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Web-based and home-based postnatal psychoeducational interventions for first-time mothers

Submission date 01/02/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/02/2016	**Overall study status** Completed	
Last Edited 05/10/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Having a baby can be a frightening and exciting time for first time mothers. It can be a challenging time, negotiating the pressures and expectations of motherhood. Studies have shown that many first-time mothers can greatly benefit from coaching and education in the time after they have had their baby, as it can help them to become happier and more confident. This study is going to look at an online educational program and a home-based educational program, to see if they are able to help to improve maternal wellbeing and self-efficiency compared to routine care. These programs aim to provide post-natal (the time after giving birth) support in order to find the most effective way of helping new mothers to feel more confident in caring for their newborn babies.

Who can participate?
First time mothers aged 21 and over, who have given birth to a healthy baby.

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group are given access to the web-based post-natal program for one month as well as continuing to receive routine care. This involves being able to access audio and video materials about post-natal care, as well as being able to get advice from an expert forum. Participants also receive three weekly telephone calls which aim to encourage them to use the website more. Participants in the second group receive the home-based post-natal program as well as continuing to receive routine care. This involves hour-long face-to-face sessions with a research assistant who is a midwife (RA) as well as receiving an information booklet giving advice about post-natal care. These participants are visited at home by the RA 5-10 days after they have had their baby and also receive three telephone follow ups in the second and forth weeks after delivery. Participants in the third group receive routine post-natal care only. At the start of the study, and then 1, 3 and 6 months after discharge from hospital, the mothers' are observed and complete a number of questionnaires to measure their parenting ability (self-efficiency) and mental wellbeing. Participants in the web-based post-natal program group are also interviewed at one month in order to find out how effective they think the program is

What are the possible benefits and risks of participating?
Participants with access to the post-natal program may benefit from improved parenting skills and a greater mental wellbeing. There are no risks to participants taking part in the study.

Where is the study run from?
The study is run from the National University of Singapore and takes place online and in participants' homes (Singapore).

When is the study starting and how long is it expected to run for?
November 2012 to June 2018

Who is funding the study?
Ministry of Health – Singapore (Singapore)

Who is the main contact?
Dr Honggu He

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness and cost-effectiveness of web-based and home-based postnatal psychoeducational interventions for first-time mothers: A randomized controlled trial

Study objectives
1. When compared with those in the control group receiving routine care, first-time mothers in both web-based and home-based psychoeducational intervention groups will report a significantly:
1.1. Higher level of self-efficacy in newborn care
1.2. Higher level of social support received
1.3. Lower level of anxiety and depression
1.4. Higher level of satisfaction with postnatal services
2. When compared with those in the home-based psychoeducational intervention group, mothers in the web-based psychoeducational intervention group will not report significantly poorer aforementioned maternal outcomes
3. It is more cost-effective to provide web-based psychoeducational intervention than home-based intervention and routine care

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHG Domain Specific Review Board (DSRB), 25/01/2016, ref: 2015/01189

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Parenting

Interventions
Participants are randomly allocaetd to one of three groups:

Intervention group 1: Participants will receive access to the web-based postnatal psychoeducational intervention for one month as well as routine care. This involves provision of online access to the website information together with audio and video materials, peer discussion forum, expert advice at the forum and three weekly telephone follow-ups. Participants also receive three weekly telephone follow-ups at the second to fourth weeks post delivery to reinforce usage of website. They will also be able to communicate at the peer

discussion forum (The RA1 will provide expert advice). Each telephone session will last for about 3 minutes.

Intervention group 2: Participants will receive the home-based postnatal psychoeducational intervention as well as routine care. This includes one-hour face-to-face education through home visit by a research assistant (RA1) who is a midwife, provision of an educational booklet and three weekly telephone follow-ups. The intervention will be delivered around 5-10 days post-delivery. The three telephone follow-ups will be delivered second to fourth weeks post-delivery. The approximate hours the mother referred to the booklet in the previous month will be asked at the end of the third telephone session.

Control group: Participants will receive routine postnatal care only.

The effectiveness of the web-based and home-based psychoeducational interventions on the improvement of maternal self-efficacy in newborn care, social support they receive, and enhanced psychological wellbeing, as well as the satisfaction with postnatal services will be examined. The cost-effectiveness of the web-based postnatal psychoeducational intervention as compared with home-based psychoeducational intervention and routine care will also be evaluated.

Intervention Type
Behavioural

Primary outcome measure
Mothers' self-efficacy in newborn care is measured using the revised Perceived Maternal Parental Self-Efficacy (PMP S-E) tool at baseline, 1, 2 and 5 months after the intervention.

Secondary outcome measures
1. Mothers' social support is measured using the 16-item Functional Social Support Measuring Scale (FSSMS) and 6-item Structural Social Support Measuring Scale (SSSMS) at baseline, 1, 2 and 5 months after the intervention
2. Mothers' psychological well-being (anxiety and depression) is measured using the Edinburgh Postnatal Depression Scale (EPDS) and the Anxiety Subscale of Hospital Anxiety and Depression Scale (HADS-A) at baseline, 1, 2 and 5 months after the intervention
3. Maternal satisfaction with postnatal support is measured using a 6-point Ordinal Descriptive Scale (ODS) at 1, 2 and 5 months after the intervention
4. Cost-effectiveness of web-based postnatal psychoeducatinal programme as compared to home-based postnatal psychoeducational programme and routine postnatal care is determined using the Healthcare Services Utilisation and Programme-related Expenses Sheet (HSUPES) at 1, 2 and 5 months after the intervention
5. Process evaluation is completed using a semi-structured interview immediately after the intervention (1 month)

Overall study start date
30/11/2012

Completion date
20/06/2018

Eligibility

Key inclusion criteria
1. Women aged 21 and above
2. First-time mothers with term pregnancy
3. Able to read and speak English
4. Have internet access through computer or smartphone
5. Planned to stay in Singapore for six months post-delivery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
A total of 204 first-time mothers will be recruited in this study.

Key exclusion criteria
1. Physical or mental disorders before and during pregnancy as identified from their medical records, which would interfere with their ability to participate in the study
2. Complicated assisted delivery such as vacuum or forceps with fourth degree perineal tear
3. Gave birth to a still-born child or a child with congenital anomalies and/or medical complications, including pathological jaundice, that required special care in hospital

Date of first enrolment
01/06/2016

Date of final enrolment
30/12/2017

Locations

Countries of recruitment
Singapore

Study participating centre
National University of Singapore
Alice Lee Centre for Nursing Studies
Yong Loo Lin School of Medicine
Level 2, Clinical Research Centre
Block MD 11
10 Medical Drive
Singapore
Singapore
117597

Sponsor information

Organisation
Ministry of Health - Singapore

Sponsor details
16 College Road
Singapore
Singapore
169854

Sponsor type
Government

Website
https://www.moh.gov.sg/content/moh_web/home/Fundings_and_Medical_Research/Health_Services_Research_Competitive_Research_Grant.html

ROR
https://ror.org/00mrhvv69

Funder(s)

Funder type
Not defined

Funder Name
Ministry of Health - Singapore

Alternative Name(s)
Ministry of Health of Singapore, MOH Singapore, Ministry of Health (Singapore), mohsingapore, Ministry of Health, Singapore, MOH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Singapore

Results and Publications

Publication and dissemination plan
Planned publication of a number of papers in peer reviewed journals.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	31/01/2018		Yes	No
Results article		21/07/2019	05/10/2022	Yes	No
Results article	Economic evaluation	11/03/2022	05/10/2022	Yes	No