ISRCTN90692907 https://doi.org/10.1186/ISRCTN90692907

Child development, parenting and primary health care program

Submission date 20/01/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/02/2020	**Overall study status** Suspended	
Last Edited 01/02/2022	**Condition category** Other	

Plain English summary of protocol
Background and study aims
Current scientific and social progress has allowed the development of knowledge of child development, looking at a child as a Person. In this contemporary era, when new multiple challenges arise for families, it is imperative to ensure the welfare of the different elements and to promote the empowerment of families. The Touchpoints model has made a significant contribution to this area.
Support for parenting is already recognized as a necessity and a right of families and should be presented as a worldwide priority by raising awareness of positive parenting among professionals working with children and parents. At the same time, parents seem to share a universal desire to improve their parenting skills and do want guidance from child development professionals, specifically from the ones who know their child and situation. Presently, there is well-established evidence that parenting programs are effective in improving both parents and child outcomes.
To this end, a parental intervention program - coined as “Crescer em Grande!” (CeG) - based on the Touchpoints model was designed for the antenatal, postnatal period and early childhood. The aim of this study is to evaluate the novel intervention program.

Who can participate?
Family physicians and nurses in the participating centres, as well as parents and babies under 18 months who are using the services at the participating centres.

What does the study involve?
Primary care providers in some of the participating clinics will receive training in the CeG intervention, which will be delivered as part of routine care with new families in the clinic. Participants will be required to fill in questionnaires at point throughout the 18-month study.

What are the possible benefits and risks of participating?
Benfits: To improve the experience of parenting for the different elements of the family system in order to support healthy child development and self-confident, supportive, strong and happy families, namely through the improvement of parenting sense of competence, couple and family

dynamics, personal mental health and well-being/quality of life.
Risks: No side effect, disadvantage or specific risk are anticipated, but unintended consequences, if any, will be reported (e.g., outcomes that worsen following the intervention).

Where is the study run from?
1. Primary Care Units from the Agrupamento de Centros de Saúde de Sintra, Sintra, Portugal
2. Primary Care Units from the Agrupamento de Centros de Saúde de Lisboa Central, Lisboa, Portugal
3. Primary Care Units from the Agrupamento de Centros de Saúde de Lisboa Norte, Lisboa, Portugal

When is the study starting and how long is it expected to run for?
December 2019 to May 2025

Who is funding the study?
Foundation for Science and Technology (FCT), Portugal

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Child development, parenting and primary health care - "Crescer em Grande!" program (CeG Program): a cluster randomised trial.

Acronym
CeG Program

Study objectives
Does a parental intervention program (“Crescer em Grande!”) based on the Touchpoints Model applied in Primary Health Care, under the Portuguese National Program for Child and Youth Health, improves parental sense of competence of parents of children under 18 months of age, compared with usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/11/2019, Ethics Committee of the Regional Health Administration of Lisbon and Tagus Valley (Avenue United States Lot 77 - 11th floor, 1749-096 Lisboa, Portugal; +351 21 842 5203; etica@arslvt.min-saude.pt), ref: 013/CES/INV/2019.

Study design
Multicentre cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Parenting abilities

Interventions

Intervention and Control
The CeG intervention will consist of two components: 1) the integration of the TP approach in PC maternal and well-child visits, with the support of 28 leaflets for parents to file in a folder, plus 2) training for PC providers in their use, based on the TP model.
The leaflets were developed to be used by PC providers with parents during the clinical visit. Each will be delivered unitarily in scheduled consultations from 26 weeks of gestation (first TP at third trimester) until the age of 18 months, anticipating TP and some parents' needs, worries /fears maybe not always addressed in healthcare visits. Topics explore several areas (e.g., baby language, sleep, crying, eating, healthy lifestyles, discipline, cognitive development) to contribute to positive parenting.

Providers in the CeG arm will complete a 5-hour training designed to enhance providers' motivation, skills and self-efficacy on using different elements of the TP Model as guidance to promote parental competence. For the sessions we developed a set of presentation slides for clinic staff that provides information on the intervention concept and philosophy, implementation and health gains to finally reach practical dimensions inspired by TP approach. Different presentation techniques will be used: interactive activities (individual and group), videos, brainstorming, reflective practice activities. The written material (leaflets) reinforces the TP principles and elaborates on main development challenges of children till the age of six years. One or more clinic representatives will be charged with encouraging and enabling other professionals in their clinic to review the leaflets folder, throughout the study.

Both CeG components were previously reviewed and discussed with academic experts from the Fundação Brazelton Gomes-Pedro, Lisbon, Portugal. To further strengthen the process, we also engaged parents and PC providers in the CeG development, through eight focus groups discussions (11 parents and nine doctors and nurses) where they looked at the program concept and written material and were invited to give feedback. Focus Group suggestions were analyzed by the research team and considered before the study´s beginning. No relevant changes were deemed necessary.

The control will consist of routine, maternal and child health 'standard-of-care' in PC (PC usual care). Physicians and nurses in the control arm provide the usual management plan based on their assessment of the family members and can deliver/suggest any written information to help parents if they intended, as they usually did in the past, before entry the study. At the end of trial data collection, we will offer clinical staff in the control arm the same CeG training previously given to the intervention arm.

Assignment/Randomisation
Randomisation units are clusters - PC units. The randomisation list will be generated by an independent statistician. The list will be stratified by type of institution (Custom Health Care Units and Family Health Units): PC units within each strata will be randomised to intervention or usual care arm.
Allocation concealment will be ensured by the following procedures: the PI will assign a meaningless random alphabet letter to each unit as participation forms are received; the final list of the participating units, anonymized, will be sent to the independent statistician so he can blindly allocate units to each trial arm and then return allocation information to the PI. Only anonymized data about participating units will be sent to the study statistician.

We will also develop two other complementary studies along with the cluster-randomized trial, as explained below:
1. Before the cluster-randomized trial beginning, we will do a cross-sectional study to assess the primary outcome (parenting sense of competence) in a first group of parents of a month-old

child who attend participating clinics. Parents will be approached in clinics by a PC provider from each site, accordingly with the same inclusion criteria. If parents agree to participate, informed consent will be obtained, and they will be asked to fill in the Parenting Sense of Competence Scale, along with the sociodemographic questionnaire and Parental Stress Inventory (as expected in trial, for the first month assessment point). An advantage of this data collection is that we can assess equivalence between clinics in the usual parenting sense of competence and statistically adjust for it in relevant data analyses, if needed. Although in a much simpler way, this first moment of data collection will replicate one trial data collection and thus, allow clinic staff time to become proficient in recruitment and data collection processes.
2. To establish if there is an improvement following the PC providers' training program, a pretest and posttest self-developed Practice and Knowledge Questionnaire (PKQ) will be used to collect the data (single-group pretest-posttest study). The posttest PKQ will be delivered in two separate moments: following the training program and at the end of the cluster-randomized trial. Practice and Knowledge Questionnaire will focus on child development, TP model (concept and practice), self-efficacy, needs and willingness to learn more about how to better support children and families. We have chosen to do it also to obtain a pre-training understanding of the providers' strengths and weaknesses when taking care of babies and their families. For this reason, the PKQ will also be applied to PC providers in the control arm (only one time at study briefing).

Intervention Type
Behavioural

Primary outcome measure
For Parents:
Parenting sense of competence using the Parenting Sense of Competence Scale (PSOC) at baseline and 18-months

Secondary outcome measures
For parents:
1. Family dynamics (Family Environment Scale – FES)
2. Couple dynamics (Revised Dyadic Adjustment Scale - RDAS)
3. Mental health including depression/anxiety and stress (Depression, Anxiety and Stress Scale-21 - DASS-21; Parental Stress Inventory – PSI)
4. Well-being/quality of life (EUROHIS-QOL-8 - QOL)
5. Psychological experience of pregnancy (Pregnancy and Motherhood Attitudes Scale - PMAS)
6. Maternal/paternal attachment (Antenatal Attachment Scale – AAS; Postnatal Attachment Scale – PAS)

For the Child:
1. Child development (Baby form; Child form; Child Behavior Checklist - CBCL, 1,5-5 - parent version)

For PC Providers:
1. Effect of the training period namely on providers' knowledge on TP model, self-efficacy and intention to use it to better support children and families (PKQ).

About the intervention CeG:
1. Acceptability, satisfaction and feasibility associated with delivering the CeG intervention arm with respect to usual care (Satisfaction Questionnaire – SQ; PC providers/parents version)
2. Evaluation of costs associated with delivering the CeG

Assessment timepoints:
First contact with parents in primary care unit, after the study start: Sociodemographic questionnaire; RDAS; QOL
26-29 weeks of pregnancy: DASS-21
30-32 weeks of pregnancy: PMAS; AAS
33-35 weeks of pregnancy: FES
36-40 weeks of pregnancy: RDAS; QOL
Newborn: Baby Form (data collected by PC provider)
1st Month: PSOC; PSI
2nd Month: DASS-21
4th Month: -
6th Month: FES; PAS
9th Month: PSOC; PSI
12th Month: -
15th Month: DASS-21; RDAS; QOL
18th Month: PSOC; PSI; CBCL; Child Form (data collected by PC provider)
Post-study: Satisfaction Questionnaire

Overall study start date
01/01/2018

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Primary Care Providers: Family physicians and family nurses from each site will be recruited if they maintain a regular clinical practice in maternal and child health visits in the PC unit
2. Parents:
2.1. Have a confirmed pregnancy
2.2. Do maternal surveillance with the family doctor and wish to maintain pediatric surveillance of their baby in the PC unit
2.3 Are at least 18 years old
2.4. Are fluent in Portuguese as judged by the consenting provider
2.5. Are able to understand all aspects of the study and provide informed consent
3. Baby/child: children of the participating parents that are born during the study

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Primary Care providers: minimum 3 physicians plus 1 nurse/per Unit x 12 Units (clusters); Recruitment of parents of 18 babies (father and/or mother) per cluster, will yield a minimum of 216 parents.

Key exclusion criteria
PC providers:
1. Within each clinic, maternal and pediatric health care delivered during the study may not be provided by any person without relevant training (e.g., a first-year family physician resident, trainee nurse)
2. PC providers will be ineligible if they are planning to retire during the study period or abandon the unit for another reason.

Parents:
1. Wish to do concomitant regular pediatric surveillance at another health unit (public or private) not motivated by the need for disease surveillance in secondary health care (e.g., hospital follow-up for cardiac disease treated by a pediatric cardiologist)
2. Intend to relocate during the study period

Date of first enrolment
01/11/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Portugal

Study participating centre
Primary Care Units from the Agrupamento de Centros de Saúde de Sintra
Sintra
Portugal
2745-837

Study participating centre
Primary Care Units from the Agrupamento de Centros de Saúde de Lisboa Central
Lisboa
Portugal
1900-138

Study participating centre
Primary Care Units from the Agrupamento de Centros de Saúde de Lisboa Norte
Lisboa

Portugal
1549-010

Sponsor information

Organisation
CINTESIS – Center for Health Technology and Services Research

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Sponsor type
Research organisation

Website
http://cintesis.eu/pt/homepage/

Funder(s)

Funder type
Government

Funder Name
(CAPES) - Portugal (FCT): Filipa Fareleira is funded by Foundation for Science and Technology (FCT) PhD Fellow Grant number PD/BD/132860/2017 Doctoral Program in Clinical and Health Services Research (PDICSS)

Results and Publications

Publication and dissemination plan
Members of the scientific community and the public will be able to access the full study protocol at http://www.isrctn.com. Substantive modifications to this protocol will be communicated to the relevant staff at participating clinics during regular communications, or to others via written summaries, published modifications to the trial profile at http://www.isrctn.com and/or via statements in scientific papers or reports arising from the study.
The full protocol will also be available on the doctoral thesis of the principal investigator.

Study findings
Findings from this study will be submitted for publication in peer-reviewed journals. The study results will also be shared with health professionals and other participants from participating PC units and through scientific conferences targeting primary and secondary care providers, research community and public health policymakers more widely.

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/05/2021	17/05/2021	Yes	No