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Postpartum depression interpersonal psychotherapy trial

Submission date	Recruitment status	[X] Prospectively registered
30/03/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/02/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Postpartum depression (PPD) is a type of depression that many women experience after having a baby. Women who have suffered from PPD are twice as likely to experience future episodes of depression over a 5-year period. PPD can affect mother-infant interactions and lead to child neglect or abuse and marital stress resulting in separation or divorce. Mother and infant deaths are rare but real consequences of PPD. Effective treatment of PPD is needed to not only help the mother but also to prevent these consequences. Antidepressant medication, cognitive behavioural therapy and interpersonal psychotherapy (IPT) are effective treatments for general depression. However, mothers are often reluctant to take antidepressants due to concerns about their transmission in breast milk or potential side effects. Although there is evidence that antidepressants are relatively safe for breastfed infants, it is important that non-drug treatments are tested for use with mothers. IPT may be an effective treatment for PPD. IPT is a brief manual-based psychotherapy that addresses relationship issues in depression. Generally, IPT consists of 12 to 20 weekly sessions lasting 50 to 60 minutes that may be provided by psychiatrists and a range of non-medical health professionals, including nurses. Unfortunately, IPT is not widely available, especially in rural and remote areas. To improve access to care, telepsychiatry has been introduced – this involves providing therapy by telephone. The aim of this study is to test the effect of telephone-based IPT on the treatment of PPD.

Who can participate?
Mothers who have had a baby 2 to 24 weeks ago and have PPD

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group receive usual postpartum care plus the telephone-based IPT. The telephone IPT includes 12 sessions with a highly trained IPT nurse. Each session is 50 minutes long and is scheduled on a weekly basis. The other group receive usual postpartum care. All participants are telephoned by one of our research nurses after 3, 6 and 9 months to ask about how they are feeling and the healthcare services they have used.

What are the possible benefits and risks of participating?
At the end of the study all participants receive a small token of appreciation. There are no known risks to participants.

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

When is the study starting and how long is it expected to run for?
September 2007 to February 2013

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

Who is the main contact?
1. Dr Cindy-Lee Dennis (cindylee.dennis@utoronto.ca)
2. Melissa Jovellanos (melissa.jovellanos@utoronto.ca)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-82332

Study information

Scientific Title
A randomised controlled trial to evaluate the effectiveness of telephone-based interpersonal psychotherapy for the treatment of postpartum depression

Study objectives
Primary question:
What is the effect of telephone-based Interpersonal Psychotherapy (IPT) by trained nurses on Postpartum Depression (PPD) at 12 weeks post-randomisation (i.e., immediately post-treatment for mothers in the intervention group)?

Secondary questions:
What is the effect of telephone-based IPT by trained nurses on:
1. PPD at 24 and 36 weeks post-randomisation (i.e., 12 and 24 weeks post-treatment for mothers in the intervention group)?
2. Depressive symptomatology at 12, 24, and 36 weeks post-randomisation?
3. Anxiety at 12, 24, and 36 weeks post-randomisation?
4. Social functioning at 12, 24, and 36 weeks post-randomisation?
5. Health service utilisation from randomisation to 36 weeks post-randomisation?

Amended as of 12/06/2009:
The following secondary question has been amended:
4. Attachment at 12, 24, and 36 weeks post-randomisation?
The following secondary question has been added:
6. Relationship quality and adjustment at 12, 24, and 36 weeks post-randomisation?

Other research questions:
1. What are the cost implications of IPT versus usual care, from a societal perspective?
2. What are mothers evaluations of their IPT experience?
3. What are nurses evaluations of their experience in providing IPT?
4. What are nurses reports of the type and intensity of their IPT activities?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Health Sciences 1 Research Ethics Board of the University of Toronto (Canada), 13/07/2006, ref: 17788

2. The Huron Country Health Unit (Canada), 12/10/2006
3. Health Sciences 1 Research Ethics Board of the University of Toronto (Canada) renewal granted 08/08/2007, expiry: 12/07/2008, ref: 20766
4. Health Sciences 1 Research Ethics Board of the University of Toronto (Canada) renewal granted 15/08/2008, expiry: 12/07/2009, ref: 22629

Study design
Multicentre two-arm randomised parallel trial with study investigator, caregiver, outcome assessor, and data analyst blinding

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Amended as of 12/06/2009:
Interpersonal psychotherapy: one-hour session of telephone-based interpersonal psychotherapy every week for 12 weeks (i.e., or a maximum of 16 sessions for up to 16 weeks per participant)
Standard care: what is usually provided by the health region for mothers identified with depressive symptomatology.

Initial information at time of registration:
Interpersonal psychotherapy: one-hour session of telephone-based interpersonal psychotherapy every week for 12 weeks beginning within 48 to 72 hours of trial randomisation.
Standard care: what is usually provided by the health region for mothers identified with depressive symptomatology.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Postpartum depression: 12 weeks post-randomisation (immediately post-treatment for mothers in the intervention group).

Secondary outcome measures
Amended as of 12/06/2009:
The following point was amended to:
4. Attachment measured with the Experiences in Close Relationships-Revised (self-report measure): 12, 24, and 36 weeks post-randomisation
The following point was added:
6. Relationship quality and adjustment with the Dyadic Adjustment Scale (self-report measure): 12, 24, and 36 weeks post-randomisation

Initial information at time of registration:
1. Postpartum depression (clinical diagnostic interview): 24 and 36 weeks post-randomisation (i.e., 12 and 24 weeks post-treatment for mothers in the intervention group
2. Depressive symptomatology (self-report measure): 12, 24, and 36 weeks post-randomisation
3. Anxiety measured with the Spielberger State-Anxiety Inventory (self report measure): 12, 24, and 36 weeks post-randomisation
4. Social functioning measured with the Social Adjustment Scale-Self Report (self report measure): 12, 24, and 36 weeks post-randomisation
5. Health service utilisation measured with a slightly modified version of the Health Service Utilisation and Cost of Care Questionnaire (self-report measure): from randomisation to 36 weeks post-randomisation

Overall study start date
01/09/2007

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Live birth
2. Infant discharged from hospital
3. Mother between two and 24 weeks postpartum
4. Clinical diagnosis of major depression using the Structured Clinical Interview for Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV)
5. Understands spoken English

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
240

Total final enrolment

241

Key exclusion criteria
Amended as of 12/06/2009:
The following point was amended to:
4. Chronic depression (episode length greater than 2 years)
The following point was added:
5. Current or past manic depression

Initial information at time of registration:
1. Current use of antidepressant medication
2. Currently receiving any form of psychotherapy administered by a trained professional
3. Active suicidal or self-harm thoughts
4. Chronic depression (episode length greater than 2.5 years)

Date of first enrolment
01/09/2007

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Canada

Study participating centre
University of Toronto
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Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-82332)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	19/04/2012		Yes	No
Results article	results	01/04/2020	10/02/2020	Yes	No