEO AND AUDIO RECORDINGS

Each Cognitive Behavioural Group Session will be recorded by the lead researcher for the purpose of the research. The session will be recorded on the lead researcher's trust encrypted laptop and in no other location. It will not be shared with any other person, nor the participant's own perinatal team, nor any third party. The recording will be kept for one week following the session to allow anonymised notes to be made for the purpose of the research, and then deleted.

WILL IT COST ME ANY EXPENSES TO TAKE PART

No. You are not expected to have to undertake an activity outside your normal treatment process, therefore extra costs are not foreseen to occur. We only expect you to have a means for video communication (tablet, computer or phone) and a reasonable Wi-Fi signal.

WHAT WILL HAPPEN WHEN THE STUDY ENDS?

When the 10 sessions of therapy are completed you will have an additional follow up session after 8 weeks. This will allow you to reflect on the therapy, ask further questions and also 'top up' the therapy.

When the study ends you will continue under the care of your health care professional in the Perinatal CMHT and General Practitioner. You, or your team, may decide you want to access further therapy options or discuss other treatments.

At the end of the follow up session Aaron McMeekin will write to your General Practitioner informing them you have taken part and completed the therapy.

When the study ends data analysis and the research write up will be conducted by the chief investigator, Aaron McMeekin.

Once the data is analysed and the write up completed, you are welcome to receive the findings and discuss these with Aaron.

The final aim is to publish the study in a scientific journal. You will have the opportunity to receive a copy of the published paper.

GMMH will keep data relating to the research study in accordance with GMMH Standard Operating Procedure (SOP). Electronic archiving will be undertaken for a period of 5 years from completion of study or submission of the final report. This ensures there is a record of the original information available for a reasonable period of time.

The paragraph summary made by Aaron after each session will remain in your GMMH electronic record. This will form part of your clinical record.

Greater Manchester Mental Health NHS Foundation Trust (GMMH) is the sponsor and the data controller for this study. Individuals from GMMH and regulatory organisations may also look at your medical and research records to make sure the research team are acting correctly. The only people in GMMH who will have access to information that identifies you will be people who need to contact you about the study or audit the data collection process.

It's important for you to be aware your rights to access, change or move information that you provide for this research are limited. This is because researchers need to manage your information in specific ways in order for the research to be reliable and accurate. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you agree to take part in this study, you will have the option to take part in future relevant research using your data saved from this study.

You can find out more about how we use your information at

https://www.gmmh.nhs.uk/research and https://www.hra.nhs.uk/information-about-patients/

WHAT IF THERE IS A PROBLEM?

If you find the research or therapy unsatisfactory, you will be supported to contact your own perinatal team or the GMMH Customer Care Team. This will not affect your ongoing care or any future referrals.

The GMMH Customer Care Team can be contacted by telephone (0800 587 4793; freephone) and email customercare@gmmh.nhs.uk

WHAT IF I CHOOSE NOT TO TAKE PART?

Your participation in this study is entirely voluntary. If you choose not to take part, it will not affect your existing treatment.

If you agree to participate but subsequently choose to withdraw, you may do this at any time. You do not have to give a reason for this.

IS THE STUDY CONFIDENTIAL

Your identity in the study will remain confidential. Access to identifying study data will be restricted to the lead author Aaron McMeekin and his secretary Grace Booth. Will Davis (co-facilitator) will be aware of your name through facilitation of the group and will be aware of group discussions. However, Will Davis will not have access to your personal records.

You will be allocated a pseudonym (a made up name) and an anonymous number when you enter the study. This will allow your questionnaire scores, quotes and feedback to be attached to the pseudonym and not your real name.

Once we have data from the research, this will be stored in a statistical programme with each participant's anonymous number.

Once anonymised, data and analysis will be shared with Aaron's study supervisor (Dr Helen Kennerley) for the purpose of research guidance. No other persons will have access. Dr Kennerley will not be able to link anything in this data to you.

Consent forms, electronic assessment forms and recordings will be stored on Aaron's trust encrypted laptop. These will only be available to Aaron. If there is any paper material this will be stored in a locked filing cabinet in Aaron's office to which only he has access. The office is locked if Aaron is not present.

Any identifying material and hardcopies stored in the encrypted laptop or locked cabinet will be destroyed within 12 months of the research being completed.

After each session Aaron will place a paragraph summary in your GMMH 'PARIS' electronic record. This will state you attended, the number of the session, the headline theme of the session and a brief risk assessment. Once uploaded this information will remain on PARIS as part of your clinical record.

Your General Practitioner and health care professional from the perinatal CMHT will be informed you are taking part in the research.

DATA PROTECTION

Your data is protected under the General Data Protection Regulation (GDPR) https://gdpr-info.eu/

Personal data used in the study will be destroyed either within 12 months of the end of the study or when the Master's examination is completed, whichever happens first.

If an external party accesses the electronic database or statistical results they will not be able to identify you as a participant.

You have a right to right to request your data is not processed, unless this request would make it very difficult to continue the research. In this scenario Aaron would endeavour to ensure your wishes are followed and discuss options with you.

You have a right for any incorrect data to be deleted or corrected unless this request would make it very difficult to continue the research. In this scenario Aaron would endeavour to ensure your wishes are followed and discuss options with you.

Your data can be deleted, until the point it is anonymised and entered on the system. Following that it would be anonymous data and may be difficult to remove. Information entered on the GMMH electronic record cannot be deleted as it will form part of your clinical record. However, if there is an inaccuracy Aaron will endeavour to ensure this is corrected to your satisfaction.

Your personal data will not be used for future research or studies without your informed consent.

WHERE CAN I GET FURTHER INFORMATION?

If you have any further questions about the study and wish to speak to Aaron McMeekin, please contact the details below 9am – 5pm.

NAME: Aaron McMeekin (aaron.mcmeekin@gmmh.nhs.uk)

ADDRESS: 11th Floor, Hexagon Tower, M9 8GQ

TELEPHONE: 0161 2710319 / 0161 2710188