ISRCTN51098220 https://doi.org/10.1186/ISRCTN51098220

The P3 PAAD Trial: A randomized trial testing the effectiveness of remote peer-administered therapeutic support for antenatal depression

Submission date
05/04/2022

Recruitment status
No longer recruiting

Registration date
08/04/2022

Overall study status
Ongoing

Last Edited
24/06/2024

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:
Antenatal depression (AD), or depression during pregnancy, is the most common complication of pregnancy in developed countries and increases risk of preterm birth (PTB). Many pregnant individuals with AD do not obtain treatment due in part to risks associated with antidepressant medications, the expense and wait times for psychological services, and perceived stigma. Accessible and timely treatment of antenatal depression is crucial to treat mental health concerns, minimize fetal impacts and associated long-term child health outcomes.
The purpose of this research study is to:
• determine the effectiveness of online therapy for pregnant people with depression in reducing preterm birth; and
• determine whether the therapy intervention will be effective for treating antenatal depression prior to delivery; improving anxiety symptoms

Who can participate:
• Participants will include individuals who:
- have previously consented to be part of the P3 Cohort study
- are pregnant and currently less than 27 weeks pregnant;
- are 18 years of age or older; and
- scored greater or equal to 10 on the Edinburgh Postnatal Depression Scale on the P3 Cohort baseline questionnaire;
- live in the Calgary Zone of Alberta Health Services; and
- are English-speaking.

• Peer counsellors will include individuals:
- with previous lived experiences of antenatal or postpartum depression and have recovered;
- who have completed a minimum of some post-secondary education;
- who have demonstrated basic understanding of mental health and an openness to evidence-based treatments for depression;
- who live in the Calgary Zone of Alberta Health Services; and
- who are English-speaking

What does the study involve?
• In the first week of enrolment, participants will be randomly assigned to either the treatment or intervention group, and this will determine if they will receive a counselling intervention to treat depression or receive a normal standard of care.
• If participants are assigned to the counselling intervention group, they will have their first counselling session over the phone or video conference during weeks 3-6 of enrollment. Participants will also receive informal peer-support from their peer counsellor on a regular basis. If a participant is assigned to the control group, they will continue to receive a normal standard of care.
• During weeks 6-8 of enrollment, participants from both groups will be invited to complete an online questionnaire specific to this study. Some questions may be sensitive in nature (e.g., questions about anxiety, depressed mood). All questionnaires will be completed online using Qualtrics survey platform.
• If a participant is in the counseling intervention group, they will continue to receive peer-support from their peer counsellor in the form of social support, advice, and information sharing 6 weeks after delivery.

What are the possible benefits and risks of participating?
Benefits for participants:
Participants who are in the counseling intervention group may find the counseling intervention beneficial to them.
Risks for participants:
Although the outcome of counseling is often positive, it often involves sharing sensitive, personal, and private information that may at times be distressing. In addition, participants will be completing questionnaires which may be sensitive in nature (e.g., questions about anxiety, depressed mood).

Benefits for peer counsellors:
Peer counsellors will receive training in behavioural activation techniques, telephone counselling and peer-support. These skills could contribute to personal knowledge and/or professional development.
Risks for peer counsellors:
Peer counsellors may feel stressed in training as it may be difficult for them to grasp concepts, however the risk is minimal and the level of stress possible would likely be very low

Overall Benefits/Risks Analysis:
If successful, a prenatal distanced-based intervention could improve maternal mental health and reduce the risk of preterm birth. The benefits of this study greatly outweigh the risks. The risks to participating in this research are minor and the benefits of this study to the medical and scholarly communities are significant.

Where is the study run from?
University of Calgary (Canada)

When is the study starting and how long is it expected to run for?
February 2020 to December 2031

Who is funding the study?
This work is supported by a joint operating grant from the Calgary Health Trust, and the Alberta Children’s Hospital Foundation (Canada)

Who is the main contact?
Kathleen Chaput, PhD, khchaput@ucalgary.ca

Study website
https://p3cohort.ca/paad_trial/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Kathleen Chaput

ORCID ID
http://orcid.org/0000-0001-7596-6019

Contact details
Department of Obstetrics & Gynecology
Foothills Medical Centre
4th Flr North Tower
1441-29 St NW
Calgary
Canada
T2N 4J8
+1 403-944-4009
khchaput@ucalgary.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
REB21-1162

Study information

Scientific Title
Effect of remote, Peer-Administered behavioural Activation and peer-support intervention for Antenatal Depression on gestational age at delivery: the single-blind, randomized control PAAD trial

Acronym

PAAD trial

Study objectives
The primary aim of this study is to conduct a randomized controlled trial to determine the effectiveness of remote, peer delivered behavioural activation therapeutic support, to individuals with antenatal depression in reducing preterm birth. We hypothesize that our intervention will be associated with an increase in gestational age at delivery compared to the standard of care.

The secondary aims of this trial are to determine whether the peer-administered intervention will be effective for treating antenatal depression prior to delivery, with persistence to 6 and 12 months postpartum; and improving anxiety symptoms.
We hypothesize that participants in the intervention group will have:
(a) Significantly greater reduction in depression symptoms from T1 to T2, and significantly lower odds of depression at T2, T3 and T4 compared to controls; and
(b) Significantly greater reduction in anxiety symptoms from T1 to T2, and significantly lower odds of anxiety at T2, T3 and T4 compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Conjoint Health Research Ethics Board (2500 University Drive N.W. Calgary, AB T2N 1N4, Canada; +1 403-220-2297; chreb@ucalgary.ca), ref: REB21-1162

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Therapy intervention for depression in pregnant individuals (antenatal depression).

Interventions
A two-arm, single-blinded, parallel groups randomized controlled trial with repeated measures will be conducted. Participants scoring >10 on the Edinburgh Postnatal Depression Scale will be recruited from the larger P3 Cohort and invited to enroll. Assessments will be conducted prior to

27 weeks' gestation at trial intake (T1), post-intervention, prior to delivery (T2), 5-6 months postpartum (T3), and 11-12 months postpartum (T4) and will include self-report questionnaires and linked medical records.

Note, the T1, T2, T3 and T4 questionnaires are questionnaires that are administered as part of the P3 Cohort study (REB20-1635). In addition, there are some additional study-specific questions that are sent out with the T2 questionnaire.
Note: footnotes and references are not required here. Research methods questions, in later section, will prompt additional questions and information

After providing informed consent, peer counsellors will complete a 5-week, pilot-tested Behavioral Activation (BA) training program. BA training consists of weekly online training videos and weekly virtual meetings with a supervising clinical psychologist, post-doctoral trainees in clinical psychology, and other peer counsellors to review the training content. After initial training, peer counsellors will complete a mock-counselling session with trainers to ensure their proficiency in applying the content from each training module. Finally the supervising psychologist will certify peers to move forward to administer the trial intervention, based on a final assessment of their BA knowledge, and competence with applying the intervention materials.

Once certified, peer counsellors will be paired with a single randomized participant and will establish contact with them to initiate and administer the intervention. Our randomization is being conducted using an online randomisation tool. The peer-delivered intervention will be conducted over telephone and/or internet video conference between the peer counsellors and participants. In addition to between 6 and 10 structured, BA therapeutic support sessions, peer counsellors will also provide informal and unstructured peer support via phone and/or text. This will include both participant-initiated and peer-counsellor-initiated check-ins, sharing of information, and peer-guidance. The peer support component will be available to participants up to 6 weeks postpartum. Peer counsellors may opt to be paired with subsequent participants following completion of the intervention and peer support components. All peer counsellors will receive weekly clinical supervision via 60-minute remote group meetings provided by a postdoctoral trainee in clinical psychology, and additional individual supervision meetings as needed, to ensure patient safety and treatment fidelity, and peer-counsellor adherence to the protocol.

The control group will receive treatment as usual, including receiving routine obstetric care and referral to community mental health resources, and will complete study assessments.

Intervention Type
Behavioural

Primary outcome measure
Gestational age at birth in days, measured using electronic health records.

Secondary outcome measures
1. Symptoms of depression at T1 and T2 measured as the overall score on the EPDS; and lower odds of scoring 10 or greater on the EPDS at T2, T3, and T4.
2. Symptoms of anxiety across all timepoints (measured by self-report questionnaire)

Trial intake (T1), post-intervention, prior to delivery (T2), 5-6 months postpartum (T3), and 11-12 months postpartum (T4)

Overall study start date
28/02/2020

Completion date
31/12/2031

Eligibility

Key inclusion criteria
Participants will be included if they:
1. Are pregnant
2. Reside in the Calgary Zone of Alberta Health Services
3. Are 18 years of age or older
4. Score greater than or equal to 10 on the Edinburgh Postnatal Depression Scale, which indicates a probable depression.
5. Participants who have been on a stable dose of anti-depressant medications (SSRIs) for three months or more, prior to pregnancy are eligible to participate.

Peer counsellors will be included if they:
1. Are mothers (or the birth-giving parent), and have recovered from past antenatal depression or postpartum depression, as this will give them the peer-perspective on the experiences and needs of the intended patient population;
2. Have at least some completed post-secondary education, as this indicates the level of education adequate to understand and enact the content, theory and practical aspects of the intervention
3. Demonstrate basic understanding of mental health, and openness to evidence-based treatments for depression as this will allow for successful and ethical delivery of the intervention

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Our target number of participants is 250. Of these participants, 125 will be controls.

Key exclusion criteria
Participants will be excluded if they:
1. Have a lifetime diagnosis of severe psychiatric illness (bipolar disorder, schizophrenia, borderline personality disorder, other psychoses), as these individuals need professional assistance beyond that which peer counsellors can provide.
2. Are engaged in an active treatment regimen for a diagnosed mental illness (counselling; non-SSRI medications), as this would act as a potential confounding variable

Peer counsellors will be excluded if they:
1. Screen positive for one or more of anxiety, depression or high stress, as these would preclude them from being suitable peer-counsellors
2. Cannot communicate effectively in English, as our study budget precludes the use of any translation services

Date of first enrolment
11/04/2022

Date of final enrolment
09/06/2023

Locations

Countries of recruitment
Canada

Study participating centre
University of Calgary
Department of Obstetrics & Gynecology
Foothills Medical Centre
4th Flr North Tower
1441-29 St NW
Calgary
Canada
T2N 4J8

Sponsor information

Organisation
University of Calgary

Sponsor details
Department of Obstetrics & Gynecology
Foothills Medical Centre
4th Flr North Tower
1441-29 St NW
Calgary
Canada
T2N 4J8
+1 403-220-7938
chreb@ucalgary.ca

Sponsor type
University/education

Website
http://www.ucalgary.ca/

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
Charity

Funder Name
Alberta Children's Hospital Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Calgary Health Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2032

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/03/2023	31/03/2023	Yes	No