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Effectiveness of "home-but not alone" mobile-health application on parental outcomes

Submission date	Recruitment status	[_] Prospectively registered
29/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2018	Other	

Plain English summary of protocol

Background and study aims
The time just after a baby is born (post-natal period) can be a stressful time for new parents. Studies have shown that many first-time mothers and fathers can greatly benefit from coaching and education in the post-natal period as it can help them to become happier and more confident when looking after their baby. Mobile phone apps have been used more and more in healthcare in recent years. This study is looking at a parenting app called “Home-but not alone” which aims to help new parents when the go home from hospital. The aim of this study is to find out whether this app is an effective way of improving parental self-efficacy (independence) and satisfaction, while reducing levels of post-natal depression (low mood after having a baby)

Who can participate?
New parents (mothers and fathers) aged 21 and over who have a healthy baby who will be going home from hospital with them.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive usual care during the four weeks of the study, which involves care in hospital after the birth and follow up appointments with their doctor. Those in the second groups receive usual care but also are given access to the “Home-but not alone” app. Both mothers and fathers are actively encouraged to use the app as much as possible and to interact with other users. The app itself involves ongoing communication with a midwife (including exchanging messages and photos), information materials about how best to cope with being a new parent (improving self-efficiency, lowering levels of depression and anxiety), and the automatic sending of push notifications for the first 10 days in order to provide parents with information relating to common questions about breastfeeding and the baby’s health. At the start of the study and again after four weeks, participants in both groups are contacted by telephone to answer questionnaires in order to assess their self-efficiency, satisfaction and mood.

What are the possible benefits and risks of participating?
Participants may benefit from learning new skills which can help them to enhance their

parenting self-efficacy, satisfaction and improve their social support network. These parents may also feel better emotionally and be less likely to suffer from post-natal depression. There are no notable risks involved with taking part 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?
December 2015 to August 2017

Who is funding the study?
National University of Singapore (Singapore)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Effectiveness of "home-but not alone" mobile-health application on parental outcomes: A randomized controlled trial

Study objectives
1. Compared with parents in control group, parents receiving M-Health App intervention will have significantly:
1.1. Higher scores in their parenting efficacy
1.2. Higher satisfaction with the Social Support received
1.3. Higher parenting satisfaction score
1.4. Reduced depression scores
2. There will be a statistically significant difference between mothers and fathers' demographics and their self-efficacy, social support, parenting satisfaction and postnatal depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Group Domain Specific Review Board (NHG-DSRB), 11/01/2016, ref: 2015/01250

Study design
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
Postnatal Parental Outcomes

Interventions
Participating couples are randomly allocated to one of two groups:

Control group: Parents continue to receive standard care only, which involves postnatal support by nurses and lactation consultants while the parents are in the hospital and routine follow-up visit with their obstetrician.

Intervention group: Parents continue to receive standard care, but are also given one months access to the “Home-but not alone”, Mobile-Health Application (M-Health App). Participants are advised to actively use the App and interact with fellow parents via App.

The features of the App are as follows:
1. Asynchronous communication, where the participants can exchange messages and photos to consult midwife pertaining to their queries as well as peer discussion among themselves. This will enable them to receive timely and reliable support in the early postpartum period. The participants will be pre-informed that midwife will respond to their queries once a day for four weeks till they have an access to the M-Health App. However, parents will be reinforced to remain vigilant that this App is an adjunct support to the support received from the hospital and in case of any emergency the hospital will still be the main point of contact.
2. A knowledge-based content consisting of information materials specially focused in enhancing parental self-efficacy, parenting satisfaction, decreasing anxiety and postnatal depression and awareness on social support from both formal and informal sources as well as videos and audios with a search function for easier access to information will be provided.
3. Push Notifications will be automatically issued every 24 hours from the day of discharge from the hospital (Day 4) till day 10 after the birth of the baby. The aim is to provide new parents with information regarding commonly asked questions such as breastfeeding, baby’s bowel moments and jaundice.

Participants in both groups are contact by telephone after four weeks (post-test) when the access to the APP will be terminated to complete a number of questionnaires.

Intervention Type
Behavioural

Primary outcome measure
Parenting self-efficacy is measured using the Parent Efficacy Scale (PES) at baseline and 4 weeks.

Secondary outcome measures
1. Parenting satisfaction is measured using the What Being the Parent of a New Baby is Like (WBPL) questionnaire at baseline and 4 weeks
2. Satisfaction with social support is measured using the Perceived Social Support for Parenting (PSSP) questionnaire at baseline and 4 weeks
3. Postnatal depression is measured using the Edinburgh Postnatal Depression Scale (EPDS) at baseline and 4 weeks

Overall study start date
28/12/2015

Completion date
17/08/2017

Eligibility

Key inclusion criteria
1. Aged 21 years or above
2. Able to read and speak English
3. Have a smart gadget with internet connection to download the M-Health Application named

"Home but not Alone"
4. Will be staying in Singapore for first four weeks after the birth of their new-born
5. Have a full-term health baby who will be discharged home with the parents
6. In a physical and emotional stable condition at the time of data collection

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
118 couples with 59 couples in each arm

Key exclusion criteria
1. Have physical or mental disorders, which will interfere with their ability to participate in the data collection
2. Have newborns with deformities and/or complications and/or disabilities
3. Have their newborns admitted to Neonatal Intensive Care Unit

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Singapore

Study participating centre
National University Hospital
5 Lower Kent Ridge Road
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Sponsor information

Organisation
National University of Singapore

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Sponsor type
University/education

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
University/education

Funder Name
National University of Singapore

Alternative Name(s)
, Universiti Nasional Singapura, , National University of Singapore: NUS, National University of Singapore (NUS), nus_singapore, National University of SG, National University Singapore, Straits Settlements and Federated Malay States Government Medical School, King Edward VII College of Medicine, University of Malaya, Singapore campus, University of Singapore, Nanyang University, NUSingapore, NUS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Singapore

Results and Publications

Publication and dissemination plan
Planned publication of at least two manuscripts in peer reviewed journals.

Intention to publish date

30/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No