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Cognitive behavioural group therapy treatment via a video communications platform for perinatal anxiety and depression: A case series

Submission date
07/02/2021

Recruitment status
No longer recruiting

Registration date
31/08/2021

Overall study status
Completed

Last Edited
12/04/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The perinatal period (conception, pregnancy until 12 months postpartum) is a time of significant change with increased risk for the development of depression and anxiety for the mother. If untreated these conditions can have significant negative outcomes on mother and baby resulting in physical, mental and economic costs with resultant morbidity and even mortality.

In 2020-21 this situation has been complicated and compounded by the current COVID-19 pandemic. Mental Health and Social services have less one-to-one or group 'physical' contact time with clients. Mothers have concerns about catching COVID-19 and transmitting it to either their unborn child or new-born baby. This has resulted in a reluctance to attend physical face to face consultations and an additional anxiety for the perinatal period. This research project aims to be an opportunity to identify new ways of working in situations where physical face to face contact is either inadvisable, impractical or declined by the client.

This study proposes to implement Cognitive Behavioural Group Therapy with an emphasis on meeting the needs of new mothers (including incorporating time management strategies and focusing on mother-baby bonding). This research was prompted by an earlier perinatal Cognitive Behavioural Therapy orientated group service evaluation undertaken by the author when a higher trainee in perinatal psychiatry in 2014. However this research is not linked to that service evaluation.

This research aims to explore the efficacy of Cognitive Behavioural Group Therapy (CBGT) via a Video Communications Platform (Microsoft TEAMS) in reducing maternal anxiety and low mood during the perinatal period. Research regarding the efficacy of Cognitive Behavioural Therapy (CBT) on a one-to-one basis for treatment of these perinatal mental health conditions is increasing. However there remains limited data regarding CBGT for maternal perinatal anxiety and depression.

When completed, the conclusions from this research will be disseminated to my employing trust (Greater Manchester Mental Health NHS Foundation Trust - GMMH) and (if wished) to the

participants. An additional aim will be to present findings at conference and to publish the research in a suitable journal (for example the BACP journal 'Counselling & Psychotherapy Research'). Although this is a small study, there is an expectation it will contribute to the larger research base currently ongoing into alternative treatments and delivery of therapy in a time of a global pandemic.

Who can participate?
Women aged 18 to 50 years who have been diagnosed with mental health complaints during the period immediately before and after giving birth, currently under the Greater Manchester Mental Health NHS Foundation Trust (GMMH) Perinatal Service.

What does the study involve?
Participants will be invited to attend 10 weekly CBGT psycho-educational sessions via Microsoft TEAMS lasting two hours focusing on perinatal CBT topics. In addition, there will be a two-hour follow-up session held at a period of a further 8 weeks. Participants will be asked to complete questionnaires during each group session and the follow-up session.

What are the possible benefits and risks of participating?
Benefits:
Existing studies exploring Cognitive Behavioural Group Therapy demonstrate participants experience a positive change in their maternal development with a reduction in depressive symptoms. This positive change can continue after the group sessions end.
This CBGT research will aim to provide a specific therapy for women who are pregnant or who have given birth. This can reduce levels of maternal anxiety and depression leading to better bonding and attachment with their child. This in turn can aid a return to improved functioning (for example undertaking more activities of daily interaction with baby).

CBGT via video telecommunications can benefit participants in line with the NHS Five Year Forward View and The Long Term Plan. It can provide an evidence based at home therapy at a time convenient for the client group. Clients with a baby may find it difficult to attend therapy with transport, obtaining childcare and ongoing pandemic restrictions potential barriers to physical attendance. Video based GCBT has the potential for these difficulties to be reduced and allow baby to be present during the therapy in an environment of the mother's choosing.

The group based setting will aim to encourage mothers to become active participants, sharing lived experience, championing each other and forming support networks that last beyond the end of the group therapy.

CBGT can potentially provide clients with a valuable alternative to pharmaceutical options.

Risks
CBT has a research base for treating anxiety and depression in the perinatal period. Therefore 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 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.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2020 to July 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Aaron McMeekin, aaronmcmeekin@nhs.net

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272394

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Nil Known

Study information

Scientific Title
Telecommunication CBGT treatment for perinatal depression and anxiety

Study objectives
Is cognitive behavioural group therapy via a video communication platform effective at reducing levels of depression and anxiety for women within the perinatal period?

Ethics approval required

Old ethics approval format

Ethics approval(s)
Not provided at the time of registration

Study design
Single centre observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Mental and behavioural disorders associated with the puerperium, postnatal depression and anxiety

Interventions
Current interventions as of 09/09/2021:
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 1 and 2 of the Greater Manchester Mental Health NHS Foundation Trust (GMMH) Perinatal Service. Patients will therefore be recruited from secondary care.

The trial population will be women (aged 18-50) 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).

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:
1. Söchting, I., 2014. Cognitive Behavioral Group Therapy: Challenges And Opportunities
2. Wenzel, A. and Kleiman, K., 2015. Cognitive Behavioral Therapy For Perinatal Distress.
3. 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. 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.

Any distress in the session will be pre-empted and planned for. The purpose of two facilitators allows one to focus on CBGT techniques while the other monitors dynamics within the group. Clients attending the group will already be aware of a 'breakout channel' via the telecommunications platform which will provide privacy to talk to a facilitator either in session or following the session.
A risk strategy will be in place to ensure clients have a pathway of support. Professionals and clients will follow GMMH risk management protocol (this is to contact the client's own care coordinator, 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.

Previous interventions:
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.

The trial population will be women (aged 18-50) 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).

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).

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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.

Intervention Type
Behavioural

Primary outcome measure
Measured at each group session (unless otherwise noted):
1. Postnatal depression measured using the Edinburgh Postnatal Depression Scale (Cox, Holden and Sagovsky, 1987)
2. Anxiety measured using the GAD-7 anxiety scale (Spitzer, Kroenke, Williams and Löwe, 2006)
3. Psychological distress measured using the Core 10 short measure (Barkham et al., 2013)
4. Global distress measured using CORE-OM completed prior to the first session and following the final session

Secondary outcome measures
Participant feedback on sessions measured at the follow-up session. The statements will be as follows at rated on a 5-point Likert scale and each question will also have a free text box for comments:
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

Overall study start date
01/03/2020

Completion date
29/07/2022

Eligibility

Key inclusion criteria
1. Aged 18 to 50 years
2. Clients of the GMMH Perinatal Service
3. 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)
4. All women recruited will be under the care of a Greater Manchester Mental Health NHS Foundation Trust (GMMH) Perinatal team and will be identified during by their perinatal health professionals within their clusters
5. Clients will require access to a laptop, smartphone or tablet computer to enable the video-based group therapy to take place

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Clients who are severely psychologically distressed and unable to undertake therapy
2. 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
3. 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
4. Clients who are excessively misusing or dependent on alcohol or illicit substances
5. Clients who have ongoing physical issues that would make it very difficult or uncomfortable to attend a CBT group
6. 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 sometimes challenging demands of looking after a small child and the ongoing COVID-19 pandemic

Date of first enrolment
06/12/2021

Date of final enrolment
03/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road
Prestwich

Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
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researchoffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and Funded

Results and Publications

Publication and dissemination plan

The research study forms the completion of a Research Masters Degree at the University of Oxford. The lead author plans to publish the findings of this research in a relevant journal allowing the participants' experiences and feedback to influence future policy and/or research. Findings from the research will aim to be disseminated via journal publication and conference presentation. At all points in the research the author is open to suggestions from the clients for appropriate forms of dissemination, taking into account confidentiality and consent. GMMH Perinatal services have an active service user feedback forum and there is the option of presenting the findings to this group, again ensuring confidentiality and consent.

Intention to publish date
29/07/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Once the data is analysed and the write up completed, participants are welcome to receive findings. Data and results from the study will be published in a journal upon completion

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.7	16/05/2021	17/08/2021	No	Yes
Protocol file	version 1.6	21/02/2021	17/08/2021	No	No