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

Submission date	Recruitment status	[ ] Prospectively registered
27/11/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PB-PG-0407-13232

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