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Telephone-based peer support intervention programme for prevention of postnatal depression

Submission date
25/07/2017

Recruitment status
No longer recruiting

Registration date
25/07/2017

Overall study status
Completed

Last Edited
02/09/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Childbirth is a time when women are at great risk of becoming mentally unwell, with postpartum mood disorders representing the most frequent form of maternal illness after delivery. These disorders range in severity from the early maternity blues to postpartum psychosis, a serious state affecting less than 1% of mothers. Within this group of disorders is postnatal depression (PND), with symptoms of dysphoria (unease or dissatisfaction), emotional liability (mood swings), insomnia (inability to sleep), anxiety, and suicidal ideation (suicidal thoughts). It most often begins in the first 12 weeks after the birth with duration frequently dependent on severity and time to start of treatment. While residual depressive symptoms are common, 50% of mothers remain clinically depressed at 6 months after the birth with an estimated 25% of untreated PND continuing past the first year. PND is a major health problem for many women, with an overall prevalence of major PND of 13%. While national statistics for Singapore are unknown, a previous study found that the prevalence of PND symptoms at 4 weeks after birth was 13%. Another study found the effects of maternal mood are not limited to mothers with clinical levels of depression and anxiety, but cut across the population – the higher the level of maternal emotional difficulty, the greater the effect on child development and the effects of maternal mood are apparent in brain regions associated with emotional and cognitive function. Hence, limiting the risk for depression and anxiety is important not just for affected individuals and families, but also for public health and society. The cause of PND remains unclear, with extensive research suggesting multiple factors. Risk factors for PND include life stress, childcare stress, marital conflict, maternal self-esteem and lack of social support. The aim of this study is to find out whether a telephone-based peer-support intervention programme can prevent PND.

Who can participate?
Mothers aged 21 or over

What does the study involve?
Mothers are randomly allocated to either the peer support group or the control group. Mothers allocated to the peer support group have access to all of the standard hospital postpartum services in addition to receiving telephone-based support from a peer volunteer. Telephone

contact is started within one week after childbirth and then as frequently as deemed necessary. Each phone call should not take more than 30 minutes. Peer support volunteers are asked to make at least four contacts. The control group participants receive standard care, which involves postnatal support from the doctors, nurses and lactation consultants from the hospital and a follow-up appointment with the obstetrician at one to four weeks after childbirth. The participants from both groups complete questionnaire surveys by telephone/email (depending upon their preference) at 4 and 12 weeks after childbirth and each session takes about 20 minutes. At the end of the intervention some of the participants are interviewed, taking about 30 minutes each.

What are the possible benefits and risks of participating?
Participation in this study provides an avenue for mothers to share about their emotional wellbeing and experiences looking after their infants, which may serve as a form of release and empowerment to the participants as they share their experiences about childcare. Both participants and peer volunteers may also help to test the effectiveness of an intervention which may be then introduced as a routine care to reach more mothers in future in Singapore. There are no foreseeable or predicted physical or psychological risks or harms and/or discomforts in participation in this study.

Where is the study run from?
National University Hospital (Singapore)

When is the study starting and how long is it expected to run for?
March 2017 to February 2020

Who is funding the study?
National University Health System (Singapore)

Who is the main contact?
Dr Shefaly Shorey

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017/00185

Study information

Scientific Title
Evaluation of telephone-based peer-support intervention programme for preventing postnatal depression: a randomized controlled trial

Study objectives
When compared with those in the control group receiving routine care, mothers receiving Peer-support Intervention Programme (PIP) will report a significantly:
1. Lower level of post natal depression
2. Lower level of anxiety
3. Lower level of loneliness
4. Higher level of social support received

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Group, Domain Specific Review Board: NHG DSRB, 06/04/2017, ref: 2017/00185

Study design
Interventional two-group single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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
Postnatal depression

Interventions
Randomisation: After confirming the eligibility criteria and obtaining the consent of participation, all mothers will be randomized into 2 different groups. The mothers who give consent to participate will be asked to pick a number from 1-118 from an opaque envelope. The Research Randomizer will be used to randomly generate 59 sets of numbers. Participants whose picked number matches with any of the 59 sets of numbers will be assigned into the intervention group (PIP intervention), and the rest to the control group.

Treatment: Mothers allocated to the peer support group will have access to all of the standard hospital postpartum services in addition to receiving telephone-based support from a peer volunteer. Telephone contact will be initiated within one week post childbirth and then as frequently as the dyad deems necessary. Peer support volunteers would be asked to make a minimum of four contacts.

Control group: Participants receive standard care, which involves postnatal support by the doctors, nurses and lactation consultants from the hospital and follow-up appointment with the obstetrician at one to four weeks post childbirth.

Follow up: After the collection of baseline data, the research assistant will telephone study participants at 4 and 12 weeks postpartum to determine trial outcomes.

Evaluation: After the peer support intervention a purposive sample of 20 mothers (10 each from intervention and control groups) and 20 peer support volunteers will be selected to participate in the interview to obtain their opinions and comments on the receipt and delivery of peer support intervention program (PIP) respectively.

Intervention Type
Other

Primary outcome measure
Postnatal depression is measured using Edinburgh Post Natal Depression Scale and Patient Health Questionnaire at recruitment (baseline), 4 weeks and 12 weeks postpartum

Secondary outcome measures
1. Anxiety is measured using State Trait Anxiety Inventory at recruitment (baseline), 4 weeks and 12 weeks postpartum
2. Loneliness is measured using UCLA Loneliness Scale at recruitment (baseline), 4 weeks and 12 weeks postpartum
3. Social support is measured using Perceived Social Support for Parenting (PSSP) at recruitment (baseline), 4 weeks and 12 weeks postpartum

Overall study start date
06/03/2017

Completion date
28/02/2020

Eligibility

Key inclusion criteria
The inclusion criteria for participants are mothers who:
1. Are 21 years old and above
2. Are able to read and speak English
3. Owns a telephone and willing to share her number
4. Plan to stay in Singapore for first three months post birth of their newborns

The inclusion criteria for the peer volunteers are mothers who:
1. Are 21 years old and above
2. Are able to read and speak English
3. Have delivered a healthy baby in the past
4. Self-reported history of and recovery from PND
5. Have phone and willing to share her number and call needy mothers as instructed by the research team
6. Plan to stay in Singapore for next 6 months from the time of recruitment to participate in mother to mother peer support intervention programme (PIP)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
118

Total final enrolment
138

Key exclusion criteria
The exclusion criteria for the participants are mothers who:
1. Have physical or mental disorders which would interfere with their ability to participate in the study
2. Have complicated assisted delivery such as vacuum or forceps with 4th degree perineal tear of the mother
3. Give birth to a newborn at stillbirth or a newborn with congenital anomalies and/or medical complications

The exclusion criteria for the peer volunteers:
1. Have physical or mental disorders which would interfere with their ability to participate in the study
2. Does not want to share their number and call needy mothers as instructed by research team

Date of first enrolment
31/07/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Singapore

Study participating centre
National University Hospital
Singapore
117597

Sponsor information

Organisation
National University of Singapore

Sponsor details
21 Lower Kent Ridge Road
Singapore
Singapore
119077

Sponsor type
University/education

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NUHS O-CRG grant, NUHS collaborative grant

Results and Publications

Publication and dissemination plan
The research results will be shared to community by presenting in the conferences and via publication in high impact factor journals.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
The data after analysis will be published via research journals. Upon reasonable request anonymized SPSS files on data can be shared by requesting from the principle investigator Dr Shefaly Shorey. No personal data of the participants will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/03/2018		Yes	No
Results article	results	29/08/2019	02/09/2019	Yes	No
Results article	results	29/08/2019	02/09/2019	Yes	No