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Effectiveness of supportive parenting educational programme

Submission date
06/02/2017

Recruitment status
No longer recruiting

Registration date
08/02/2017

Overall study status
Completed

Last Edited
18/02/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Pregnancy, childbirth and the period following having a baby can be a stressful time for new parents. Both mothers and fathers report feelings of helplessness and have expressed their desire for further support from healthcare professionals during this time. Most of the support packages currently available focus on the mother's needs only, neglecting those of new fathers. This study is looking at a new programme called SEPP (Supportive Educational Parenting Programme), which has been designed to support both mothers and fathers during pregnancy and the period after children are born, so that the new parents can support each other and provide better care to their baby. The aim of this study is to investigate the effectiveness and cost-effectiveness of SEPP in supporting new parents self-efficacy and mental wellbeing compared with standard care.

Who can participate?
Couples aged 21 years and over who are expecting a baby and have access to a smartphone with internet access.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard care, which involves receiving support from hospital staff throughout pregnancy and for four weeks after having their baby. Those in the second group take part in SEPP. This involves a 30 minute educational session during pregnancy, delivered either face-to-face or by telephone; a 90 minute educational session after birth for the new parents, delivered either face-to-face or by telephone; and one month's access to a specially designed mobile application which provides information, notifications about what to expect about their baby's development and an interactive forum whether a nurse or midwife will answer any questions they may have. The initial information session cover topics such as bonding, what to expect immediately after birth and mental wellbeing during pregnancy and after birth. At the start of the study and then again immediately after birth and then four and 12 weeks after birth, participants complete a range of questionnaires to assess their parenting skills and mental wellbeing. At the end of the study, the cost-effectiveness of the program is assessed by comparing costs to those arising from standard treatment.

What are the possible benefits and risks of participating?
Participants may benefit from having an avenue to their experiences about childcare, which they may find empowering. There are no notable risks involved with participating.

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

When is the study starting and how long is it expected to run for?
July 2016 to December 2018

Who is funding the study?
National University Health System Clinician Research Grant (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
NUHSRO/2016/023/CRG/02

Study information

Scientific Title
Effectiveness of supportive educational parenting programme on parental outcomes in Singapore: a
randomized controlled trial

Study objectives
Study aims:
1. Examine the effectiveness of Supportive Educational Parenting Programme (SEPP) on parental outcomes including parental self-efficacy (primary outcome), parental bonding, emotional well-being including postnatal depression and anxiety, help seeking behavior (social support) and parenting satisfaction (secondary outcomes)
2. Evaluate the cost-effectiveness of SEPP as compared to routine perinatal care.

Hypotheses:
1. When compared with those in the control group receiving routine care, parents receiving SEPP will report significantly: higher level of self-efficacy; higher level of parental bonding with new-born care; lower level of depression and anxiety; higher level of social support received; and higher level of parenting satisfaction
2. It is more cost-effective to provide SEPP intervention than routine care

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Group, Domain Specific Review Board: NHG DSRB, 07/07/2016, ref: 2016/00651

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

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
Postpartum care

Interventions

Participants are randomised to one of two groups using a research randomizer. The participants will be asked to randomly pick a number (retrieved from the randomizer) from an opaque envelope and based on that number they will be randomly divided into intervention group or control group. If both parents/couples (pregnant woman and her partner) are willing to participate in the study and complete the consent procedure, demographic and baseline data will be collected using self-administering questionnaires (PES, PEIBQ, PSSP, EPDS, STAI & WPBL).

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 child birth.

Intervention group
Participants receive the Supportive Educational parenting Programme (SEPP). The SEPP involves:
1. A 30 minute face-to-face or telephone educational session during pregnancy (after 28 weeks of gestation)
2. A 90 minute face-to face or telephone education after the childbirth for the new parents
3. One month access to the Mobile Health Application (M-Health App).
The telephone educational session during the pregnancy will cover topics on parental bonding, expectations in the immediate postpartum period and emotional needs of parents both during pregnancy and after the childbirth. The telephone educational session after the childbirth will cover topics on parental bonding, expectations in the immediate postpartum period, parenting self-efficacy, depression, and social support. The features of the M-Health App include:
1. Knowledge-based information on baby and mother care (audio & video files)
2. Daily push notifications on what to expect about baby's development in first 4 weeks post childbirth
3. An interactive forum with other parents and a registered nurse/midwife where they can post queries which will be answered once a day by the registered nurse/midwife for the first 4 weeks post-baby's birth.
Weekly reminder notification will be sent daily for the 4 weeks, to remind participants to access the app.

For all participants, data collected at baseline (PES, PEIBQ, PSSP, EPDS, STAI & WPBL) is repeated after childbirth before hospital discharge, at the end of week 4 post-partum and 3 months post-partum.

Intervention Type
Behavioural

Primary outcome measure
Parenting self-efficacy is measured using the Parenting Efficacy Scale (PES) at baseline, post-natal (before hospital discharge), 4 weeks post-natal and 12 weeks post-natal.

Secondary outcome measures
1. Parental bonding is measured using the Parent-to-Infant Bonding Scale (PIBQ) at baseline, post-natal (before hospital discharge), 4 weeks post-natal and 12 weeks post-natal
2. Social support is measured using the Perceived Social Support for Parenting (PSSP) questionnaire at baseline, post-natal (before hospital discharge), 4 weeks post-natal and 12 weeks post-natal
3. Parenting satisfaction is measured using the Parenting Satisfaction (What Being The Parent of a Baby is Like) (WPBL) questionnaire at baseline, post-natal (before hospital discharge), 4 weeks

post-natal and 12 weeks post-natal
4. Postnatal Depression and Anxiety are measured using the Edinburgh Postnatal Depression Scale (EPDS) and the State Trait Anxiety Inventory (STAI-Form Y-1 & Form Y-2) at baseline, post-natal (before hospital discharge), 4 weeks post-natal and 12 weeks post-natal
5. Cost-effectiveness of SEPP as compared to routine perinatal care Health Services Used Due to Maternal and/or Infant Related Health Issues and cost-effectiveness of SEPP compared to routine perinatal care are measured using the Healthcare Services Utilization and Programme-related Expenses Sheet (HSUPES) 4 and 12 weeks post-natal

Overall study start date
07/07/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 21 years and over
2. Able to read and speak English
3. Low-risk singleton pregnancy at more than 28 weeks of gestation
4. Have a smartphone with internet access
5. Plan to stay in Singapore for first three months after giving birth

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
118 couples

Key exclusion criteria
1. Physical or mental disorders which would interfere with their ability to participate in the study
2. High-risk pregnancy including placenta-previa major, pre-eclampsia, pregnancy induced hypertension etc.
3. Complicated assisted delivery such as vacuum or forceps with 4th degree perineal tear of the mother
4. Give birth to a new-born at stillbirth or a new-born with congenital anomalies and/or medical complications

Date of first enrolment
01/08/2016

Date of final enrolment
06/07/2017

Locations

Countries of recruitment
Singapore

Study participating centre
National University Hospital
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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 Health System Clinician Research Grant

Results and Publications

Publication and dissemination plan

The main findings from the trial will be published in high impact factor journals.

Intention to publish date
08/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Shefaly Shorey (nurssh@nus.edu.sg)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/01/2018		Yes	No
Results article	results	13/02/2019		Yes	No
Results article	results	13/02/2019	18/02/2019	Yes	No