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Parenting, child development and Primary Care - "Crescer em Grande!" intervention (CeG!) based on the Touchpoints approach: a cluster-randomised controlled trial protocol.

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ABSTRACT

Introduction: Despite support for parenting being already recognized as a priority, there remains a paucity of evidence on how to facilitate its adoption in regular visits of maternal and child health Primary Care (PC). We describe the protocol for a study to assess the effect of an innovative universal Touchpoints-based intervention - "Crescer em Grande!" (CeG!) when supporting the process of transition to parenthood and early infancy, at multiple PC units.

Methods and analysis: A cluster-randomised trial will be conducted in 12 PC units (clusters) from the Lisbon region, Portugal. Participants will be family physicians and nurses, as well as 216 expecting parents and future babies till 18 months who are using the PC services. Sites will be randomised to either the CeG! or usual care. The CeG! will consist of: 1) the integration of the Touchpoints 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 on how to perform the CeG! into existing practice. Parents will be required to fill in questionnaires at point throughout their child's 18-month, mostly online. The primary outcome will be the self-perception of parental competence (Parenting Sense of Competence Scale). Other outcomes include: family functioning, couple dynamics, mental health, well-being/quality of life, psychological experience of pregnancy, attachment, child development. Acceptability, satisfaction and feasibility of CeG! will also be obtained from providers' and parents' perspectives. Costs associated with delivering the CeG! will be calculated. Study analyses will be under the principle of intention-to-treat.

Ethics and dissemination: Approval was obtained from the Ethics Committee of the Regional Health Administration. The results will be shared with participants and disseminated via peer-reviewed published papers, presentations at scientific and professional conferences.

Trial registration number: ISRCTN90692907.

Keywords: Parenting, Touchpoints, Intervention, Primary Care.

ARTICLE SUMMARY

Strengths and Limitations of this Study

1. We developed a challenging Primary Care (PC) cluster-randomised trial to assess the effect of a preventative, innovative Touchpoints-based intervention (CeG!) at multiple PC units from the Portugal National Health System, its impact on parental competence of parents of children under 18 months of age and relation with other dimensions like parents' mental health, child development and family well-being, that remain to be studied.

2. The CeG! intervention was designed to be implemented in a real-world setting, in a non-stigmatizing context (with no identifying entrance criteria), as part of routine care (no additional schedule), along with well-known and reliable family health professionals, in order to support the process of transition to parenthood and early infancy that has well-known implications in future developmental pathways.

3. The CeG! includes Touchpoints-based written materials (leaflets) developed by a group of PC providers, including doctors and one nurse; leaflets' content, organization and design were also reviewed with academic experts and later by PC providers and parents using a focus group approach to reach the final version.

4. The trial will take place in 12 PC units from the Lisbon district, Portugal; therefore, our conclusions may potentially not be generalizable to other realities.

5. We will use self-report measures instead of structured observations and independent assessments of the intervention, which can influence responses as a result of social convenience.

INTRODUCTION

The family, despite structural changes it has been suffering, maintains a prominent place in society as an elementary unit of organization and emotional support.[1] In the 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. This is particularly true in the transition between the well-identified family life cycle stages. An example of the latter is the transition to parenthood[2 3] and the parental task of the early years, a period identified as crucial for shaping children's future.[4-7]

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.[1 8] The literature shows that valued parents, supported, knowledgeable of child development and sensitized to positive strategies, use fewer punitive strategies, can better understand the behavior of the child, feel less stressed. This way, they can foster a better parent-child relationship and family welfare, feeling more competent to face any approaching parental challenge.[9-12]

Indeed, an essential part of being a "good parent" is how parents perceive themselves as capable of performing the varied tasks associated with parenting: parental self-efficacy beliefs[13] and their satisfaction derived from the parenting role.[13 14] This feeling of parental competence is a central construct to understand the dynamic processes of the family system. It has been widely studied as having implications on parenting behavior, mental health and well-being; parent-child interactions; and children's development and behavior.[15-21]

The Touchpoints (TP) model began to emerge after Brazelton's seminal work in the '60s to support the families' needs and worries, valuing its strengths, promoting parental competence, and giving empowerment back to families. Nowadays, the TP Network comprises communities and systems of care (health, education and social services) over 100 sites in 33 states in the United States and at several other places internationally, including Portugal.[22] This well-established model of development and intervention assumes its importance given that it is dynamic and presupposes predictable periods of disorganization (touchpoint definition) – from the perinatal period throughout the child's development in which the anticipatory care by the PC professionals has recognized importance.[23 24] It is also a relational, inclusive, non-prescriptive approach based on the construction of an alliance between professionals and parents, parents and child, professionals and children, valuable for teams.[25] We believe this kind of approach with parents needs to be integrated into preventive and universal care plans to support families and thereby to improve their quality of life. In 2015, an American Parent National Survey[26] with 2.200 parents of children birth to 5 years from a wide range of backgrounds showed that fully half of the parents are not getting the support they need not only when they feel overwhelmed or stressed but also in making everyday decisions. Those parents share a universal desire to improve their parenting skills and do want guidance from child development professionals, mainly from the ones who know their child and situation. They believe that good parenting can be learned, and most say that if they knew more positive parenting strategies, they would use them - "needs and demands" also found in other studies.[27-29]

Presently, there is well-established evidence that parenting programs are effective in improving both parents and child outcomes.[9-12 30-33]

However, parenting programs are generally built to work jointly with families who have children at risk or with behavioral, emotional or social difficulties. Therefore, it brings advantages to a relatively small group of parents. Relevant difficulties in recruitment and sustained parental adherence have also been described, sometimes compromising effectiveness.[34-36] Universal approaches to parenting support are an additional offer that assumes itself as a public health intervention.[37] The general aim is to enhance the quality of the early family environment as it could benefit those at risk of adverse parenting but also other families in the population at large. One promising strategy for reaching families widely is the PC setting - a non-stigmatizing, favorable setting for parenting interventions not only throughout the child's development but also for the perinatal period to support parents' transition into parenthood. The main reasons are due to PC provider's rapport and credibility with families and a well-established mechanism for consistent contact through regular well-child visits during pregnancy and the first three years of a child's life.[38-40] Thus, the PC offers an ideal setting to promote positive parenting and reduce income-related developmental disparities.[41] Despite these advantages, PC providers often lack the time needed, so research is required within the PC setting to study different solutions, optimizing this setting.

To this end, a parental intervention based on the TP model - "Crescer em Grande!" (CeG!) (“Grow Big!”, English translation merely indicative for readers´ understanding) - was designed to support parents in perinatal period and early childhood. To the best of our knowledge, no preventive, universal family-based parenting interventions using the TP approach were previously developed worldwide for PC maternal and well-child visits. Within this context, we developed a PC cluster-randomised trial (CRT) with the objective of assessing the effect of CeG! on parenting sense of competence of parents of children under 18 months of age, compared with usual care, and its relation with other dimensions like parental mental health, child development and family well-being.

METHODS AND ANALYSIS

Trial design

Sites will be randomised to either the CeG! intervention or usual care arms in a parallel, multicenter, CRT. The clusters will be PC units. Participants will be comprised of PC providers (of each PC unit) and a subset of parents and their newborn babies attending these units. The unit of analysis will be the parents.

We decided on a cluster design as it is the most rigorous to prevent eventual contamination within any site if providers were chosen as the unit of randomisation (since it would not be possible to do parents' randomisation because patients are attached to their family physician).

Our protocol is under the SPIRIT recommendations for clinical trial protocols.[42]

Study setting

The trial will take place in 12 PC units from the Lisbon region (Portugal), permitting the recommended minimum of four clusters per trial arm to minimize potential confounding from cluster effect.[43] Clusters will be from the two types of PC units of National Health Service: Custom Health Care Units and Family Health Units (type-A and type-B).

Participating PC units will be selected as a convenience sample in order to guarantee similar populations, as well as some consultation properties: they cater to a mainly urban population; have 20 to 30 minutes of sequential nurse and physician consultations each and must have at least 80% of PC providers working as a stable team during the last year before the start of the trial. In each unit, at least three family physicians and one nurse must be willing to participate for the unit to be included in the study.

To minimize contamination, we will only recruit one PC unit per building, and no unit may employ a study investigator.

Intervention

The CEG! Intervention is based on the TP model. The TP model is a new paradigm of human development and clinical intervention inspired by a relational model. It assumes that favoring the bond of the baby to his family has significant repercussions from the perinatal period and throughout the children's development. The model focuses on a non-linear process of development and how it is experienced by all involved. It presupposes well-identified and predictable periods of disorganization – the touchpoints – when the child's behavior seems to fall apart, typically preceding a spurt in development. Touchpoints are often accompanied by parental frustration and self-doubt. Therefore, they offer unique opportunities to make a difference in the lives of children and families because each TP outlines universal themes that might be coming up for the family, opportunities for practice to support the child/family system and suggestions for anticipatory guidance to help to predict the next TP. This model is anchored in the premise that the enhancement of a child's ability to reach their developmental potential cannot happen without supporting and enhancing the family's emotional and relational functioning, so children can have parents who are convinced of their skills and competencies. Thus, the TP Relational Framework presupposes a transformation in working with families by choosing strategies to support families' positive attributes, values and desires for raising their child on a collaborative attitude and empathic involvement instead of the traditional prescriptive and objective approach. This "paradigm shift" (Table 1) is supported by a set of TP Guiding Principles and Parent and Provider Assumptions – tools to use and be intentional when working with families across articulated work between professionals and health, education, and social services to build a common language. The Principles of Touchpoints must be seen as general guidelines “for using the developmental knowledge and relational skill at each of the touchpoints in making judgments that support good parenting”.[44] The TP Parent and Provider

Assumptions represent a set of beliefs providers should hold and strive to act upon in working with families.[44-46]

Table 1. The Touchpoints paradigm shift.

From:	To:
- Deficit	- Positive
- Linear Development	- Multidimensional Development
- Prescriptive	- Collaborative
- Objective Involvement	- Empathetic Involvement
- Strict Discipline Boundaries	- Flexible Discipline Boundaries

Source: adapted from Touchpoints Reference Guide and Participant Training Materials, 2016.[44]

Thus, the CeG! presents itself as a preventative intervention to contribute to positive parenting, consisting 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 on how to deliver, perform and integrate the CeG! Intervention into existing practice. The leaflets were developed with the collaboration of 13 PC providers (doctors and one nurse) to be used by the PC team and families as part of routine care. Each will be delivered unitarily in scheduled consultations from 26 weeks of gestation (considering first TP at the third trimester) until the age of 18 months, anticipating the TP and parents' needs, worries, fears, maybe not always addressed in healthcare visits (Table 2).

Providers in the CeG! arm will complete a 5-hour training designed to enhance their motivation, skills, and self-efficacy to use different elements of the strength-based TP model as guidance to promote parental competence. For the sessions, we developed a set of presentation slides for clinic staff that elucidates on the intervention concept and philosophy, implementation strategies and health gains. The focus will be on reflecting on the developmental process and challenges faced by the different elements of the system: child, parents and health providers, to start getting into a practical perspective through the TP Relational Framework. The aim is to help PC providers rethink their practice with families of young children. Specific strategies (TP Principles and Assumptions) and examples of implementation will be provided as a guide to adopting a 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 the developmental sequence of main expected changes in a child and family's life until the age of six. One or more unit representatives will be charged with encouraging and enabling other professionals in their unit to review the leaflets folder throughout the study.

The control will consist of routine, maternal and well-child 'standard-of-care' in PC (usual care arm). 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 entering the study. At the end of the trial data collection, we will offer clinical staff in the control arm the same CeG! training previously given to the intervention arm.

Patient and Public Involvement

CeG! design and different stakeholders' involvement

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 group discussions (11 parents and nine doctors and nurses) where they looked at the general 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, and all the participants revealed good acceptance.

No patients were involved in the CRT design, recruitment, conduct and burden of the intervention.

Participants, study description and recruitment

Participants

Primary Care Providers: Family physicians and family nurses from each site will be recruited if they maintain a regular clinical practice in maternal and well-child visits in the PC unit. After a letter of introduction from the principal investigator (PI), the investigators will discuss the project with each PC unit team, its documented benefits and time commitments and ask each PC provider to sign an informed consent approved by their Regional Health Administration's Ethics Committee. If there is a team composed by a family physician and a family nurse for each list of users, both will need to enter the study. In case of an occasional PC providers' absence, each PC unit guarantees that another PC provider enrolled in the study will hold maternal and child health visits. 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). Primary Care providers will be ineligible if they are planning to retire during the study period or abandon the unit for other reasons.

Parents: Participants will be recruited through the physicians' list or a list of patients waiting for physician assignment (Custom Health Care Units), at each of the 12 sites. Parents (fathers and/or mothers) are eligible if they: 1) have a confirmed pregnancy; 2) do maternal surveillance with the family doctor and wish to maintain pediatric surveillance of their baby in the PC unit; 3) are at least 18 years old; 4) are fluent in Portuguese as judged by the consenting provider; and 5) can understand all aspects of the study and provide informed consent. Mothers or fathers are included if interested regardless of their partners' decline. Parents will be ineligible if they: 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); or 2) intend to relocate during the study period.

Baby/child: children of the participating parents that are born during the study.

There will be no financial incentive for study participation.

Study description and recruitment

Overall Cluster-Randomised Trial

Once the PC providers complete training for the CeG! intervention or get the study's briefing on the usual care arm, a group of parents (of 216 babies) will be recruited and followed longitudinally for the CRT. All eligible parents will be invited to participate in the trial during pregnancy, in person, during a clinic visit (ideally before the 26 weeks of pregnancy). At this initial contact, a PC provider will discuss the purpose of the study and study procedures with the parent and assess his interest. If interested, the PC provider will obtain the parent's written informed consent to participate. Parents will be recruited consecutively until the required sample number is reached.

Parents will be asked to complete questionnaires in multiple scheduled assessment points until the child's 18-month well-child visit (Table 3).

We will also develop two other complementary studies along with the CRT (Figure 1), as explained below:

- before the CRT 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 units. For 4 to 6 weeks, all that parents will be approached in units by a PC provider from each site, accordingly with the same inclusion criteria (see above, *Parents*). 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 the trial, for the first-month assessment point). An advantage of this data collection is that we can assess equivalence between units 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 to become proficient in recruitment and data collection processes.
- to establish if there is an improvement following the PC providers' training period, a pretest and posttest self-developed Practice and Knowledge Questionnaire (PKQ) will be used to collect the data (*single-group pretest-posttest study*) along with a sociodemographic and professional questionnaire. The posttest PKQ will be delivered in two separate moments: following the training period and at the end of the CRT. 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 (antenatal and postnatal). For this reason, the PKQ will also be applied to PC providers in the control arm (only one time at the study briefing).

Figure 1. Data collection schematic.

Feb, February; CeG!, *Crescer em Grande!*; CRT, cluster-randomised trial; Dec, December; HP, health providers; Jan, January; PCP, Primary Care Provider; Pre-PKQ, Pretest Practice and Knowledge Questionnaire; Post-PKQ, Posttest Practice and Knowledge Questionnaire.

Note: Possible calendar changes due to the COVID-19 pandemic.

Outcomes

Primary outcome

For parents:

- Difference in mean change (from the first month to the 18-month well-child visit) in parenting sense of competence between the two trial arms, using the Parenting Sense of Competence Scale (PSOC).

Secondary outcomes

For parents:

- Difference in mean change (from the first to the last research assessment for each instruments - Table 3) between the two trial arms for family functioning (Family Environment Scale – FES), couple dynamics (Revised Dyadic Adjustment Scale - RDAS), mental health including depression/anxiety and stress (Depression, Anxiety and Stress Scale-21 - DASS-21; Parental Stress Inventory – PSI) and well-being/quality of life (EUROHIS-QOL-8 - QOL), at antenatal and postnatal periods.
- Differences in the psychological experience of pregnancy (Pregnancy and Motherhood Attitudes Scale - PMAS) between the two trial arms, only at the antenatal period.
- Differences in maternal/paternal attachment (Antenatal Attachment Scale – AAS; Postnatal Attachment Scale – PAS) between the two trial arms, at antenatal and postnatal periods.

For the Child:

- Differences in child development between the two trial arms (Baby form; Child form; Child Behavior Checklist - CBCL 1,5-5 - parent version).

For PC Providers:

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

About the CeG! intervention:

- Comparison of acceptability, satisfaction, and feasibility of delivering the CeG! with respect to usual care (Satisfaction Questionnaire – SQ; PC providers/parents version).
- Evaluation of costs associated with delivering the CeG!

Table 2. The CeG! topics by Touchpoints and scheduled routine care in Primary Care.

Care visits	Touchpoints†		Topics
Pregnancy			
26-29w	Prenatal	The Ideal Baby	Touchpoints definition
30-32w			Mummy and Daddy – I just arrived, what now?
33-35w			Baby and feeding
36-40w	Newborn	The Real Baby	Role of caregivers in development
Child			
Home visit	-	-	Child Safety
			Vaccination
1st visit	3 w	The Energy Sink	Baby's language
1st M	6-8 w	The Rewarding Baby	Sleeping
2nd M	4 M	Looking Outward	Cognitive development (1)
4th M	7 M	Up at Night	Feeding
6th M	9 M	The Pointer	Frequent symptoms in childhood
			Breath-holding Stranger and Separation anxiety
9th M	12 M	The Walker	Conquering autonomy/Walking
12th M	15 M	The Clinger	Child and discipline (1)
15th M	18 M	Rebel with a Cause	Toilet training
18th M	24 M	Getting to "No!"	Aggression/ Most common discipline challenges (2)*
2 y	3 y	"Why?"	Pacifier/Thumb sucking /Transitional object
3 y	4 y	"What I do Matters"	Fears and nightmares Imaginary friend
4 y	5 y	"Who I am Matters"	Most common discipline challenges (3)**
5 y	6 y	Entering the Real World	Cognitive development (2)
Other	When necessary		Bedwetting Sibling rivalry

M, months; w, weeks; y, years.

† Source: adapted from Touchpoints reference guide for health care providers, 2012.[45]

* Most common discipline challenges (2) – tantrums; hitting, biting.

** Most common discipline challenges (3) – whimpering, lying, retorting, complaining.

Sample size calculation

The primary outcome will be analyzed as the mean change of the PSOC score between the first month and the 18-month well-child visit in each parent. There will be an average change in each arm, and the effect of the intervention will be the difference between these averages.

A sample size of parents of 18 babies (fathers and/or mothers) per cluster, in 12 clusters, was calculated, considering a power of 80%, a type I error of 5%, an intracluster correlation coefficient (ICC)=0.03[47] and a medium effect size of 0.5.[48]

All calculations are based on the formula for comparison of two means in CRT and assume a 20% loss to follow-up. We used the UCSF Clinical & Translational Science Institute - Sample Size Calculators, available at http://www.sample-size.net.

Since the average number of births per unit, per year, is approximately 150[49] and assuming conservatively that 50% of parents choose to participate in the research project, we estimate that recruitment can be completed in three months, enrolling a minimum of one to two participants a week, per PC unit.

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.

As a CRT, only limited blinding could be enforced. Although it is not possible to blind participants and the research team to the trial arm of each assigned unit, consent will not identify other study arms, avoiding participants to know they are in a trial.[43] The study statistician will remain blinded during the study period until the database is locked, all analyses are completed, and the study unblinded.

Data collection, management and analysis

Assessment

Although the leaflets are designed to accompany pregnancy and the development of children from zero to six years of age, in this study it is chosen to include only assessment points until the child reaches 18 months of age due to the time available for the project, namely for data collection; a higher concentration of the number of TP in the first 18 months of the child's life, as well as the number of well-child visits; also the first 18 months as a phase of significant family adaptation with the birth of a new element.

Parents' enrollment and baseline assessment will be done at the first clinical contact at the PC unit after the study begins (after cross-sectional study in the control arm; after the training period in CeG! arm). Once individual informed consent is obtained, a PC provider in each arm will deliver parents a self-completion sociodemographic questionnaire to collect baseline data, namely: age, gender, marital status, level of education, family's elements and income perception, occupation, support network, among others. Two additional tools assessing couple dynamics (Revised Dyadic Adjustment Scale) and health-related quality of life (EUROHIS-QOL-8) will be delivered.

Relevant sociodemographic information on eligible individuals who decide not to enroll in the study will be anonymously collected. In addition to these data, the provider involved in the recruitment will ask decliners about the reason for the decline.

Multiple assessment points will continue till 18 months well-child visit (Table 3), using the instruments bellow – all validated for the Portuguese population except for the forms developed for the study.

- Parenting Sense of Competence Scale[14 50] (PSOC) - this is a self-completion questionnaire addressed to parents (Cronbach alpha of .76[50]), designed to assess self-perception of parental competence regarding two dimensions: satisfaction and efficacy. The PSOC consists of 16 items (9 for satisfaction and 7 for efficacy) answered on a 5-point scale ranging from "strongly disagree" to "strongly agree." Results are obtained by adding the quotations of individual items, after the inversion of some; a higher result indicates higher levels of confidence in parenting capacities. The total score ranges from 16 to 80 (no cutoffs).
- Sociodemographic and Professional Questionnaire - demographic and professional characteristics (*e.g.,* number of years of practice after vocational training, currently training residents) will be examined for PC providers at each unit. The instrument was developed for the study and will be applied after the study briefing.
- Sociodemographic Questionnaire (SDQ) for parents - demographic, lifestyle and pregnancy questionnaire. The instrument was developed for the study.
- Baby form (BF); Child form (CF) - data on birth and baby/child clinical characteristics (weight, length, APGAR index, feeding and health status) collected by PC provider. The instrument was developed for the study.
- Revised Dyadic Adjustment Scale[51] (RDAS) - the scale is organized in three subscales: Dyadic Consensus, Dyadic Satisfaction and Dyadic Cohesion.
- EUROHIS-QOL-8[52] (QOL)- evaluates the perception of the quality of life of adults (physical, psychological, social and environmental domains).
- Depression, Anxiety and Stress Scale-21[53] (DASS-21) - negative emotional states evaluation scale, short form of the DASS-42,[54] with 21 items distributed by three factors: Depression, Anxiety and Stress.
- Pregnancy and Motherhood Attitudes Scale[55] (PMAS) - evaluates the psychological experience of pregnancy organized in 7 dimensions: The Imagined Son, Good Mother, Pregnancy as a Factor of Change/Personal Growth, Difficult Aspects of Pregnancy/Maternity, Relationship with One's Own Mother, Husband/Companion Support, and Body Image and Need of Dependency. It will be performed only by the mother of the child.
- Attachment Scale (Antenatal and Postnatal)[56 57] - both scales evaluate two dimensions: Bonding Quality and the Time Spent in the Bonding Mode or Intensity of Concern (maternal/paternal version).
- Family Environment Scale[58] (FES) - examines each family member's perceptions of the family in three ways—as it is (real), as it would be in a perfect situation (ideal) and as it will probably be in new situations (expected). We will use the *Relation* dimension of the *Family Environment* Scale.[59] This dimension includes three subscales: cohesion, expressiveness and conflict.
- Parental Stress Inventory[60] (PSI) - measures the level of parental stress specifically in the postnatal period.
- Child Behavior Checklist for Ages 1.5-5[61] (CBCL 1.5-5) - is part of the Achenbach System of Empirically Based Assessment[62] that offers a comprehensive approach to assessing adaptive and maladaptive functioning. The CBCL evaluates the overall functioning of children and young people and has been described as one of the most comprehensive and psychometrically sound measures for parent report of infant and toddler social-emotional development.[63]
- Satisfaction Questionnaire (SQ) - a satisfaction questionnaire related to satisfaction with care, parents-providers relationship, research involvement, acceptability and perspectives on intervention effectiveness will be organized (closed + open questions). It will be applied to clinical staff and parents (PC providers/parents' version).

Data collection and management

We will collect study data via longitudinal parents' assessments, through self-completion questionnaires, administered mainly after each healthcare visit, as shown in Table 3.

When a parent agrees to participate, a PC provider will register the name in an electronic platform for the purpose, and a code, which includes the letter randomly assigned to the PC unit, will be automatically assigned. Identification will be kept until the end of the data analysis. Only the clinical staff from each unit will know the parents who participate in the study.

Except for the first assessment of the study (on paper support), questionnaires will be completed online (via e-mail correspondence and phone message). Data will be collected through an electronic platform developed specifically for this purpose, which will allow the automatic submission of questionnaires to the parents in the timings defined, facilitating the entire data collection and storage process. Regular e-mail reminders will be sent to parents in case of non-response; 48 hours before a clinical visit, an email will also be sent to each participants' health providers.

The electronic application will be developed in full compliance with the new General Data Protection Regulation. The servers will be housed in the European Union, certified with compliance with all safety standards, and with regularly backed backups and maintenance of duplicate databases in geographically distinct locations, protecting the information from any eventual loss. An administrator profile will be created only for the PI. The registration of the e-mail/phone number of the users will be encrypted, with the decryption key only in possession of the PI. The individuals' visible identifier will be the random code assigned to them at the beginning of the study.

Only the PI's profile will have access to the control panel of the study's evolution, manually register questionnaires on paper, or reinforce the sending of e-mails to request the completion of missing questionnaires. After the end of the study, all data will be permanently erased from the servers. The data will be stored for five years on an external encrypted disk, which requires the use of a password.

If parents cannot answer electronically, there will also be a paper version of the study forms. In this case, the questionnaires must be completed in the unit. There will be a closed return box in each PC unit so that parents can place their completed coded questionnaires, ensuring their privacy and anonymity. At each consultation, PC providers should remind these participants of the placement of the questionnaires in the box available for this purpose. A team investigator will collect the questionnaires frequently from each unit. If necessary, the PI will contact the clinic representative, signaling a missing questionnaire for a specific code. Those site visits will also allow the study investigators to monitor the enrollment process, intervention delivery, and protocol adherence. Email greetings on particular dates (e.g., child´s birthday, Christmas) will be sent to reinforce parents´ adherence.

At each visit, information on attendance to health visit, eventual dropouts and reasons for dropout will be collected by a PC provider directly on the electronic platform.

To test the excellent functioning of the electronic platform and get feedback from PC providers and parents on the trial process, we will do a small pilot previously with 3-4 pregnant couples within a PC unit that does not enter the CRT.

Table 3. Assessment points and related evaluation tools.

	Maternal Health Care	Primary Health Care visits									Child Health Care				
	First contact*	**26-29w**	**30-32w**	**33-35w**	**36-40w**	**Newborn**	**1st M**	**2nd M**	**4th M**	**6th M**	**9th M**	**12th M**	**15th M**	**18th M**	**Post study**
Assessment tools (Parents)	SDQ RDAS QOL	DASS-21	PMAS** AAS	FES	RDAS QOL	BF†	PSOC PSI	DASS-21	-	FES PAS	PSOC PSI	-	DASS-21 RDAS QOL	PSOC PSI CBCL CF†	SQ

* First contact with parents in primary care unit, after the study start: after cross-sectional study in the control arm; after the training period in CeG! arm (parents' recruitment).
** Only performed by mother.
† Data collected by PC provider.
AAS, Maternal/Paternal Antenatal Attachment Scale; BF, Baby form; CBCL, Child Behavior Checklist 1.5-5; CF, Child form; DASS-21, Depression, Anxiety and Stress Scale-21; FES, Family Environment Scale; QOL, EUROHIS-QOL-8; M, month; PAS, Maternal/Paternal Postnatal Attachment Scale; PMAS, Pregnancy and Motherhood Attitudes Scale; PSI, Parental Stress Inventory; PSOC, Parenting Sense of Competence Scale; RDAS, Revised Dyadic Adjustment Scale; SDQ, sociodemographic questionnaire; SQ, satisfaction questionnaire; w, weeks.

Statistical methods

The intention-to-treat principle will be adopted. Participants' data will not be included in any analyses if they withdraw consent.

Initially, a descriptive statistical analysis of the variables studied for participants at each PC unit will be performed by the study group (CeG! and control) and strata (type of unit: Custom Health Care Units and Family Health Units). Categorical variables will be described by absolute and relative frequencies; continuous variables by means (and SD) if they are normally distributed or by medians (and IQR) if not; ordinal variables will be presented by medians (and IQR).

Recognizing that cluster randomisation might not achieve balance on descriptive variables between individuals at baseline, adjusting for these variables will be considered in the model. Therefore, both groups' outcomes will be compared using linear-mixed effect models adjusting for baseline measurements with a random intercept for the PC unit level to account for clustering effect. Statistical significance will be set at $p < 0.05$.

Additionally, to determine if specific subpopulations respond differently to CeG! intervention, we will perform subgroup analyses based on baseline characteristics. This analysis will be conducted among the different types of family structures, families expecting their first child versus families with one or more children, mothers with above high school education versus mothers with high school or below, and families experiencing financial strain versus families who are not. We will test for significance of subgroups using statistical tests for interaction.

Reporting of results will follow the principles of Consolidated Standards of Reporting Trials statements and the extension for CRT.[43 64]

Rates and reasons for missing data will be assessed and reported. Several aspects will be considered to ensure data consistency: verifying variables type, list all the possible values for each variable, check spelling errors and improper entries, and investigate missing data. The out-of-range, unreliable, or invalid values must be evaluated carefully. Furthermore, assessing the best method to deal with missing data must be probed. One or more imputation algorithms, such as the mean or median values, or deep learning methods, must be implemented and assessed using different metrics such as distributional accuracy.

Process evaluation

Regular site visits will allow the study researchers to monitor the enrolment process, intervention delivery and protocol adherence. To enable early correction of any errors during data collection, there will be close supervision of data on the platform with subsequent contact with unit representative wherever needed; platform chat is available for any doubts during data insertion. Parents will be instructed to contact their healthcare team whenever any questions arise; a study's telephone contact and an e-mail will be available.

We anticipate no harm arising from the intervention's implementation; therefore, no data monitoring committee was established. If we become aware of any harm or other adverse events, either through study data or other avenues, we will review and address these according to standard institutional processes, in consultation with the relevant ethics committee. We will also file regular reports on trial progress with the ethics committee. We have not devised any stopping guidelines, although we intend to carry out mid-term analyses of trial outcome data, according to the different measurement points. If any relevant health information is identified during the analysis of the participants' data, it shall be communicated to the attending family physician who will act in accordance.

Program costs

To help inform potential financing and adoption of the CeG! intervention, compared with usual care, we intend to estimate the incremental costs to deliver the intervention (e.g., costs in printing leaflets, training costs) and overhead costs minus costs attributable only to research activities (e.g., PC unit study monitoring visits).

ETHICS AND DISSEMINATION

This trial is conceived in accordance with the fundamental ethical principles of autonomy, beneficence, justice, and non-maleficence and will be conducted under the principles expressed in the Declaration of Helsinki.

Research ethics approval

Approved by the Ethics Committee of the Regional Health Administration of Lisbon and Tagus Valley (Portugal); registration number: 013/CES/INV/2019 (date: 18.11.2019).

Consent

When adopting a CRT, it is not usually feasible to obtain participants' consent to randomisation. Instead, consent to randomisation is typically provided by a surrogate decision-maker at the cluster level. We will obtain agreement to randomisation from a representative from each clinic (the executive director of each Health Centre Groups involved). We will seek PC care providers' and eligible patients' written informed consent to participate in the study's data collection.

Privacy and confidentiality

Data confidentiality and anonymity will be ensured by the PI in full compliance with the new General Data Protection Regulation, both during the implementation phase of the study and in any resulting presentations or publications. The results will only be used in the framework of this study. All personal information will be safeguarded by assigning a meaningless random code, which will link the answers, without identification, across all the time points. Finally, restricted access to participant-level data and files will be ensured.

Dissemination policy

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 units during regular communications; to others via written summaries, published modifications to the trial profile at http://www.isrctn.com or via statements in scientific papers arising from the study.

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 units and through scientific conferences targeting primary and secondary care providers, and research community more widely. The full protocol and the results of this research project will also be available on the PI's doctoral thesis. Once the study is completed and primary manuscripts published, data will be available upon request to the PI.

AUTHOR CONTRIBUTIONS

FF conceived the overall study, drafted the protocol and registered the trial. MRX contributed to the development of the study protocol and helped monitor the study process. CM provided overall guidance in CRT design. AT performed sample size calculations and statistical guidance in the development of the protocol. FF and JV participated in the trial methods adaptation to the local context and have responsibilities for day-to-day running of the trial. All authors read and approved the final version manuscript.

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COMPETING INTERESTS STATEMENT

MRX is member of the Administrative Board (non-executive) of the Fundação Brazelton/Gomes-Pedro para as Ciências do Bebé e da Família, Portugal.
All remaining autors: none to declare.

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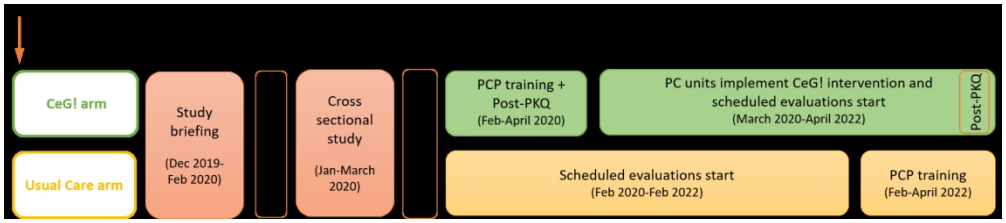

Figure 1. Data collection schematic.
Feb, February; CeG!, Crescer em Grande!; CRT, cluster-randomised trial; Dec, December; HP, health providers; Jan, January; PCP, Primary Care Provider; Pre-PKQ, Pretest Practice and Knowledge Questionnaire; Post-PKQ, Posttest Practice and Knowledge Questionnaire.
Note: Possible calendar changes due to the COVID-19 pandemic.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Pages
Administrative information			
✓ Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
✓ Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	-
Protocol version	3	Date and version identifier	-
✓ Funding	4	Sources and types of financial, material, and other support	18
✓ Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,18
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	-
Introduction			
✓ Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4,5
	6b	Explanation for choice of comparators	7

✓ Objectives	7	Specific objectives or hypotheses	5
✓ Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6,9
Methods: Participants, interventions, and outcomes			
✓ Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
✓ Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6, 8
✓ Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6,7,9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	(N/A)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14,16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
✓ Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10
✓ Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended	Fig.1
✓ Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12

✓ Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

Methods: Assignment of interventions (for controlled trials)

Allocation:

✓ Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
✓ Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
✓Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
✓ Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12

Methods: Data collection, management, and analysis

✓ Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14

✓ Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
✓ Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
✓ Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
✓ Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
✓ Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
✓ Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
✓ Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
✓ Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8,9,17

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	(N/A)
✓ Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14,17
✓ Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
✓ Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14,17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	(N/A)
✓ Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	-
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	(N/A)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Parenting, child development and Primary Care - "Crescer em Grande!" intervention (CeG!) based on the Touchpoints approach: a cluster-randomised controlled trial protocol.

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Parenting, child development and Primary Care - "Crescer em Grande!" intervention (CeG!) based on the Touchpoints approach: a cluster-randomised controlled trial protocol.

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ABSTRACT

Introduction: Despite support for parenting being already recognized as a priority, there remains a paucity of evidence on how to facilitate its adoption in regular visits of maternal and child health Primary Care (PC). We describe the protocol for a study to assess the effect of an innovative universal Touchpoints-based intervention - "Crescer em Grande!" (CeG!) when supporting the process of transition to parenthood and early infancy, at multiple PC units.

Methods and analysis: A cluster-randomised trial will be conducted in 12 PC units (clusters) from the Lisbon Metropolitan Area, Portugal. Participants will be a minimum of three family physicians and one nurse/unit, as well as 216 expecting parents and future babies till 18 months who are using the PC services. Sites will be randomised to either the CeG! or usual care. The CeG! will consist of: 1) the integration of the Touchpoints 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 on how to perform the CeG! into existing practice. Parents will be required to fill in questionnaires at point throughout their child's 18-month, mostly online. The primary outcome will be the self-perception of parental competence (Parenting Sense of Competence Scale). Other outcomes include: family functioning, couple dynamics, mental health, well-being/quality of life, psychological experience of pregnancy, attachment, child development. Acceptability, satisfaction and feasibility of CeG! will also be obtained from providers' and parents' perspectives. Costs associated with delivering the CeG! will be calculated. Study analyses will be under the principle of intention-to-treat.

Ethics and dissemination: Approval was obtained from the Ethics Committee of the Regional Health Administration. The results will be shared with participants and disseminated via peer-reviewed published papers, presentations at scientific and professional conferences.

Trial registration number: ISRCTN90692907.

Keywords: Parenting, Touchpoints, Intervention, Primary Care.

ARTICLE SUMMARY

Strengths and Limitations of this Study

1. We designed a challenging Primary Care (PC) cluster-randomised trial to assess the effect of a preventative, innovative Touchpoints-based intervention (CeG!) at multiple PC units from the Portuguese National Health Service (NHS), its impact on parental competence of parents of children under 18 months of age and relation with other dimensions like parents' mental health, child development and family well-being, that remain to be studied.

2. The CeG! intervention was developed to be implemented in a real-world setting, in a non-stigmatizing context (with no identifying entrance criteria), as part of routine care (no additional schedule), along with well-known and reliable family health professionals, in order to support the process of transition to parenthood and early infancy that has well-known implications in future developmental pathways.

3. The CeG! includes Touchpoints-based written materials (leaflets) developed by a group of PC providers, including doctors and one nurse; leaflets' content, organization and design were also reviewed with academic experts and later by PC providers and parents using a focus group approach to reach the final version.

4. The trial will take place in 12 PC units from the Lisbon Metropolitan Area, Portugal; therefore, our conclusions may potentially not be generalizable to other realities.

5. We will mainly use self-report measures instead of structured observations and independent assessments of the intervention, which can influence responses as a result of social convenience.

INTRODUCTION

The family, despite structural changes it has been suffering, maintains a prominent place in society as an elementary unit of organization and emotional support.[1] In the 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. This is particularly true in the transition between the well-identified family life cycle stages. An example of the latter is the transition to parenthood[2 3] and the parental task of the early years, a period identified as crucial for shaping children's future.[4-7]

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.[1 8] The literature shows that valued parents, supported, knowledgeable of child development and sensitized to positive strategies, use fewer punitive strategies, can better understand the behavior of the child, feel less stressed. This way, they can foster a better parent-child relationship and family welfare, feeling more competent to face any approaching parental challenge.[9-12]

Indeed, an essential part of being a "good parent" is how parents perceive themselves as capable of performing the varied tasks associated with parenting: parental self-efficacy beliefs[13] and their satisfaction derived from the parenting role.[13 14] This feeling of parental competence is a central construct to understand the dynamic processes of the family system. It has been widely studied as having implications on parenting behavior, mental health and well-being; parent-child interactions; and children's development and behavior.[15-21]

The Touchpoints (TP) model began to emerge after Brazelton's seminal work in the '60s to support the families' needs and worries, valuing its strengths, promoting parental competence, and giving empowerment back to families. Nowadays, the TP Network comprises communities and systems of care (health, education and social services) over 100 sites in 33 states in the United States and at several other places internationally, including Portugal.[22] This well-established model of development and intervention assumes its importance given that it is dynamic and presupposes predictable periods of disorganization (touchpoint definition) – from the prenatal period throughout the child's development in which the anticipatory care by the PC professionals has recognized importance.[23 24] It is also a relational, inclusive, non-prescriptive approach based on the construction of an alliance between professionals and parents, parents and child, professionals and children, valuable for teams.[25] We believe this kind of approach with parents needs to be integrated into preventive and universal care plans to support families and thereby to improve their quality of life. In 2015, an American Parent National Survey[26] with 2.200 parents of children birth to 5 years from a wide range of backgrounds showed that fully half of the parents are not getting the support they need not only when they feel overwhelmed or stressed but also in making everyday decisions. Those parents share a universal desire to improve their parenting skills and do want guidance from child development professionals, mainly from the ones who know their child and situation. They believe that good parenting can be learned, and most say that if they knew more positive parenting strategies, they would use them - "needs and demands" also found in other studies.[27-29]

Presently, there is well-established evidence that parenting programs are effective in improving both parents and child outcomes,[9-12 20 30-36] but few are universal and start during pregnancy.[10 20 32 34] Parenting programs are generally built to work jointly with families who have children at risk or with behavioral, emotional, or social difficulties. Therefore, it brings advantages to a relatively small group of parents. Relevant difficulties in recruitment and sustained parental adherence have also been described, sometimes compromising effectiveness.[37-39] Universal approaches to parenting support are an additional offer that assumes itself as a public health intervention.[34] The general aim is to enhance the quality of the early family environment as it could benefit those at risk of adverse parenting but also other families in the population at large.

One promising strategy for reaching families widely is the PC setting - a non-stigmatizing, favorable setting for parenting interventions not only throughout the child's development but also for the perinatal period to support parents' transition into parenthood. The main reasons are due to PC provider's rapport and credibility with families and a well-established mechanism for consistent contact through regular visits during pregnancy and the first three years of a child's life.[35 40 41] Thus, the PC offers an ideal setting to promote positive parenting and reduce income-related developmental disparities.[36] Despite these advantages, PC providers often lack the time needed, so research is required within the PC setting to study different solutions, optimizing this setting.

To this end, a parental intervention based on the TP model - "Crescer em Grande!" (CeG!) (“Grow Big!”, English translation merely indicative) - was designed to support parents in prenatal period and early childhood. To the best of our knowledge, no preventive, universal family-based parenting interventions using the TP approach were previously developed worldwide for PC maternal and well-child visits.

AIM

We designed a PC cluster-randomised trial (CRT) with the aim of assessing the effect of CeG! on parenting sense of competence of parents of children under 18 months of age, compared with usual care, and its relation with other dimensions: parental mental health and well-being (stress, depression, anxiety, psychological experience of pregnancy, attachment, quality of life), child development (physical/sensory-motor, psycho-social), and family well-being (family and couple functioning).

METHODS AND ANALYSIS

Trial design

Sites will be randomised to either the CeG! intervention or usual care arms in a parallel, multicenter CRT. The clusters will be PC units. Participants will be comprised of PC providers (of each PC unit) and a subset of parents and their newborn babies attending these units. The unit of analysis will be the parents.

We decided on a cluster design as it is the most rigorous to prevent eventual contamination within any site if providers were chosen as the unit of randomisation (since it would not be possible to do parents' randomisation because patients are attached to their family physician). Our protocol is under the SPIRIT recommendations for clinical trial protocols.[42]

Study setting

The trial will take place in 12 PC units from the northern region of the Lisbon Metropolitan Area, Portugal, permitting the recommended minimum of four clusters per trial arm to minimize potential confounding from cluster effect.[43] Clusters will be from the two types of PC units of the NHS: Custom Health Care Units and Family Health Units. These public local PC units cover the entire Portuguese territory, and are organized in small group-based practices, with family physicians, similar number of nurses, and fewer secretaries. In some units, health providers are paid a fixed salary (Custom Health Care Units), while in Family Health Units, they can have performance related pay.[44]

Intervention

The CEG! Intervention is based on the TP model. The TP model is a new paradigm of human development and clinical intervention inspired by a relational model. It assumes that favoring the bond of the baby to his family has significant repercussions from the perinatal period and throughout the children's development. The model focuses on a non-linear process of development and how it is experienced by all involved. It presupposes well-identified and predictable periods of disorganization – the TP – when the child's behavior seems to fall apart, typically preceding a spurt in development. Touchpoints are often accompanied by parental frustration and self-doubt. Therefore, they offer unique opportunities to make a difference in the lives of children and families because each TP outlines universal themes that might be coming up for the family, opportunities for practice to support the child/family system and suggestions for anticipatory guidance to help to predict the next TP. This model is anchored in the premise that the enhancement of a child's ability to reach their developmental potential cannot happen without supporting and enhancing the family's emotional and relational functioning, so children can have parents who are convinced of their skills and competencies. Thus, the TP Relational Framework presupposes a transformation in working with families by choosing strategies to support families' positive attributes, values and desires for raising their child on a collaborative attitude and empathic involvement instead of the traditional prescriptive and objective approach. This "paradigm shift" (Table 1) is supported by a set of TP Guiding Principles and Parent and Provider Assumptions – tools to use and be intentional when working with families across articulated work between professionals from health, education, and social services to build a common language. The Principles of TP must be seen as general guidelines “for using the developmental knowledge and relational skill at each of the touchpoints in making judgments that support good parenting”.[45] The TP Parent and Provider Assumptions represent a set of beliefs providers should hold and strive to act upon in working with families.[45-47]

Table 1. The Touchpoints paradigm shift.

From:	To:
- Deficit	- Positive
- Linear Development	- Multidimensional Development
- Prescriptive	- Collaborative
- Objective Involvement	- Empathetic Involvement
- Strict Discipline Boundaries	- Flexible Discipline Boundaries

Source: adapted from Touchpoints Reference Guide and Participant Training Materials, 2016.[45]

Thus, the CeG! presents itself as a universal, preventative intervention to contribute to positive parenting, consisting 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 on how to deliver, perform and integrate the CeG! Intervention into existing practice.

The leaflets were developed with the collaboration of 13 PC providers (doctors and one nurse) to be used by the PC team and families as part of routine care. Each will be delivered unitarily in scheduled consultations from 26 weeks of gestation (first TP in the third trimester) until the age of 18 months, anticipating the TP and parents' needs, worries, fears, maybe not always addressed in healthcare visits (Table 2). Following the Portuguese NHS recommendations, during the study period, each family will receive approximately six prenatal surveillance visits, and nine well-child visits.[40 41]

Providers in the CeG! arm will complete a 5-hour training designed to enhance their motivation, skills, and self-efficacy to use different elements of the strength-based TP model as guidance to promote parental competence. For the sessions, we developed a set of presentation slides for clinic staff that elucidates on the intervention concept and philosophy, implementation strategies and health gains. The focus will be on reflecting on the developmental process and challenges faced by the different elements of the system: child, parents and health providers, to start getting into a practical perspective through the TP Relational Framework. The aim is to help PC providers rethink their practice with families of young children. Specific strategies (TP Principles and Assumptions) and examples of implementation will be provided as a guide to adopting a 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 the developmental sequence of main expected changes in a child and family's life until the age of six. One or more unit representatives will be charged with encouraging and enabling other professionals in their unit to review the leaflets folder throughout the study.

The control will consist of routine, maternal and well-child 'standard-of-care' in PC (usual care arm). 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 entering the study. At the end of the trial data collection, we will offer clinical staff in the control arm the same CeG! training previously given to the intervention arm.

Patient and Public Involvement

CeG! design and different stakeholders' involvement

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 group discussions (11 parents and nine doctors and nurses) where they looked at the general 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, and all the participants revealed good acceptance.

No patients were involved in the CRT design, nor will be involved in recruitment, conduction, and burden of the intervention.

Study description and recruitment

Units

Participating PC units will be selected as a convenience sample pertaining to the same geographical area (northern region of the Lisbon Metropolitan Area), which includes 9 Groups of Health Centers (management structures of PC units). The PI met with acquainted executive and research directors from 3 Groups of Health Centers; together they identified the eligible PC units accordingly to inclusion/exclusion criteria; a letter of introduction was sent to each PC unit, via an invitation email; first responders will be recruited consecutively until the required sample number is reached (n=12).

PC units are eligible if they have: 20 to 30 minutes of sequential nurse and physician consultations each; at least 80% of PC providers working as a stable team during the last year before the start of the trial; at least three family physicians and one nurse willing to participate for the unit to be included in the study.

To minimize contamination, we will only recruit one PC unit per building, and no unit may employ a study investigator.

Participants

Primary Care Providers: At least three family physicians and one family nurse from each site will be recruited if they maintain a regular clinical practice in maternal and well-child visits in each PC unit. After a letter of introduction from the principal investigator (PI), the investigators will discuss the project with each PC unit team, its expected benefits and time commitments and ask each PC provider to sign an informed consent approved by their Regional Health Administration's Ethics Committee. If there is a team composed by a family physician and a family nurse for each list of users, both will need to enter the study. In case of an occasional PC providers' absence, each PC unit guarantees that another PC provider enrolled in the study will hold maternal and well-child visits. Within each clinic, prenatal 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). Primary Care providers will be ineligible if they are planning to retire during the study period or abandon the unit for other reasons.

Parents: Participants will be recruited through the physicians' list or a list of patients waiting for physician assignment (Custom Health Care Units), at each of the 12 sites. Parents (at least one parent per expecting baby i.e. fathers and/or mothers) are eligible if they: 1) have a confirmed pregnancy in the early second trimester; 2) do prenatal surveillance with the family doctor and wish to maintain pediatric surveillance of their baby in the PC unit; 3) are at least 18 years old;

4) are fluent in Portuguese as judged by the consenting provider; and 5) can understand all aspects of the study and provide informed consent. Mothers or fathers are included if interested regardless of their partners' decline. Parents will be ineligible if they: 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); or 2) intend to relocate during the study period.

Baby/child: children of the participating parents that are born during the study.

There will be no financial incentive for study participation.

Study description

Overall Cluster-Randomised Trial: Once the PC providers complete training for the CeG! intervention or get the study's briefing on the usual care arm, a group of parents (of 216 babies) will be recruited and followed longitudinally for the CRT. All eligible parents will be invited to participate in the trial during pregnancy, in person, during the first clinic visit of the second trimester (usually performed between 14th and 20th weeks of pregnancy[41]). At this initial contact, a PC provider will discuss the purpose of the study and study procedures with the parent and assess his interest. If interested, the PC provider will obtain the parent's written informed consent to participate. Parents will be recruited consecutively until the required sample number is reached.

Parents will be asked to complete questionnaires in multiple scheduled assessment points until the child's 18-month well-child visit (Table 3).

We will also develop two other complementary studies along with the CRT (Figure 1), as explained below:

- before the CRT 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 units. The objective of this data collection is that we can assess equivalence between units in the usual parenting sense of competence before initiating the intervention, and statistically adjust for it in relevant data analyses, if needed. For 4 to 6 weeks, all that parents will be approached in units by a PC provider from each site, accordingly with the same inclusion criteria (see above, *Parents*). 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 the trial, for the first-month assessment point). Although in a much simpler way, this first moment of data collection will replicate one trial data collection and, thus, allow clinic staff to become proficient in recruitment and data collection processes.
- to establish if there is an improvement following the PC providers' training period, a pretest and posttest self-developed Practice and Knowledge Questionnaire (PKQ) will be used to collect the data (*single-group pretest-posttest study*) along with a sociodemographic and professional questionnaire. The posttest PKQ will be delivered in two separate moments: following the training period and at the end of the CRT. 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 (prenatal and postnatal). For this reason, the PKQ will also be applied to PC providers in the control arm (only one time at the study briefing).

Figure 1. Data collection schematic.
Feb, February; CeG!, *Crescer em Grande!*; CRT, cluster-randomised trial; Dec, December; HP, health providers; Jan, January; PCP, Primary Care Provider; Pre-PKQ, Pretest Practice and Knowledge Questionnaire; Post-PKQ, Posttest Practice and Knowledge Questionnaire.
Note: The study was interrupted on March 2020 due to the COVID-19 pandemic. CRT (recruitment of expecting parents) will start only when the PC visits are reinitiated in Portugal on a face-to-face basis.

Outcomes

Primary outcome

For parents:

- Difference in mean change (from the first month to the 18-month well-child visit) in parenting sense of competence between the two trial arms, using the Parenting Sense of Competence Scale (PSOC).

Secondary outcomes

For parents:

- Difference in mean change (from the first to the last research assessment for each instrument - Table 3) between the two trial arms for family functioning (Family Environment Scale – FES), couple dynamics (Revised Dyadic Adjustment Scale - RDAS), mental health including depression/anxiety and stress (Depression, Anxiety and Stress Scale-21 - DASS-21; Parental Stress Inventory – PSI) and well-being/quality of life (EUROHIS-QOL-8 - QOL), at prenatal and postnatal periods.
- Differences in the psychological experience of pregnancy (Pregnancy and Motherhood Attitudes Scale - PMAS) between the two trial arms, only at the prenatal period.
- Differences in maternal/paternal attachment (Antenatal Attachment Scale – AAS; Postnatal Attachment Scale – PAS) between the two trial arms, at prenatal and postnatal periods.

For the Child:

- Differences in child development (physical/sensory-motor, psycho-social) between the two trial arms (Baby form; Child form including The Modified Mary Sheridan Scale; Child Behavior Checklist - CBCL 1,5-5 - parent version).

For PC Providers:

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

About the CeG! intervention:

- Comparison of acceptability, satisfaction, and feasibility of delivering the CeG! with respect to usual care (Satisfaction Questionnaire – SQ; PC providers/parents' version).
- Evaluation of costs associated with delivering the CeG!

Table 2. The CeG! topics by Touchpoints and scheduled routine care in Primary Care.

Care visits	Touchpoints†		Topics
Pregnancy			
26-29w	Prenatal	The Ideal Baby	Touchpoints definition
30-32w			Mummy and Daddy – I just arrived, what now?
33-35w			Baby and feeding
36-40w	Newborn	The Real Baby	Role of caregivers in development
Child			
Home visit	-	-	Child Safety
			Vaccination
1st visit	3 w	The Energy Sink	Baby's language
1st M	6-8 w	The Rewarding Baby	Sleeping
2nd M	4 M	Looking Outward	Cognitive development (1)
4th M	7 M	Up at Night	Feeding
6th M	9 M	The Pointer	Frequent symptoms in childhood
			Breath-holding Stranger and Separation anxiety
9th M	12 M	The Walker	Conquering autonomy/Walking
12th M	15 M	The Clinger	Child and discipline (1)
15th M	18 M	Rebel with a Cause	Toilet training
18th M	24 M	Getting to "No!"	Aggression/ Most common discipline challenges (2)*
2 y	3 y	"Why?"	Pacifier/Thumb sucking /Transitional object
3 y	4 y	"What I do Matters"	Fears and nightmares Imaginary friend
4 y	5 y	"Who I am Matters"	Most common discipline challenges (3)**
5 y	6 y	Entering the Real World	Cognitive development (2)
Other	When necessary		Bedwetting Sibling rivalry

M, months; w, weeks; y, years.

† Source: adapted from Touchpoints reference guide for health care providers, 2012.[46]

* Most common discipline challenges (2) – tantrums; hitting, biting.

** Most common discipline challenges (3) – whimpering, lying, retorting, complaining.

Sample size calculation

The primary outcome will be analyzed as the mean change of the PSOC score between the first month and the 18-month well-child visit in each parent. There will be an average change in each arm, and the effect of the intervention will be the difference between these averages.

A sample size of parents of 18 babies (fathers and/or mothers) per cluster, in 12 clusters, was calculated, considering a power of 80%, a type I error of 5%, an intracluster correlation coefficient (ICC)=0.03[48] and a medium effect size of 0.5.[49]

All calculations are based on the formula for comparison of two means in CRT and assume a 20% loss to follow-up. We used the UCSF Clinical & Translational Science Institute - Sample Size Calculators, available at http://www.sample-size.net.

Since the average number of births per unit, per year, is approximately 150[50] and assuming conservatively that 50% of parents choose to participate in the research project, we estimate that recruitment can be completed in three months, enrolling a minimum of one to two participants a week, per PC unit.

Assignment/Randomisation

Randomisation units are clusters - PC units - that will be allocated (Microsoft Excel random number generator) to intervention or control groups using simple randomisation in a 1:1 ratio, stratified by type of institution (Custom Health Care Units and Family Health Units). The randomisation list will be generated by an independent statistician.

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 anonymized list of the participating units 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.

As a CRT, only limited blinding could be enforced. Although it is not possible to blind participants and the research team to the trial arm of each assigned unit, consent will not identify other study arms, avoiding participants to know they are in a trial.[43] The study statistician will remain blinded during the study period until the database is locked, all analyses are completed, and the study unblinded.

Data collection, management, and analysis

Assessment

Although the leaflets are designed to accompany pregnancy and the development of children from zero to six years of age, in this study it is chosen to include only assessment points until the child reaches 18 months of age due to: the time available for the project, namely for data collection; a higher concentration of the number of TP in the first 18 months of the child's life, as well as the number of well-child visits; also the first 18 months as a phase of significant family adaptation with the birth of a new element.

Parents' enrollment and baseline assessment will be done at the first visit of their second trimester of pregnancy (usually performed between 14th and 20th weeks of pregnancy[41]) at the PC unit after the study begins (after cross-sectional study in the control arm; after the training period in CeG! arm). Once individual informed consent is obtained, a PC provider in each arm will deliver parents a self-completion sociodemographic questionnaire to collect baseline data, namely: age, gender, marital status, level of education, family's elements and income perception, occupation, support network, among others. Two additional tools assessing couple dynamics (Revised Dyadic Adjustment Scale) and health-related quality of life (EUROHIS-QOL-8) will be delivered.

Relevant sociodemographic information on eligible individuals who decide not to enroll in the study will be anonymously collected. In addition to these data, the provider involved in the recruitment will ask decliners about the reason for the decline.

Multiple assessment points will continue till 18 months well-child visit (Table 3), using the instruments bellow – all validated for the Portuguese population (except forms developed for the study).

- Parenting Sense of Competence Scale[14 51] (PSOC) - this is a self-completion questionnaire addressed to parents (Cronbach alpha of .76[51]), designed to assess self-perception of parental competence regarding two dimensions: satisfaction and efficacy. The PSOC consists of 16 items (9 for satisfaction and 7 for efficacy) answered on a 5-point scale ranging from "strongly disagree" to "strongly agree." Results are obtained by adding the quotations of individual items, after the inversion of some; a higher result indicates higher levels of confidence in parenting capacities. The total score ranges from 16 to 80 (no cutoffs).
- Sociodemographic and Professional Questionnaire - demographic and professional characteristics (*e.g.,* number of years of practice after vocational training, currently training residents) will be examined for PC providers at each unit. The instrument was developed for the study and will be applied after the study briefing.
- Sociodemographic Questionnaire (SDQ) for parents - demographic, lifestyle and pregnancy questionnaire. The instrument was developed for the study.
- Baby form (BF); Child form (CF) - data on birth and baby/child clinical characteristics (weight, length, APGAR index, feeding and health status, including The Modified Mary Sheridan Scale) collected by PC provider. The instruments were developed for the study.
- Revised Dyadic Adjustment Scale[52] (RDAS) – evaluates dyadic relation; the scale is organized in three subscales: Dyadic Consensus, Dyadic Satisfaction and Dyadic Cohesion.
- EUROHIS-QOL-8[53] (QOL)- evaluates the perception of the quality of life of adults (physical, psychological, social and environmental domains).
- Depression, Anxiety and Stress Scale-21[54] (DASS-21) - negative emotional states evaluation scale, short form of the DASS-42,[55] with 21 items distributed by three factors: Depression, Anxiety and Stress.
- Pregnancy and Motherhood Attitudes Scale[56] (PMAS) - evaluates the psychological experience of pregnancy organized in 7 dimensions: The Imagined Son, Good Mother, Pregnancy as a Factor of Change/Personal Growth, Difficult Aspects of Pregnancy/Maternity, Relationship with One's Own Mother, Husband/Companion Support, and Body Image and Need of Dependency. It will be performed only by the mother of the child.
- Attachment Scale (Antenatal and Postnatal)[57 58] - both scales evaluate two dimensions: Bonding Quality and the Time Spent in the Bonding Mode or Intensity of Concern (maternal/paternal version).
- Family Environment Scale[59 60] (FES) - examines each family member's perceptions of the family in three ways—as it is (real), as it would be in a perfect situation (ideal) and as it will probably be in new situations (expected). We will use the *Relation* dimension of the *Family Environment* Scale.[61] This dimension includes three subscales: cohesion, expressiveness and conflict.
- Parental Stress Inventory[62] (PSI) - measures the level of parental stress specifically in the postnatal period.
- Child Behavior Checklist for Ages 1.5-5[63] (CBCL 1.5-5) - is part of the Achenbach System of Empirically Based Assessment[64] that offers a comprehensive approach to assessing adaptive and maladaptive functioning. The CBCL evaluates the overall functioning of children and young people and has been described as one of the most comprehensive and psychometrically sound measures for parent report of infant and toddler social-emotional development.[65]
- Satisfaction Questionnaire (SQ) - a satisfaction questionnaire related to satisfaction with care, parents-providers relationship, research involvement, acceptability and perspectives on intervention effectiveness will be organized (closed + open questions). It will be applied to clinical staff and parents (PC providers/parents' version).

Data collection and management

We will collect study data via longitudinal parents' assessments, through self-completion questionnaires, administered mainly after each healthcare visit, as shown in Table 3.

When a parent agrees to participate, a PC provider will register the name in an electronic platform for the purpose, and a code including the letter randomly assigned to the PC unit will be automatically assigned. Identification will be kept until the end of the data analysis. Only the clinical staff from each unit will know the parents who participate in the study.

Except for the first assessment of the study (on paper support), questionnaires will be completed online (via e-mail correspondence and phone message). Data will be collected through an electronic platform developed specifically for this purpose, which will allow the automatic submission of questionnaires to the parents in the timings defined, facilitating the entire data collection and storage process. Regular e-mail reminders will be sent to parents in case of non-response; 48 hours before a clinical visit, an email will also be sent to each participants' health providers.

The electronic application was developed in full compliance with the new General Data Protection Regulation. The servers will be housed in the European Union, certified with compliance with all safety standards, and with regularly backed backups and maintenance of duplicate databases in geographically distinct locations, protecting the information from any eventual loss. An administrator profile will be created only for the PI. The registration of the e-mail/phone number of the users will be encrypted, with the decryption key only in possession of the PI. The individuals' visible identifier will be the random code assigned to them at the beginning of the study.

Only the PI's profile will have access to the control panel of the study's evolution, manually register questionnaires on paper, or reinforce the sending of e-mails to request the completion of missing questionnaires. After the end of the study, all data will be permanently erased from the servers. The data will be stored for five years on an external encrypted disk, which requires the use of a password.

If parents cannot answer electronically, there will also be a paper version of the study forms. In this case, the questionnaires must be completed in the unit. There will be a closed return box in each PC unit so that parents can place their completed coded questionnaires, ensuring their privacy and anonymity. At each consultation, PC providers should remind these participants of the placement of the questionnaires in the box available for this purpose. A team investigator will collect the questionnaires frequently from each unit. If necessary, the PI will contact the clinic representative, signaling a missing questionnaire for a specific code. Those site visits will also allow the study investigators to monitor the enrollment process, intervention delivery, and protocol adherence. Email greetings on particular dates (e.g., child´s birthday, Christmas) will be sent to reinforce parents´ adherence.

At each visit, information on attendance to health visit, eventual dropouts and reasons for dropout will be collected by a PC provider directly on the electronic platform. In each PC unit, there is also a form for the health staff to record any other relevant occurrence during the trial.

To test the excellent functioning of the electronic platform and get feedback from PC providers and parents on the trial process, we will previously conduct a small pilot (without intervention) with 3-4 expecting parents within a PC unit that does not enter the CRT,.

Table 3. Assessment points and related evaluation tools.

	Maternal Health Care					Primary Health Care visits					Child Health Care				
	2nd Trimester (1st visit)*	26-29w	30-32w	33-35w	36-40w	Newborn	1st M	2nd M	4th M	6th M	9th M	12th M	15th M	18th M	Post study
Assessment tools (Parents)	SDQ RDAS QOL	DASS-21	PMAS** AAS	FES	RDAS QOL	BF†	PSOC PSI	DASS-21	-	FES PAS	PSOC PSI	-	DASS-21 RDAS QOL	PSOC PSI CBCL CF†	SQ

* First visit of second trimester with parents in primary care unit, after the study start: after cross-sectional study in the control arm; after the training period in CeG! arm (parents' recruitment).

** Only performed by mother.

† Forms filled by PC provider.

AAS, Maternal/Paternal Antenatal Attachment Scale; BF, Baby form; CBCL, Child Behavior Checklist 1.5-5; CF, Child form; DASS-21, Depression, Anxiety and Stress Scale-21; FES, Family Environment Scale; QOL, EUROHIS-QOL-8; M, month; PAS, Maternal/Paternal Postnatal Attachment Scale; PMAS, Pregnancy and Motherhood Attitudes Scale; PSI, Parental Stress Inventory; PSOC, Parenting Sense of Competence Scale; RDAS, Revised Dyadic Adjustment Scale; SDQ, sociodemographic questionnaire; SQ, satisfaction questionnaire; w, weeks.

Statistical methods

The intention-to-treat principle will be adopted. Participants' data will not be included in any analyses if they withdraw consent. The study statistician will not be involved in intervention delivery or data collection and will remain blinded until all analyses are completed.

Initially, a descriptive statistical analysis of the variables studied for participants at each PC unit will be performed by the study group (CeG! and control) and strata (type of unit: Custom Health Care Units and Family Health Units). Categorical variables will be described by absolute and relative frequencies; continuous variables by means (and SD) if they are normally distributed or by medians (and IQR) if not; ordinal variables will be presented by medians (and IQR).

Recognizing that cluster randomisation might not achieve balance on descriptive variables between individuals at baseline, adjusting for these variables will be considered in the model. Therefore, both groups' outcomes will be compared using linear-mixed effect models adjusting for baseline measurements with a random intercept for the PC unit level to account for clustering effect. Possible missing patterns will be handled by multiple imputation and the linear-mixed models for the longitudinal analysis. Statistical significance will be set at $p < 0.05$.

Additionally, to determine if specific subpopulations respond differently to CeG! intervention, we will perform subgroup analyses based on baseline characteristics. This analysis will be conducted among gender-difference of parents, different types of family structures, families expecting their first child versus families with one or more children, mothers with above high school education versus mothers with high school or below, and families experiencing financial strain versus families who are not. We will test for significance of subgroups using statistical tests for interaction. If required, multiple comparisons adjustments will be performed through alpha adjustment.

Reporting of results will follow the principles of Consolidated Standards of Reporting Trials statements and the extension for CRT.[43 66]

Rates and reasons for missing data will be assessed and reported. Several aspects will be considered to ensure data consistency: verifying variables type, list all the possible values for each variable, check spelling errors and improper entries, and investigate missing data. The out-of-range, unreliable, or invalid values must be evaluated carefully. Furthermore, assessing the best method to deal with missing data must be probed. One or more imputation algorithms, such as the mean or median values, or deep learning methods, must be implemented and assessed using different metrics such as distributional accuracy.

Process evaluation

Regular site visits will allow the study researchers to monitor the enrolment process, intervention delivery and protocol adherence. To enable early correction of any errors during data collection, there will be close supervision of data on the platform with subsequent contact with unit representative wherever needed; platform chat is available for any doubts during data insertion. Parents will be instructed to contact their healthcare team whenever any questions arise; a study's telephone contact and an e-mail will be available.

We anticipate no harm arising from the intervention's implementation; therefore, no data monitoring committee was established. If we become aware of any harm or other adverse events, either through study data or other avenues, we will review and address these according to standard institutional processes, in consultation with the relevant ethics committee. We will also file regular reports on trial progress with the ethics committee. We have not devised any stopping guidelines, although we intend to carry out mid-term analyses of trial outcome data, according to the different measurement points. If any relevant health information is identified during the analysis of the participants' data, it shall be communicated to the attending family physician who will act in accordance.

Program costs

To help inform potential financing and adoption of the CeG! intervention, compared with usual care, we intend to estimate the incremental costs to deliver the intervention (e.g., costs in printing leaflets, training costs) and overhead costs minus costs attributable only to research activities (e.g., PC unit study monitoring visits).

ETHICS AND DISSEMINATION

This trial is conceived in accordance with the fundamental ethical principles of autonomy, beneficence, justice, and non-maleficence and will be conducted under the principles expressed in the Declaration of Helsinki.

Research ethics approval

Approved by the Ethics Committee of the Regional Health Administration of Lisbon and Tagus Valley (Portugal); registration number: 013/CES/INV/2019 (date: 18.11.2019).

Consent

When adopting a CRT, it is not usually feasible to obtain participants' consent to randomisation. Instead, consent to randomisation is typically provided by a surrogate decision-maker at the cluster level. We obtained agreement to randomisation from a representative from each unit (the executive director of each Group of Health Centers involved). We will seek PC care providers' and eligible patients' written informed consent to participate in the study's data collection.

Privacy and confidentiality

Data confidentiality and anonymity will be ensured by the PI in full compliance with the new General Data Protection Regulation, both during the implementation phase of the study and in any resulting presentations or publications. The results will only be used in the framework of this study. All personal information will be safeguarded by assigning a meaningless random code, which will link the answers, without identification, across all the time points. Finally, restricted access to participant-level data and files will be ensured.

Dissemination policy

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 units during regular communications; to others via written summaries, published modifications to the trial profile at http://www.isrctn.com or via statements in scientific papers arising from the study.

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 units and through scientific conferences targeting primary and secondary care providers, and research community more widely. The full protocol and the results of this research project will also be available on the PI's doctoral thesis. Once the study is completed and primary manuscripts published, data will be available upon request to the PI.

AUTHOR CONTRIBUTIONS

FF conceived the overall study, drafted the protocol and registered the trial. MRX contributed to the development of the study protocol and helped monitor the study process. CM provided overall guidance in CRT design. AT performed sample size calculations and statistical guidance in the development of the protocol. FF and JV participated in the trial methods adaptation to the local context and have responsibilities for day-to-day running of the trial. All authors read and approved the final version manuscript.

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COMPETING INTERESTS STATEMENT

MRX is member of the Administrative Board (non-executive) of the Fundação Brazelton/Gomes-Pedro para as Ciências do Bebé e da Família, Portugal.
All remaining autors: none to declare.

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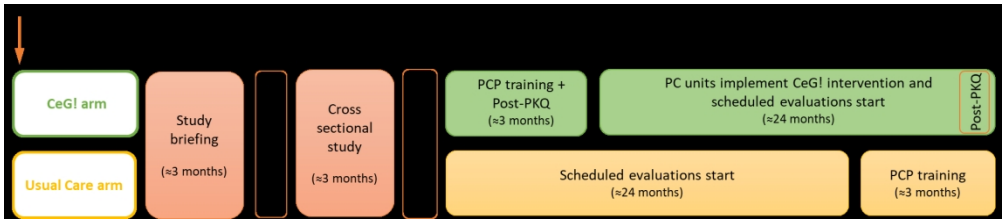

Figure 1. Data collection schematic.
Feb, February; CeG!, Crescer em Grande!; CRT, cluster-randomised trial; Dec, December; HP, health providers; Jan, January; PCP, Primary Care Provider; Pre-PKQ, Pretest Practice and Knowledge Questionnaire; Post-PKQ, Posttest Practice and Knowledge Questionnaire.
Note: The study was interrupted on March 2020 due to the COVID-19 pandemic. CRT (recruitment of expecting parents) will start only when the PC visits are reinitiated in Portugal on a face-to-face basis.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Pages
Administrative information			
✓ Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
✓ Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	-
Protocol version	3	Date and version identifier	-
✓ Funding	4	Sources and types of financial, material, and other support	18
✓ Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,18
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	-
Introduction			
✓ Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4,5
	6b	Explanation for choice of comparators	7

✓ Objectives	7	Specific objectives or hypotheses	5,10
✓ Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6,9,12
Methods: Participants, interventions, and outcomes			
✓ Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6,8
✓ Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6,8,9
✓ Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6,7,9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	(N/A)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14,16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
✓ Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10,12, 13
✓ Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended	Fig.1
✓ Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12

✓ Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

Methods: Assignment of interventions (for controlled trials)

Allocation:

✓ Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
✓ Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
✓Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
✓ Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12,16
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12,16

Methods: Data collection, management, and analysis

✓ Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14

✓ Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
✓ Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
✓ Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
✓ Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
✓ Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
✓ Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
✓ Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
✓ Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8,9,17

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	(N/A)
✓ Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14,17
✓ Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
✓ Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14,17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	(N/A)
✓ Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	-
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached (4 CF)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	(N/A)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.