ISRCTN56529202 https://doi.org/10.1186/ISRCTN56529202

Evaluating collaborative care for postpartum depression in pediatric primary care settings (EPDS) trial

Submission date
23/09/2014

Recruitment status
No longer recruiting

Registration date
02/10/2014

Overall study status
Completed

Last Edited
02/10/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In Canada, over 49,000 mothers experienced depression in the first year following childbirth. This, in turn, has put the healthy development of at least 80,000 children at risk. This is because postpartum depression can affect a mothers ability to look after their child. Symptoms can include a lack of energy, feeling irritable, having problems concentrating and not being able to meet her babies needs for love and affection. This may result in a number of damaging effects to the baby, including the baby being slower than usual to speak (delayed language development), problems emotionally bonding to others and behavioural problems. Postpartum depression has been clearly identified as something that can affect a childs long-term development. Finding treatments to successfully treat the condition is, therefore, essential. Unfortunately, postpartum depression often remains undetected and untreated. Collaborative care is a proven, successful approach to treating people with depression. It involves a number of different mental health professionals working together and with the patient and their loved ones. It includes diagnosis and treatment, management of the condition and providing support to the family as required. However, this approach has not yet been looked at as a possible treatment for postpartum depression. Here, we want to look at the effect of a collaborative care type of treatment on postpartum depression among mothers attending well-child visits in an early childhood primary care practice.

Who can participate?
Mothers aged ≥ 18 years, participating in the TARGet Kids! study, have given birth less than 6 months ago and suffering from depression. The TARGet Kids! study is a research study that is investigating how health issues early in life can lead to health problems as an adult.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive standard postpartum care and also collaborative care. Those in group 2 only receive standard postpartum care. All participants are asked to complete questionnaires (either online or by telephone) 6

months, 9 months and, finally, 1 year later. Some information about the participants child is also collected through their participation in the TARGet Kids! study during routine medical appointments at 12, 18, and 24 months.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part in this study. However, the results from the study are likely to present valuable information about how to successfully manage postpartum depression. In addition to this, if participants indicate that they may harm their baby or any other children, child welfare services will be contacted, as required by law. In the event of any immediate safety concerns or danger, emergency services (9-1-1) will be called. In these rare instances, participation may indicate possible psychological, social, and legal risks.

Where is the study run from?
The trial has been set up by the University of Toronto (Canada) in collaboration with the Hospital for Sick Children in Toronto (Canada).

When is the study starting and how long is it expected to run for?
January 2015 to March 2020

Who is funding the study?
The Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?
Dr Cindy-Lee Dennis
cindylee.dennis@utoronto.ca

Contact information

Type(s)
Scientific

Contact name
Dr Cindy-Lee Dennis

Contact details
University of Toronto
Lawrence S. Bloomberg Faculty of Nursing
155 College Street
Suite 130
Toronto
Canada
M5T 1P8
+1 (0) 416 946 8608
cindylee.dennis@utoronto.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOP-133601

Study information

Scientific Title
Evaluating collaborative care for Postpartum Depression in pediatric primary care Settings (EPDS) trial: a multi-centre randomised controlled trial

Acronym
EPDS Trial

Study objectives
We hypothesize that mothers who receive the studys collaborative care treatment, compared to those who receive usual postpartum care, will have (1) decreased rates of depressive symptoms and anxiety, and (2) increased quality of life and health service use for mental health issues. Children of depressed mothers who receive the treatment will have better cognitive, behavioural, and language outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Toronto Office of Research Ethics, 4/9/2014, ref. #30497

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Postpartum depression

Interventions

Mothers randomly assigned to the treatment group will have access to usual postpartum care in addition to the treatment provided by the study, which will include the four standard criteria for collaborative care: (1) a multi-professional approach to care; (2) a structured management plan; (3) scheduled participant follow-ups; and (4) enhanced inter-professional communication.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depressive symptoms as identified by the EPDS and Structured Clinical Interview for DSM-V (SCID-V) at 6 months post-randomization (immediately post-treatment)

Secondary outcome measures
What is the effect of the collaborative care treatment on:
The mothers
1. Depressive symptoms at 9 and 12 months post-randomization?
2. Anxiety at 6, 9, and 12 months post-randomization?
3. Quality of life at 6, 9, and 12 months post-randomization?
4. Health service use at 12 months randomization?
The childs
5. Cognitive development at 24 months of age?
6. Temperament at 12 and 24 months of age?
7. Language development at 18 months of age?
Other questions:
1. What is the nature and intensity of the collaborative care treatment activities?
2. What are mothers evaluations of their collaborative care experience?
3. Cost implications?

Overall study start date
05/01/2015

Completion date
31/03/2020

Eligibility

Key inclusion criteria
Mothers who meet the following criteria:
1. Has a healthy child participating in the TARGet Kids! study
2. Is between 0 to 6 months postpartum
3. Edinburgh Postnatal Depression Scale (EPDS) score >9 at TARGet Kids! baseline and trial recruitment (2-stage assessment)
4. Understands spoken English

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
360

Key exclusion criteria
1. Current use of antidepressant medication
2. Current receipt of any form of psychotherapy administered by a trained professional
3. Active suicidal or self-harm thoughts

Date of first enrolment
05/01/2015

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
University of Toronto
Toronto
Canada
M5T 1P8

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
Lawrence S. Bloomberg Faculty of Nursing
155 College Street
Suite 130
Toronto
Canada
M5T 1P8
+1 (0) 416 978 2392
cindylee.dennis@utoronto.ca

Sponsor type
University/education

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health - CIHR (MOP-133601) (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration