Mums 4 Mums: telephone peer support for women experiencing post-natal depression

Submission date	Recruitment status No longer recruiting	Prospectively registered	
27/11/2008		[X] Protocol	
Registration date	Overall study status Completed Condition category	Statistical analysis plan	
30/01/2009		Results	
Last Edited		Individual participant data	
30/12/2020	Mental and Behavioural Disorders	☐ Record updated in last year	

Plain English summary of protocol

Not provided at time of registration

Study website

http://www2.warwick.ac.uk/fac/med

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

MUMS 4 MUMS: structured telephone peer support for women experiencing post-natal depression - a pilot and exploratory randomised controlled trial (RCT) of its clinical and cost-effectiveness

Acronym

Mums 4 Mums

Study objectives

The current proposal aims to adapt for use in the UK a peer-support intervention shown to be effective in Canada, to pilot its use, and provide preliminary data on its effectiveness in reducing depressive symptomatology among women suffering from post-natal depression (PND).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Warwickshire Local Research Ethics Committee gave approval in June 2008 (ref: 08/H1211/94)

Study design

Exploratory 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

Post-natal depression

Interventions

Consenting participants will be randomly allocated to either intervention or standard care by a researcher independent to the study. Although blinding of service users and providers is not possible, the researchers collecting follow-up data will be blind to the allocation. Analysis of the clinical data will be carried out on an intention-to-treat basis and blind to allocation group. All

participants will receive standard care; women allocated to the intervention group will also receive telephone support calls over a period of 6 months from peer supporters who have been specially trained to deliver the intervention (i.e. the same peer supporters that delivered the pilot study intervention). Outcome measures will be collected at baseline, 6 and 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Depressive symptomatology, measured using the Edinburgh Post-natal Depression Scale (EPDS), measured at baseline, 6 months and 12 months.

Secondary outcome measures

- 1. Self-efficacy, e.g. Maternal Self-Efficacy Scale, Depression Coping Self-Efficacy Scale
- 2. Parenting stress, e.g. Parenting Stress Inventory (PSI)
- 3. Maternal loneliness, e.g. Loneliness Scale
- 4. Maternal satisfaction with peer support, e.g. Peer Support Evaluation Inventory
- 5. Peer supporters' experience, e.g. Peer Volunteer Experience Questionnaire

Outcomes will be measured at baseline, 6 months and 12 months.

Overall study start date

01/12/2008

Completion date

31/03/2011

Eligibility

Key inclusion criteria

- 1. Women aged greater than 16 years of age at the time of giving birth
- 2. Experiencing depressive symptomatology (i.e. Edinburgh Post-natal Depression Questionnaire [EPDS] greater than or equal to 13 and/or clinical judgment)
- 3. Receptive to receiving telephone support

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

80

Total final enrolment

28

Key exclusion criteria

- 1. A score of 19 or above on the EPDS
- 2. Pose a suicide risk or a risk to their children
- 3. Receiving specialist psychiatric care or suffering from any mental illnesses (other than PND) or learning difficulties
- 4. Not able to speak English
- 5. Not accessible via the telephone

Date of first enrolment

01/12/2008

Date of final enrolment

31/03/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Warwick Medical School

Coventry United Kingdom CV4 7AL

Sponsor information

Organisation

University of Warwick (UK)

Sponsor details

University House Coventry England United Kingdom CV4 7AL

Sponsor type

University/education

Website

http://www2.warwick.ac.uk/

ROR

https://ror.org/01a77tt86

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0407-13232)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

2018 results in thesis http://wrap.warwick.ac.uk/114368/

Intention to publish date

31/12/2018

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	25/03/2011		Yes	No