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Effectiveness of peer support for the prevention of postpartum depression

Submission date	Recruitment status	[ ] Prospectively registered
19/07/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/02/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00604604

Secondary identifying numbers
MCT 66874

Study information

Scientific Title
A randomised controlled trial to evaluate the effectiveness of peer (mother-to-mother) support for the prevention of postpartum depression

Study objectives
Among mothers at-risk for Post-Partum Depression (PPD) (Edinburgh Postnatal Depression Scale [EPDS] score more than nine), what is the effect of peer support on PPD at 12 weeks postpartum?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the University of Toronto research ethics board and other participating sites in the summer of 2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Mothers allocated to the peer support group will have access to all of the standard community postpartum services in addition to receiving telephone-based support from a peer volunteer (a mother who has previously experienced, and recovered from, postpartum depression and has participated in a 4-hour training session). Telephone contact will be initiated within 48 to 72 hours of trial randomisation and then as frequently as the dyad deems necessary.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Postpartum Depression (PPD), as diagnosed by the Structured Clinical Interview (SCID-I) for Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) at 12 weeks postpartum.

Secondary outcome measures
1. PPD, as diagnosed by the SCID-I, at 24 weeks postpartum
2. Depressive symptomatology, as measured by the EPDS, at 12 and 24 weeks postpartum
3. Anxiety, as measured by the Spielberger State-Anxiety Inventory, at 12 and 24 weeks postpartum
4. Loneliness, as measured by the short-version University of California, Los Angeles (UCLA) Loneliness Scale, at 12 and 24 weeks postpartum
5. Health Service Utilisation, as measured by a modified version of the Health Service Utilisation and Cost of Care Questionnaire, at 12 and 24 weeks postpartum

Overall study start date
01/07/2004

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Live birth
2. Aged 18 - 49 years old, female
2. Discharged from hospital
3. Less than two weeks postpartum
4. Scored more than nine on the EPDS
5. Availability of a peer volunteer who speaks the potential participant's language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
700

Key exclusion criteria

1. Infant not discharged home with mother
2. Current use of anti-depressant or anti-psychotic medication

A prior self-reported mental illness, including prior PPD, will not be an exclusion criterion.

Date of first enrolment
01/07/2004

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Canada

Study participating centre
University of Toronto
Toronto, ON
Canada
M5T 1P8

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
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+1 416 978 2163
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Sponsor type
University/education

Website
http://www.utoronto.ca/

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT 66874)

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?
Results article	results	15/01/2009		Yes	No
Results article	results	17/04/2014		Yes	No