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Perinatal psychological care to mothers and fathers of SGA infants

Submission date
15/03/2018

Recruitment status
No longer recruiting

Registration date
03/05/2018

Overall study status
Completed

Last Edited
05/02/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Small for gestational age (SGA) is a term used to describe a baby who is smaller than usual for the number of weeks of pregnancy. Previous research has highlighted the difficulties of SGA infants and the importance of an appropriate treatment, but most of studies about this question have being focused on the postnatal (after birth) stage. There is evidence that maternal prenatal stress leads to cognitive, behavioural and emotional problems for the children, and that prenatal stress increases the risk of SGA at birth. In view of the fact that foetuses have the capacity to perceive olfactory (smell), auditory (sound) and visual stimuli, and can learn and remember, it is clear that in the prenatal stage it is possible to provide early stimulation to enhance the development of the foetus, especially in the case of the SGA foetus, and thus help prevent future difficulties. To date, few intervention programmes have been included the prenatal stage of development. However, these programmes present a series of limitations, such as the use of self-reports to register the distress experienced. This study intends to avoid subjectivity by also using psychophysiological markers. Besides, few studies have considered resilience as a protective variable, consequently, in this study, this factor will be taken into account, and its effects will be analysed. The low level of adherence by parents to intervention programmes is a major obstacle to their effective application. To solve this problem, the psychological attention programme will be supported by a software system based on mobile technologies (APP) that will facilitate adaptation to the characteristics and needs of the families concerned and stimulate adherence to the programme. Another serious deficiency is that the few previous intervention programmes in this respect have been focused exclusively on the mothers. Nevertheless, the role of the father should not be ignored; his accompaniment during pregnancy and his inclusion in the process and in caring for the mother and child facilitates family adaptation and strengthens the father-child bond. For these reasons, a psychological attention programme is proposed that is focused on the entire family: parents and babies. Taking the above into account, this study addresses the following goals:
1. To compare the results of the psychological attention programme with those of usual care or non-prenatal psychological attention, as regards the parents' mental health, their ability to provide stimulation to the foetus and their parenting abilities, together with development, the cognitive, language and behavioural development of the SGA baby during the first year of life

and children's health.
2. To evaluate the psychological attention programme efficiency via APP in terms of effectiveness, viability and feedback from the parents and babies involved.

Who can participate?
Parents whose foetuses are identified as SGA

What does the study involve?
Participants are randomly allocated to the control group or the psychological attention group. Before the birth the parents in the control group receive standard care provided in the Guidelines on Management of the Small-for-Gestational- Age Fetus published by the College of Obstetricians and Gynecologists (2014, RCOG). The parents in the psychological attention group receive standard care and also a psychological attention programme composed of various modules, supported by the APP, focused on cognitive-behavioural therapy, relaxation techniques, mother and infant care, psychoeducation and prenatal stimulation. After the birth the babies in the control group receive the Queensland Maternity and Neonatal Clinical Guidelines Programme (2016), performed by paediatricians. Psychologists also carry out an assessment of the baby, followed by several developmental assessments during their first year of life. The babies in the psychological attention group receive the same care as those in the control group. In addition, their parents are given the psychological postnatal programme, supported by the APP, composed of four modules: cognitive-behavioural therapy, relaxation techniques, psychoeducation about family functioning and care for SGA babies, and emotional intelligence. The follow-up of the parents and babies takes place over two periods: from week 28-32 of pregnancy until the birth, and from birth until age 12 months (corrected age, in the case of SGA babies who are also premature). The parents and their children are evaluated and examined by psychologists at a consultation in the Virgen de las Nieves University Hospital (Granada, Spain).

What are the possible benefits and risks of participating?
The benefits expected from this programme are that the parents acquire the skills necessary to regulate their own emotional and physical health and to provide the baby with stimulation; thus, their parenting abilities (before and after the birth) will be enhanced, with positive repercussions on the child and alleviating the difficulties of being born SGA. There are no expected risks.

Where is the study run from?
1. Universidad de Granada (Spain)
2. Hospital Universitario Virgen de las Nieves (Spain)

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

Who is funding the study?
Consejería de Salud, Junta de Andalucía (Spain)

Who is the main contact?
Prof. Mercedes Bellido-Gonzalez

Contact information

Type(s)

Scientific

Contact name
Prof Mercedes Bellido-González

ORCID ID
https://orcid.org/0000-0003-1853-859X

Contact details
Campus Cartuja. s/n
Granada
Spain
034

Additional identifiers

Protocol serial number
PC-0526-2016-0526

Study information

Scientific Title
A randomised controlled trial, termed PErinatal CAre Trial (PECAT), to assess the effectiveness of a psychological attention programme to improve the emotional health of parents and to enhance the neurodevelopment of SGA infants

Acronym
PECAT

Study objectives
PRENATAL PHASE HYPOTHESES
Hypothesis 1.1. The adherence of participants to a prenatal psychological attention programme can be increased by the provision of an adaptable, customisable support system based on mobile technologies (APP- PRE).
Hypothesis 2.1. The parents in the psychological attention group will achieve a significantly enhanced general emotional state (lower depression, stress and anxiety, and greater resilience) with respect to those in the non-psychological, or control group, by the end of the prenatal programme.
Hypothesis 2.2. The parents in the psychological attention group will achieve a significant improvement in their physiological signs of stress, with respect to those in the non-psychological, or control group, by the end of the prenatal programme.
Hypothesis 2.3. The parents in the psychological attention group will have greater competence in their prenatal stimulation skills than those in the control group.
Hypothesis 2.4. The small-for-gestational age (SGA) newborns in the psychological attention group will have a developmental neonatal outcome that is significantly better than that of those in the non-psychological care group.
Hypothesis 3.1. There is a significant relationship between mental health, stimulation skills, neonatal behaviour, neonatal care and the use of the APP- PRE modules.
Hypothesis 4.1. Effectiveness. A significantly lower proportion of parents in the psychological attention group than in the control group will receive mental health care.

Hypothesis 4.2. Viability. More than 90% of the parents will complete the APP-PRE modules.
Hypothesis 4.3. Usability feedback. More than 90% of the parents in the psychological attention group will report on the clarity of the exercises, and the ease of understanding and navigability of the online application.

POSTNATAL PHASE HYPOTHESES
Hypothesis 5.1. The adherence of the participants in the postnatal psychological attention programme will be enhanced by the provision of an adaptable, customisable support system based on mobile technologies (APP-POST).
Hypothesis 6.1. The parents in the psychological attention group will present a significant decrease in depression symptoms and perceived stress and anxiety. Moreover, they will display greater resilience and baby attachment, at least during the follow-up performed in the first year of the baby's life, compared to the parents in the control group.
Hypothesis 6.2. The parents in the psychological attention group will acquire greater competence in parenting skills, related to care of their babies, than those in the control group.
Hypothesis 6.3. The SGA babies in the psychological attention group will present cognitive, language and behaviour development that is significantly greater than that of those in the control group.
Hypothesis 7.1. There is a significant relationship between mental health, parenting skills, baby neurodevelopment and use of the APP-POST modules.
Hypothesis 8.1. Effectiveness. The psychological attention group will contain a significantly lower proportion of women requiring mental health assistance than the control group.
Hypothesis 8.2. Viability. More than 90% of the psychological attention group parents will complete the APP-POST modules.
Hypothesis 8.3. Usability feedback. More than 90% of the parents in the psychological attention group will report their reasoned opinions on the clarity of the exercises and the ease of comprehension and navigability of the online application.
Hypothesis 9.1. According to the health values considered acceptable in the Andalusian Health System, taking into account the expected incremental costs of the psychological attention programme and the expected results (such as the remission of symptoms of stress or depression and the increased educational competences developed in the parents), the programme will be profitable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Research Committee of Granada, 30/11/2016, CEI-GR: 16/11-C-31; Internal code PEIBA 1457-N-16

Primary study design
Interventional

Study design
Single-centre randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Risk pregnancy, small-for-gestational-age fetuses

Interventions
The randomisation will be carried out using the Epidat 4.1 program. The longitudinal follow-up of the parents and babies will take place over two periods: prenatal, from week 28-32 of pregnancy until the birth, and postnatal, from birth until age 12 months (corrected age, in the case of SGA babies who are also premature). The parents and their children will be evaluated and examined by psychologists at a consultation enabled for this purpose in the Virgen de las Nieves University Hospital (Granada, Spain).

I. DURING THE PRENATAL PHASE
Control Group
The parents in the control group will receive the Gynaecological and Obstetric Standard Protocol, drawn up following the Guidelines on Management of the Small-for-Gestational-Age Foetus published by the College of Obstetricians and Gynaecologists (2014, RCOG).

Psychological Attention Group
The parents in the psychological attention group will receive the same Gynaecological and Obstetric Standard Protocol, and in addition a psychological attention programme composed of various modules, supported by the APP, focused on cognitive-behavioural therapy, relaxation techniques, mother and infant care, psychoeducation and prenatal stimulation.

II. DURING THE POSTNATAL PHASE
Control Group
The babies in the control group will receive the Queensland Maternity and Neonatal Clinical Guidelines Programme (2016), performed by paediatricians. Additionally, psychologists will carry out a neonatal assessment after birth, followed by several developmental assessments during the babies' first year of life.

Psychological Attention Group
The babies in the psychological attention group will receive the same paediatric and psychological protocol as those in the control group. In addition, their parents will be given the psychological postnatal programme, supported by the APP, composed of four modules: cognitive-behavioural therapy, relaxation techniques, psychoeducation about family functioning and care for SGA babies, and emotional intelligence.

Intervention Type
Behavioural

Primary outcome(s)
Prenatal:
1. Adherence to the APP-PRE: the participants' adherence to the psychological attention programme sessions will be measured by the APP, which registers daily session activity and records the answers given to questions asked at the end of each session
2. General emotional state (depression, stress, anxiety and resilience) measured using the Spanish versions of standardised questionnaires [Edinburgh Depression Scale (EPDS, García-Esteve L, Ascaso C, Ojuel J, Navarro P. 2002), Perceived Stress Scale (PSS-14, Remor, EP., 2006), SCL-90 Anxiety Subscale (SCL-90, González de Ribera, 2002) and Connor Davidson–Resilience Scale for Chronic Stress (CD-RISC 10, Crespo, M., Fernández-Lansac, V., & Soberón, C. 2014).)], to be completed by all participants at various moments in this phase of the study:
PSS-14: WEEK 20, WEEK 28-32, WEEK 41 (AT BIRTH)
EPDS-10: WEEK 20, WEEK 28-32, WEEK 41 (AT BIRTH)
Anxiety subscale SCL-90: WEEK 20, WEEK 28-32, WEEK 41 (AT BIRTH)

CD-RISC-10: WEEK 20, WEEK 28-32, WEEK 41 (AT BIRTH)
3. Physiological signs of stress, monitored by an Empatica Embrace® bracelet. This device contains a sensor of psychophysiological responses such as heart rate and body temperature. The bracelet will be used by both parents during the ultrasound examination. In the experimental group, it will be worn during ultrasound at two moments: before and after the psychological attention programme (one month's duration). In the control group it will be worn during ultrasound at two moments, with a separation of one month
4. Stimulation skills in the experimental group will be measured by an instrument developed specifically for this study, and performed at birth in an observational session with the parents and their babies
5. The neonatal development of the babies will be measured according to the Neonatal Behaviour Assessment Scale, NBAS (Brazelton, 1997) at birth

Postnatal:
1. Adherence by the participants will be measured by the APP, which records daily session activity and by reference to the answers given to questions asked at the end of each session
2. General emotional state and parent-baby attachment during the first year of life will be measured using the questionnaires above and, for attachment, the Postpartum Bonding Questionnaire (PBQ-25, García-Esteve et al., 2015) to be completed at week 41, age 3 months, and age 12 months
3. Competence in parenting skills will be measured, using a specially-developed instrument at birth in an observational session with the parents and their babies
4. The cognitive, language and behavioural development of the babies in the experimental group will be measured by the Bayley Scales of Infant Development III, (Bayley, 2006; Spanish adaptation by CDIAP Parc Taulí, Universidad de Murcia and department of I+D Pearson Clinical & Talent Assessment, 2015) at 3, 6 and 12 months of age

Key secondary outcome(s)

Prenatal:
1. Depression requiring mental health care, measured using the instruments commented above
2. Viability measured by recording the parents' daily use of the APP and by the answers given to questions shown at the end of each session. In addition, a specific questionnaire about the APP has been designed, regarding its usability, manageability and clarity, among other questions
3. Feedback on usability measured by recording the parents' daily use of the APP and by the answers given to questions (developed specifically for this study) about its usability, manageability and clarity, among other aspects

Postnatal:
1. Depression requiring mental health care, measured using the instruments commented above
2. Viability measured by recording the parents' daily use of the APP and by the answers given to questions shown at the end of each session. In addition, a specific questionnaire about the APP has been designed, regarding its usability, manageability and clarity, among other questions
3. Feedback on usability measured by recording the parents' daily use of the APP and by the answers given to questions (developed specifically for this study) about its usability, manageability and clarity, among other aspects
4. Profitability assessed from the records contained in the hospital database on the number of premature births, caesarean sections and requests for mental health care for parents and for early care for babies, evaluated at the end of the postnatal program

Completion date

31/12/2020

Eligibility

Key inclusion criteria
Parents whose foetuses are identified as Small-for-Gestational-Age (birth weight below the 10th percentile, taking into account the gestational age)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
110

Key exclusion criteria
1. Parents who are drug users
2. Mothers who present high depression scores (score >15 on the Edinburgh Scale) or other psychiatric disorders, and/or are receiving psychotherapy
3. Infants whose parents or guardians do not speak Spanish as a mother tongue
4. Parents who do not give their signed informed consent

Date of first enrolment
19/11/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Granada
Departamento de Psicología Evolutiva y de la Educación
Spain
034

Study participating centre

Universidad de Granada
Departamento de Personalidad, Evaluación y Tratamiento Psicológico
Spain
034

Study participating centre
Universidad de Granada
Departamento de Metodología de las Ciencias del Comportamiento
Spain
034

Study participating centre
Universidad de Granada
Departamento de Lenguajes y Sistemas Informáticos
Spain
034

Study participating centre
Hospital Universitario Virgen de las Nieves
Servicio de Ginecología y Obstetricia
Spain
034

Study participating centre
Hospital Universitario Virgen de las Nieves
Servicio de Pediatría
Spain
034

Sponsor information

Organisation
Fundación Pública Andaluza para la investigación Biosanitaria Andalucía Oriental (FIBAO)

Organisation
Consejería de Salud, Junta de Andalucía

Funder(s)

Funder type
Government

Funder Name
Consejería de Salud, Junta de Andalucía

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Mercedes Bellido-Gonzalez. All of the individual participant data collected during the trial will be available after deidentification, along with the Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, and Analytic Code. The data will be available immediately following publication until 5 years after publication for researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. The proposal should be directed to Prof. Mercedes Bellido-Gonzalez. To gain access data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/11/2022	07/09/2023	Yes	No
Basic results		03/09/2023	07/09/2023	No	No