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Optimising psychological treatment for anxiety disorders in pregnancy: a feasibility study for a trial of time-intensive CBT versus weekly CBT

Submission date
16/06/2019

Recruitment status
No longer recruiting

Registration date
27/06/2019

Overall study status
Completed

Last Edited
23/10/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims

Anxiety disorders include a range of problems including panic disorder, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD) and social anxiety disorder. They affect about 11% of pregnant women, impact on women's day to day functioning and often last into the postnatal period if untreated. In mothers, parenting, breastfeeding and mood can be affected and children are at an increased risk of developing behavioural and emotional difficulties. Anxiety during pregnancy has been linked to these effects on children and it is therefore an important time to treat maternal anxiety disorders. Cognitive behaviour therapy (CBT) is known to be an effective treatment for anxiety disorders. Many women prefer psychological treatments to medication during pregnancy and so this is often a good fit for women with these disorders. CBT is usually delivered over a period of three months. Recently, good results have been demonstrated with CBT delivered in fewer but longer sessions over two to three weeks for OCD, PTSD, panic disorder and social anxiety. However, this format has not yet been tested with pregnant women. The aim of this study is to investigate if a shorter format of a well-established psychological therapy for anxiety disorders can be used with pregnant women. It will establish if pregnant women find this format acceptable and useful, and if this way of delivering the treatment can later be tested in a large trial.

Who can participate?

Pregnant women over 18 with one of the anxiety disorders under investigation can take part. They must be eligible for treatment in South London and Maudsley NHS Trust (resident or referred for treatment in Lewisham, Lambeth, Southwark or Croydon) and begin the study before they are 25 weeks (updated 26/11/2019, previously: 20 weeks) pregnant.

What does the study involve?

This research is a small trial (known as a feasibility study). Women taking part receive either intensive CBT (IN-CBT) or standard CBT for their anxiety disorder. They are randomly allocated to one of these two treatments and each consists of individual treatment with a trained

therapist. Interviews with women undertaking the treatments investigate the views of both versions of CBT and if the study assessments are acceptable and useful. This information will determine if a larger trial testing IN-CBT against standard weekly CBT will later be possible.

What are the possible benefits and risks of participating?
CBT is an evidence-based treatment that is routinely offered for anxiety disorders and it is expected that all women taking part could benefit. Participants will have to complete some additional questionnaires which may be a burden.

Where is the study run from?
The study will take place in primary care psychological therapy centres in the South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2018 to September 2022

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Fiona Challacombe
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
232385

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 41746; IRAS 232385

Study information

Scientific Title
Optimising psychological treatment for Anxiety DisordErs in Pregnancy: a feasibility study for a Trial of time-intensive CBT versus weekly CBT (ADEPT)

Acronym
ADEPT

Study objectives
This is a feasibility study which aims to answer the following questions:
1. Is antenatal IN-CBT acceptable to women with anxiety disorders?
2. Is it feasible to test the effectiveness of IN-CBT compared with standard CBT in a full-scale trial?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2019, Surrey Borders NHS REC, Health Research Authority (Skipton House, 80 London Road, London SE1 6LH, Tel: +44 (0)20 7972 2568; Email: nrescommittee.london-surreyborders@nhs.net), ref: 19/LO/0622

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety disorders (post-traumatic stress disorder, obsessive-compulsive disorder, social anxiety disorder, panic disorder) in pregnant women

Interventions
Women taking part will receive either intensive CBT (IN-CBT) or standard CBT for their anxiety disorder. They will be randomly allocated to one of these two treatments and each arm consists of individual treatment with a trained therapist.

Standard CBT: This will comprise 8-10 hours (depending on the disorder) of one-to-one CBT on a one hour per week basis. This is termed 'high intensity' CBT in IAPT services and will be offered to all women who participate in the trial and are randomised to standard CBT. Two follow-up sessions of one hour will then be offered by the treating therapist which will include one in late pregnancy, one at 1 month postpartum.

Intensively delivered CBT (IN-CBT): This will deliver the disorder-specific treatment in 4-5 sessions over 1-2 weeks, delivered at the earliest convenient point between 5 and 8 months of pregnancy, and totalling 8-10 hours. Two follow-up sessions of one hour will then be offered which will include one in late pregnancy, one at 1 month postpartum.

Interviews with women undertaking the treatments will investigate views of both versions of CBT and if the study assessments are acceptable and useful. This information will determine if a larger trial testing IN-CBT against standard weekly CBT will later be possible.

Added 17/06/2020:
Treatments may take place via phone or video link using Microsoft Teams, depending on current public health restrictions.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 17/06/2020:
This is a feasibility study so feasibility parameters (primarily recruitment and participation) are the main outcomes and one aim is to determine the primary outcome of a full-scale trial.
1. Recruitment rate defined as the number of participants recruited/month. An acceptable recruitment rate would be at least 3 participants/month
2. Acceptability of randomisation. A take-up of >70% of eligible participants is required to be deemed feasible.
3. If the intervention is received as intended in both arms in terms of being the intended mode of treatment and treatment fidelity using a content checklist. A minimum of 70% of participants in the trial would need to complete >60% of each intervention in hours for each to be deemed feasible, i.e. 7.5 hours out of 12. For completers in the intensive arm, these treatment hours (8 out of 10 hours) will need to be completed in the two-week window for IN-CBT to be considered

to be delivered as intended
4. Acceptability of both interventions to participants; this will be determined by qualitative investigation, a brief rating scale asking if the treatment was useful at the end of treatment and numbers completing treatment
5. Participation and data completion at 3-month outcome assessment; a follow-up rate of >70% is required to determine feasibility
6. Acceptability of assessment measures to participants; this will be determined by qualitative interview and brief rating scales asking if it was useful and clear

Previous primary outcome measures:
This is a feasibility study so feasibility parameters (primarily recruitment and participation) are the main outcomes and one aim is to determine the primary outcome of a full-scale trial.
1. Recruitment rate defined as the number of participants recruited/month. An acceptable recruitment rate would be at least 3 participants/month
2. Acceptability of randomisation. A take-up of >70% of eligible participants is required to be deemed feasible.
3. If the intervention is received as intended in both arms in terms of being the intended mode of treatment and treatment fidelity using a content checklist. A minimum of 80% of participants in the trial would need to complete >60% of each intervention in hours for each to be deemed feasible, i.e. 7.5 hours out of 12. For completers in the intensive arm, these treatment hours (8 out of 10 hours) will need to be completed in the two-week window for IN-CBT to be considered to be delivered as intended
4. Acceptability of both interventions to participants; this will be determined by qualitative investigation, a brief rating scale asking if the treatment was useful at the end of treatment and numbers completing treatment
5. Participation and data completion at 3-month outcome assessment; a follow-up rate of >80% is required to determine feasibility
6. Acceptability of assessment measures to participants; this will be determined by qualitative interview and brief rating scales asking if it was useful and clear

Key secondary outcome(s))

Current secondary outcome measures as of 26/11/2019:
Measured at pre-treatment baseline assessment, every treatment session, after the first 2 hours of treatment, late pregnancy follow up session, 1-month postnatal follow-up session, 3 months outcome:
1. Anxiety measured using GAD-7. This is the potential primary outcome measure of a full-scale trial
2. Depression symptoms measured using PHQ-9
3. Impact of a person's mental health difficulties on their ability to function in terms of work, home management, social leisure, private leisure and personal or family relationships measured using the Work and Social Adjustment Scale
5. Disorder specific measures: one of the following will be used depending on primary disorder.
5.1. OCD symptoms measured using the Obsessive-Compulsive Inventory-Revised (OCI)
5.2. Panic. Avoidance of a range of specific situations over the last week measured using the Mobility Inventory (alone)
5.3. PTSD symptoms measured using the Impact of Events Scale (IES)
5.4. Social Phobia severity measured by the Social Phobia Inventory (SPIN)
Measured after the first 2 hours of treatment only:
6. Therapeutic alliance between participant and therapist measured using the Working Alliance Inventory – Short Revised
Measured at pre-treatment baseline assessment, late pregnancy follow up session, 1-month

postnatal follow-up session:
7. Pregnancy anxiety measured using the Pregnancy-Related Anxiety Questionnaire (PRAQ)
Measured at 1-month postnatal follow-up session, 3 months outcome:
8. Maternal perception of her felt bonding with the infant measured using the Postpartum Bonding Questionnaire (PBQ)

Measured at 3 months outcome only:
9. Mother-Infant Interactions captured in a 3-minute video clips taken during play and nappy change at home and subsequently assessed by a trained rater using the CARE Index
10. Resource use measured using the Adult Service Use Measure (AD-SUS)
11. Qualitative interview to investigate treatment experiences in women undergoing IN-CBT and those undergoing standard CBT (in a subset of participants)

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Previous secondary outcome measures:
Anxiety symptoms measured using GAD-7 pre and post treatment

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/11/2019:
1. Women over the age of 18 years
2. A current primary anxiety disorder according to DSM-V criteria OCD, PTSD, Social anxiety or panic disorder)
3. Pregnant (12 weeks – 25 weeks)
4. Eligible to be seen under Lambeth, Lewisham, Southwark, Croydon IAPT services
5. Available for either intensive or weekly treatment
6. Either not on psychotropic medication or on a stable dose of medication for at least six weeks with no plans to change this during the intervention

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5. Available for either intensive or weekly treatment
6. Either not on psychotropic medication or on a stable dose of medication for at least six weeks with no plans to change this during the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
59

Key exclusion criteria
Current exclusion criteria as of 26/11/2019:
1. Women with a primary DSM-V depressive disorder, affective or psychotic disorder or current problems with substance abuse
2. Women with 'complex PTSD' (prolonged multiple traumas affecting a number of domains)
3. Women who have high-risk conditions requiring significant additional management (e.g. Multiple Sclerosis, Lupus, Polycystic Ovary Syndrome)
4. Women who are receiving psychological therapy elsewhere
5. Unable to read English adequately to complete questionnaires

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Previous exclusion criteria:
1. Women with a primary DSM-V depressive disorder, affective or psychotic disorder or current problems with substance abuse
2. Women with 'complex PTSD' (prolonged multiple traumas affecting a number of domains)
3. Women who have a medically high-risk pregnancy at the time of recruitment
4. Women who are receiving psychological therapy elsewhere
5. Unable to read English adequately to complete questionnaires

Date of first enrolment
15/07/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London and Maudsley NHS Trust
Maudsley Hospital
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the numbers are small and so potentially identifiable. Data will be held at King's College London as per IG protocols.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/10/2023	23/10/2023	Yes	No
Protocol article		30/04/2021	13/08/2021	Yes	No

HRA research summary			28/06/2023	No	No
Other publications	Qualitative analysis	12/10/2023	12/10/2023	Yes	No
Participant information sheet	version v3	22/09/2019	26/11/2019	No	Yes
Participant information sheet	version V4	03/06/2020	17/06/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V1	06/02/2019	27/06/2019	No	No
Protocol file	version v2	19/09/2019	26/11/2019	No	No
Protocol file	version V3	03/06/2020	17/06/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes