

# **The Growing up Happily in the Family II Program: study protocol for a large scale randomized controlled trial of a group- and home-based positive parenting program in parents of young children at psychosocial risk**

María José Rodrigo<sup>1</sup>, Juan Carlos Martín<sup>2</sup>, Sonia Byrne<sup>1\*</sup>, Miriam Álvarez<sup>3</sup>, Sonia Padilla<sup>4</sup>, Arminda Suárez<sup>5</sup>, Adriana Álamo<sup>1</sup>, Miriam Cruz<sup>1</sup>, Nauzet Gutiérrez<sup>3</sup>, Graziano Pellegrino<sup>4</sup> and Hector Cebolla<sup>6</sup>

<sup>1</sup>Department of Developmental Psychology and Education, University of La Laguna, Spain.

<sup>2</sup>Department of Education. University of Las Palmas de Gran Canaria, Spain.

<sup>3</sup>Department of Communication Science and Social Work, University of La Laguna, Spain.

<sup>4</sup>Hestia Foundation for Intervention and Family, Psychoeducational and Social Investigation. Canary Islands, Spain.

<sup>5</sup>Department of Didactics and Educational Research, University of La Laguna, Spain.

<sup>6</sup>Government Area for Families, Equality and Social Welfare of the City Council of Madrid (Spain) and Spanish National Research Council.

Correspondence: sbyrne@ull.edu.es

<sup>1</sup>Department of Developmental Psychology and Education, University of La Laguna, Campus de Guajara, 38205 La Laguna, Canary Islands, Spain.

## **Abstract**

**Background:** In the area of child maltreatment prevention, there is an increasing use of evidence-based parenting programs based on the promotion of positive parenting. There is evidence that attending parenting programs is especially beneficial for families showing inadequate parenting, experiencing unemployment, low educational background, lack of social support, or migration. However, less is known about effect of large-scale selective approaches to parenting support during the early years of parenthood. This protocol describes an experimental evaluation of group- and home-based parenting support, the Growing Up Happily in the Family II (GHAF) program aimed at the promotion of parental capacities to encourage resilience and autonomous functioning in at risk families to be implemented in the Municipality of Madrid (Spain).

**Methods/design:** Participants will be 1551 households with dependent children. Inclusion criteria are parents with children under eight years old in families receiving the Minimum Living Income (*Ingreso Mínimo Vital*, IMV) or local emergency aid for basic needs (*Tarjeta Familias*, TF) with residence in the Municipality of Madrid, Spain. Households are randomized to one of three conditions, following a factorial design that tested the combined effects of three components: (A) attending workshop training of socio-occupational skills to foster *employability*; (B) provision of *respite time* for family-work conciliation, and (C) attending twenty group sessions and seven home visiting sessions of the *GHAF program*. Condition 1 received (A) only. Condition 2 received (A) plus (B); and Condition 3 received (A) plus (C); total duration is seven months on a weekly basis. Analyses will employ administrative data from both the Municipality of Madrid and the Spanish Ministry of Social Inclusion, Social Security and Migrations. Data of study variables will be obtained by external evaluators at four time points of the intervention: initial, intermediate, final and follow up. Primary study

outcomes are measured by the Adult-Adolescent Parenting Inventory, Parental Sense of Competence scale, Parenting Stress Index, and Social Support Survey. Other measures included risk factors, child developmental status, economic hardship, family-work conciliation, family climate and resilience. Quality of implementation is measured through checklists and focus groups reporting parents' and practitioners' appraisals over the sessions and satisfaction with the program.

**Discussion:** The protocol describes an experimental evaluation of a large-scale, selective group- and home-based parenting support program that will bring evidence on the effectiveness of the program as compared to active control conditions, to whom the program works well, predictors of follow-up effects and impact of the quality of the implementation on the outcomes obtained.

**Trial registration:** ISRCTN91206647 (registered in 02/12/2022 before data collection).

**Keywords:** Parenting support, Selective prevention, Group intervention, Home-visiting intervention, Early intervention, Municipal Social Services, Psychosocial risk, Positive parenting.

#### Administrative information

The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standardprotocol-items-for-clinical-trials/>).

Title	The Growing up Happily in the Family II Program: study protocol for a randomized controlled, large-scale trial of a group- and home-based positive parenting program in parents of young children at psychosocial risk
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<i>Author details {5a}</i>	<sup>1</sup> Department of Developmental Psychology and Education, University of La Laguna, Spain. <sup>2</sup> Department of Education. University of Las Palmas de Gran Canaria, Spain. <sup>3</sup> Department of Communication Science and Social Work, University of La Laguna, Spain. <sup>4</sup> Hestia Foundation for Intervention and Family, Psychoeducational and Social Investigation. Canary Islands, Spain. <sup>5</sup> Department of Didactics and Educational Research, University of La Laguna, Spain.

	<sup>6</sup> Government Area for Families, Equality and Social Welfare of the City Council of Madrid (Spain) and Spanish National Research Council.
<i>Name and contact information for the trial sponsor {5b}</i>	-Department of Developmental Psychology and Education, University of La Laguna, Spain. -Government Area for Families, Equality and Social Welfare of the City Council of Madrid (Spain)
<i>Role of sponsor {5c}</i>	Universities are jointly responsible for the GHAF program, study design, data analyses, results reports, and results dissemination. Government Area for Families, Equality and Social Welfare of the City Council of Madrid is responsible for running family recruitment, hiring the practitioners, contracting private company for data collection and collaborate in result dissemination.

## Background

### Specific background and explanation of rationale {6a}

In the area of child maltreatment prevention, there is an increasing use of evidence-based parenting programs based on the promotion of positive parenting in Europe. The programs are based on the concept of positive parenting and aimed at strengthening and empowering at-risk families and children [1-3]. The Positive Parenting initiative launched in 2006 by the Council of Europe Recommendation Rec.19 on Policy to Support Positive Parenting focuses on the empowerment of parents and vulnerable families in the context of family support services [4]. Positive parenting has been defined in the Recommendation as parental behavior ensuring the fulfillment of the best interests of the child “that is nurturing, empowering, non-violent and provides recognition and guidance which involves the setting of boundaries to enable the full development of the child” (p. 6). Under this positive approach, it is recognized that the parenting task needs social and psychoeducational support to be adequately performed.

Attending parenting programs is especially beneficial for families showing inadequate parenting, experiencing unemployment, low educational background, lack of social support, or migration [5-8]. Psychosocial stressful events faced by parents (i.e., material deprivation, unemployment, high life stress, low education, illness, etc.) can have deleterious effects on parenting, including the development of negative disciplinary practices [9]. Social isolation and insufficient social contact with relatives, families, and friends are also common among families at psychosocial risk who are more likely to maltreat their children [10-12]. Research into the efficacy of group and home-based programs involving at psychosocial risk families has shown an increase in parents’ beliefs and knowledge about healthy child development, a decrease in negative discipline strategies, an increase in parents’ confidence in their capacities as parents, and the development of practical skills to deal with stressors related to parenting [8] [13-17].

In summary, the existing literature suggests that preventive programs targeted at risk populations may have beneficial effects on parenting. However, less is known about effect of selective approaches to parenting support during the early years of parenthood. For many parents raising toddlers and young children can be difficult and entail plenty of challenges [18, 19]. The fast developmental changes occurring in the child’s physical, cognitive, emotional, and social abilities demand a continuous adjustment of parental competences and strategies to deal with them. Also, new concerns in time

management issues appear in terms of how to reconcile family and work or ensure access to affordable, quality childcare [20, 21]. Satisfaction with the couple usually decreases due to limitations to spending time together [22]. The situation can be aggravated for vulnerable families with complex needs that should be met through the provision of social support. The effects to be gained from intervening with at-risk families at these early stages of parenting in a large-scale study using both group and home-based modalities and examining a broad set of parenting and family outcomes leading to a more autonomous functioning are largely unknown.

### ***Rational of the Growing Up Happily in the Family II Program***

The GHAF is a program to prevent child maltreatment targeted at caregivers of children up to eight years old in at-risk psychosocial contexts delivered in group-based and home-visit formats [23, second version]. It is aimed at the promotion of parental capacities to encourage resilience and autonomous functioning in the family as promotional and protective factors for child development. Those families are receiving either local emergency aid for household basic needs (TF) or national level income benefits (IMV). TF is a local program created in 2020 for channeling economic aid to households in huge material deprivation and it is now widely used for mitigating the immediate consequences of absolute poverty. Households with dependent children have an advantage in accessing this aid through a favorable calculation of household income per capita. Authorized expenses cover food, cleaning, and personal hygiene materials. IMV was also created in 2020 by the central government as a social security non-contributory allowance aimed at addressing the risk of poverty and social exclusion. The IMV is not specifically a tool for family support, but alleviating child poverty is among its important goals. As of March 2021, more than 40% of the 565.000 beneficiaries were families with minors in Spain. Thus, GHAF can be a good complement to promote the capacities of parents to achieve a more positive and autonomous functioning of needy families. All beneficiaries of FT are also potential users of IMV since the income requirements for accessing the first of these programs is under the threshold set for the latter.

A second rationale is that the content of this program is well founded on the research on attachment [24, 25], parental childrearing practices [26], child self-regulation [27], parental sense of competence [28, 29], and family stress and social support [30, 31]. The program focuses on warmth and sensitive caring, positive expectations of child development, socialization strategies for the child's self-regulation, family-school partnership, and social support as protective factors for child development. Thus, the GHAF has a wide range of possible learning outcomes most of which relate to a central rationale of empowering parents by enhancing their sense of competence, lowering parental stress in the early parenting years, and increasing their autonomous functioning.

A third formulated rationale behind the GHAF program is that includes a home-visit second part that offers individualized information, guidance, advice, practical help in everyday routines, and emotional support to families depending on the child age. It is a way to help the transfer of the knowledge acquired in the group sessions to the home scenario. The strategy of training and reinforcing parental figures in their educational role is essential to provide children with a stimulating, protective and safe environment that meets their basic needs, even in the most adverse situations [27, 32]. These needs may go unmet due to the extreme vulnerability of childhood and because it is a very demanding stage of parenting that requires a very considerable investment of time and effort, sometimes incompatible with the harsh living conditions of the main caregivers.

A final formulated rationale behind the project is that GHAF is an evidence-based program meeting all the quality standards of the prevention science [33, 34]. Indeed, the evaluation of the first version of the program [35] in both modalities has shown its effectiveness when applied in social services, educational centers, and NGOs in Spain, and translated into Portuguese to be used in Portugal and Brazil. Improvements have been obtained in parental attitudes towards parenting and education, better and more adjusted perception of parental skills, reduction of parental stress and improvement of the family educational scenario [36-40]. Quality of implementation factors such as greater program adherence, fewer crucial content adaptations, participant responsiveness, and better didactic functioning of the sessions predicted positive changes in parental child-rearing attitudes [37].

### **Specific objectives and hypotheses**

The objective of this study is to determine whether a group- and home-based parent support program as compared to the two active control conditions can lead to:

1. Improved quality of parenting attitudes and practices, improvements in parental sense of competence, reduced parental stress and increased social support network (primary outcomes)
2. Moderating role of risk status y child developmental adjustment on primary outcome effects (secondary outcomes)
3. Improvement in the employment situation, reduced perceived financial difficulties and less difficulties in family-work conciliation leading to a more autonomous functioning (tertiary outcomes).
4. Improved quality in family climate and improved resilience facing adversities (tertiary outcomes)
4. Moderating role of quality of implementation of GHAF program on primary and tertiary outcomes effects.

### **Methods**

#### **Trial design**

GHAF-RCT is a large scale, multi-site randomized controlled trial, with double blind for participants and practitioners at baseline, and for external evaluators during all the measurements. The design involves three parallel arms that tested the combined effects of three components: (A) training of socio-occupational skills to foster employability; (B) provision of respite time for family-work conciliation, and (C) attending group and home sessions of the Growing up Happily in the Family II program (GHAF) for the promotion of positive parenting. Control condition 1 received (A) only. Control condition 2 received (A) plus (B); and Intervention condition 3 received (A) plus (C). The overall duration of the action for each group is around seven months. Figure 1 provides an overview of the trial design based on CONSORT guidelines.

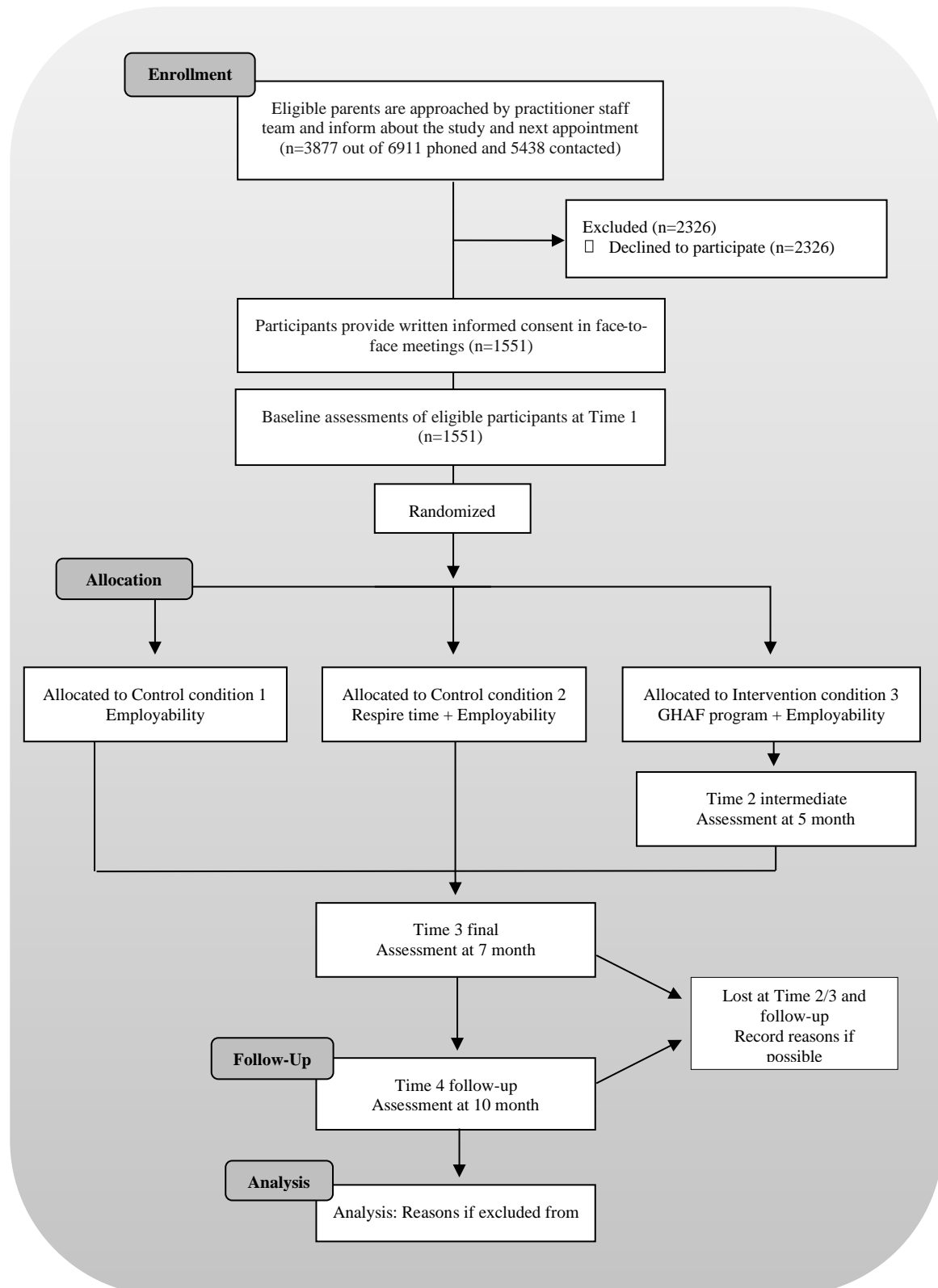


Fig. 1 CONSORT diagram showing study design

## **Participants**

### *Inclusion criteria*

Carer participants: 1. Perceived the IMV as residents in the Municipality of Madrid / or TF program. 2. Have at least one child aged up to eight years old who they care for. 3. Can comprehend and understand Spanish to provide consent to the study. 4. Can provide written informed consent.

Staff participants: 1. Provisional full-time members of the Madrid City Council staff specially hired for this action. 2. Have worked on family support for at least six months. 3. Ability to take part in interviews to explain the action and collected written informed consent from the families. 4. Received training from the university experts.

### *Exclusion criteria*

Carer participants:

1. Participants who do not have a sufficiently good working knowledge of Spanish to provide written informed consent and understand and complete questionnaires.
2. Participants whose current mental symptoms or drug addiction seriously compromise their ability to concentrate on the assessments or intervention sessions.
3. Participants whose infant will be removed from their care on a non-temporary basis

Staff participants:

1. Professionals who work on a part-time basis only.
2. Have less than six months experience of working with families.
3. Graduate disciplines are out of the preferred profile: psychologist, social workers, pedagogist and social educators.

## **Setting**

This study is conducted in the social services and civic centers of the municipality of Madrid (21 districts), Spain. Recruitment started in June 2022 and ended in November 2022. All parents that fulfill the inclusion criteria received an individual appointment for a meeting to be held at the service and were informed about the study. In a second meeting, parents signed the informant consent upon acceptance and receive more information about the evaluation procedure. There were informed of a Thank You in the form of a city-travel voucher and a school kit to be received at the initial, and a tablet with a SIM card at their intermediate or final assessment.

## **Interventions**

During the project period, the experimental group will receive the GHAF II program plus the training of socio-occupational skills, that latter as the other two control conditions.

### **The Growing Up Happily in the Family II program**

GHAF is a group- and home-based manualized program that promote parental capacities that prepares families for their role as parents in adverse conditions. The group-based sessions include five modules: (1) Sensitive and Responsive Parenting, (2) Coming to Know Our Children, (3) Regulating Child Behavior, (4) First Family-School

Relationships, and (5) Parenting: A Solitary Task? That are estimated to be delivered in twenty sessions of 1½-hour over five months.

The subsequent home-visit part of the GHAF program is also manualized and involves interactive activities of daily routines and stimulation sequences aimed at enriching the family learning scenario, strengthening the parent-child relationship, and improving child development. Estimated duration is seven weekly sessions over one month and a half. The program allows for some flexibility in the session timing considering the participants' needs, and sessions may also address other cross-cutting topics, depending on the age of the children in question

### **Meeting structure, didactics, and teaching material**

The group and home versions of the program are delivered in face-to-face sessions including a break. The two practitioners who were involved in the group sessions are also engaged in the home sessions to give a family a sense of continuity in the support provided. In the group session, parents can bring their children who will be cared for by volunteer staff. Break and refreshments are also provided in the middle of the group session.

The structure of the sessions and the didactics followed the experiential methodology, which helps parents to verbalize their interpretations of a variety of family situations, enrich their interpretations with other parents' views, reflect on the consequences of their actions on family life, and reach commitments to change in a non-directive and participative atmosphere [6, 41]. This methodology has two phases that help to organize the activities within the sessions: 1) an impersonal phase that comprises an introduction to the topic and the observation of what other parents do in concrete situations of daily life, to encourage perspectivism and alternative thinking in parents; 2) and a personal phase that comprises the parents' explanation of their thinking, acting and feeling in those situations, to make an analysis of consequences and to verbalize personal objectives of change at home. The teaching style is dialogic, and participants are directly involved through discussion and hands on activities.

The manual includes the teaching materials of the program that consist of vignettes, videos, case studies, guided fantasies, puzzles, games, and group discussions to facilitate the learning process. Participants often have limited education along with low levels of literacy and verbal comprehension (a sizable proportion can be migrant families). Therefore, audiovisual materials worked very well to illustrate daily life situations that facilitate the transfer to their family life. The renewal version keeps all the previous characteristics of the first version but update the illustrations and videoclips, added more examples of family diversity, address new areas of socialization such as digital parenting, and aims at reaching higher quality standards of testing effectiveness using RCT in a large-scale and multi-site trial.

### **Adherence**

A set of procedures will ensure that the program is delivered to meet the standardized version of GHAF. Program fidelity is supported by the detailed Manual and the training. All practitioners receive 40 face-to-face hours of initial and 10 face-to-face hours of intermediate training and group dynamics; plus 6 hours of webinars on the evaluation and quality of implementation for the group part. They also received 20 face-to-face hours of initial training and 10 face-to-face hours of intermediate training for the home



visiting part of the program. They also attend a closing meeting of 12 hours to discuss about the outcomes of the action. Throughout the action, online support was provided for practitioners <https://educa.asociacionhestia.org/login/index.php>. During the program, practitioners and parents fill out a checklist at the end of each session, while a final measure of satisfaction of the program will be also obtained from the participants.

### **Control conditions**

Control condition 1: Participants receive training of socio-occupational skills only, attending different workshops according to their job profile and interests. The Madrid City Council Employment Agency (Labor Guidance Unit) is responsible for this training. The duration and distribution of training will be recorded since it can be flexible according to the employment profile.

Control condition 2. Participants receive a home assistant to provide respite time for family-work conciliation plus the training of socio-occupational skills. A private company specialized in this type of social work is contacted to provide assistants for this action. The provision of help is unconditional and may include housework, shopping, picking up children from school, and looking after the child while the parents are busy. It is instrumental support without any systematic educational content aimed at parents or children. Total childcare time is over 40 hours and can be used throughout the duration of the program.

### **Measures including outcomes**

Our analyses will employ four main data sources with information about parents and children: survey type information from parents and practitioners, administrative data from practitioners, local registers from social services in Madrid, and administrative register-based data maintained by Ministry of Social Inclusion, Social Security and Migrations. All data sources will be linked, and data will only be accessed in anonymous form. Survey data will be collected face-to-face in meeting gathering 25 parents each by an external company specialized in evaluation in social projects. Survey data will be obtained at four time points, at baseline, intermediate, final and 3-month follow up. No monetary incentives are used to motivate participation.

### **Primary outcome measures**

Parental attitudes and child-rearing practices is measured using the *Adult-Adolescent Parenting Inventory* (APPI) at baseline, intermediate, and final testing reported by parents.

Parental confidence and competence are measured using *Parental Sense of Confidence* (PSOC) questionnaire at baseline, intermediate, and final testing reported by parents.

Parental stress is measured using *Parenting Stress Index* (PSI-Brief) at baseline, intermediate, and final test reported by parents.

Parental social support is measured using the *Social Support Survey* (MOS) at baseline and final testing reported by parents.

## **Secondary outcome measures**

Family risk profile is measured using the *Protocol of Evaluation of the Psychosocial Risk* at baseline reported by the practitioners.

Developmental status and perceived adjustment scale is measured using the *Milestones for surveillance of cognitive, language, and motor development* of the child at baseline reported by parents.

## **Tertiary outcome measures**

Employment situation is measured using indicators drawn from the *Sociodemographic Profile* at baseline and 3 months follow-up testing reported by parents

Perceived financial difficulties is measured using the *Economic Hardship Questionnaire* (EHQ) at baseline and 3 months follow-up testing reported by parents.

Difficulties in family-work conciliation is measured using *The Spanish Work-Family Conflict Scale* (SP\_WFCS) at baseline and 3 months follow-up testing reported by parents.

Family climate is measured using the *Family Adaptability and Cohesion Evaluation Scale* (FACE III) at baseline and 3 months follow-up testing reported by parents.

Resilience facing difficulties is measured using the *Connor-Davidson Resilient Scale* (CD-RISC 10) at baseline and 3 months follow-up testing reported by parents.

## **Implementation measures**

To test the quality of the group- and home-based implementation, a variety of implementation components are tested based on the model by Berkel, Mauricio, Schoenfelder, and Sandler [42]: adherence (dosage and duration of the sessions), adaptations (number and type), quality of delivery (material resources, goal-related activities, clear guidelines, and objectives reached), implementation barriers, group and participant responsiveness (participation and interest, group cohesion and positive climate, and participant satisfaction with the program) and impact on professional development. Checklists and reports from surveys and focus groups conducted with program facilitators and participants are compiled at sessions and at the end of the program to assess implementation components.

## **Sample size**

The number of families receiving the IMV in Madrid are 6,911 families, of which 5,438 were contacted, 3,877 were eligible and accepted to be visited, inform about the study and received the informed consent, and finally 1,551 families accepted. Previous studies on the effects of parenting education with parents at psychosocial risk found on average effect that varied between small to medium size effects depending on the outcome measure [e.g., 43, 44]. Stronger effects emerged if interventions included more than five sessions and were led by professionals rather than semiprofessionals. Thus, we expected small to moderate size effects to be a conservative estimate of effect on the outcomes in

the present study, given our large sample size and our expert professional team. Our power analyses use the 2013 version of the Optimal Design software developed by Spybrook and collaborators, setting a power of 0.80 and significance level of 0.05 to detect an effect size of 0.2. For the analyses, we consider women or men as dropouts from the GHAF program if they miss five consecutive group meetings without reasonable reason or apologies (such as illness). Even if the program does not significantly improve participants' primary outcome in preliminary analyses, this will not lead us to discontinue the program thereby ignoring possible secondary, tertiary and short-term outcomes. We will perform a dropout analysis that characterizes dropouts in terms of sociodemographic variables if more than 1/4 of study participants drop out after initial randomization and prior to the 10 months follow-up, given the large sample size and the long duration of the intervention.

## **Randomization**

After written consent has been obtained, participants are asked to complete the first battery of outcome measures (the baseline assessment) before participants are randomly allocated to either Control condition 1, Control condition 2 or Intervention Condition 3. Randomization is provided by independent statistical experts from the Ministry of Social Inclusion, Social Security and Migrations following the method of generating the allocation sequence (computer-generated random numbers) till reaching equal number of participants in each arm, and a list of three factors: family type (one-parent / two-parent), years in social services (before 2018/ after 2018) and city zone habitat (north / south) for stratification. Once the experts inform the arm to which the participant has been allocated, participants are informed of the randomization outcome and provided with a leaflet outlining what they can now expect.

## **Implementation**

Randomization and allocation into the three conditions will be carried out by the external governmental statistical experts coding the randomization mechanism, which is concealed to the research team. A private external company collects the survey data and build the coded anonymized database supported by the research team. Practitioners collect data at the end of the sessions only to assess the quality of the program implementation.

## **Blinding**

The research team, practitioners, and families remain blind to study conditions during recruitment, consent, and baseline, though blinding after this point in time is not possible. The external company in charge of the assessments is blind during baseline, intermediate, final and follow up assessments. Therefore, a double-blind system is ensured at several points and agents.

## **Statistical methods**

Reporting of results will follow the guideline of the CONSORT- statement. The minimum level of significance will be 0.05. The first round of analysis is the comparison among the three conditions on parenting attitudes, parental sense of competence, parental stress, and social support network, also considering the

contribution of risk status and child developmental adjustment as covariates. ANCOVA, MANCOVA and hierarchical regression analysis will be performed with their corresponding post hoc tests and effect sizes. Growth curve modeling with the primary outcomes including three time points of measurement will be also performed to examine the shape of the progress at each condition. Similar ANCOVA can be performed among the three conditions on employment situation, perceived financial difficulties, family-work conciliation, family climate, and resilience with two time points, also considering the contribution of risk status and child developmental adjustment.

On a second round, latent profile analyses (LPA) performed with the change scores on primary and tertiary outcomes obtained in the intervention condition can be performed to examine the interindividual variability in the pattern of effects obtained. The sociodemographic measures, the risk status, and child developmental adjustment measures can be used to perform multinomial regression analyses to obtain the model that better explain the contribution of these variables in the assignment of cluster membership. This is a way to capture to whom the program works better.

On a third round, change scores in primary and secondary outcome measures will be used as predictors in regression analyses of the change in the tertiary outcomes at follow up such as employment situation, perceived financial difficulties, family-work conciliation, family climate and resilience facing adversities in the three conditions.

On the fourth round, the set of implementation measures will be used in ANCOVA and regression analyses on the program change scores to examine their contribution to the primary, secondary and tertiary outcomes. This is a way to examine the impact of the quality of implementation on the final set of results, in the intervention condition only. All the analyses are conducted using updated versions of MPlus, IBM SPSS, STATA and R.

Finally, qualitative data analysis will be performed using ATLAS.ti v8 with the two focus groups to be held with professionals and parents. Focus groups will be digitally recorded, transcribed verbatim and subject to framework analysis to allow both inductive and deductive coding. An initial coding framework will be developed to reflect previous dimensions obtained on this topic. This framework will be augmented and extended to encompass new emerging themes in a second categorization cycle. Finally, a third cycle of categorization is carried out to revise the preliminary coding schema to eliminate low-frequency codes, split codes, and merged codes. Coding will be undertaken by members of the research team, experienced and trained in qualitative data analysis and overseen by others expert members on the topic. The study also involves an implementation quantitative measure involving survey results on the professional impact of the experience of participating in the program. Therefore, it is possible to examine to what extent there is a fitness with the corresponding subthemes obtained from the focus group with professionals, following a mixed-method methodology.

### **Dates defining periods of recruitment, testing, and follow-up**

Figure 2 shows a schedule of the study enrolment, interventions, and assessments.

		<b>STUDY PERIOD</b>						
	<b>Enrolment</b>	<b>Baseline</b>	<b>Allocation</b>	<b>Intervention (from 0 months)</b>				<b>Close-out</b>
<b>TIMEPOINT</b>	Months 1-5	Month 6 (Time 1)	Month 7	Group session Months 1-5	Inter media (Time 2)	Home-visit Months 6-7	Final (Time 3)	3-month follow up (Time 4)
<b>ENROLMENT:</b>								
Eligibility screen	<b>X</b>							
Informed consent	<b>X</b>							
Allocation			<b>X</b>					
<b>INTERVENTION:</b>								
Control 1				<b>X</b>		<b>X</b>		
Control 2				<b>X</b>		<b>X</b>		
Program 3				<b>X</b>		<b>X</b>		
<b>ASSESSMENT:</b>								
Primary measures		<b>X</b>			<b>X</b>		<b>X</b>	
Secondary measures		<b>X</b>						
Tertiary measures		<b>X</b>						<b>X</b>
Implementation measures				<b>X</b>		<b>X</b>	<b>X</b>	

Figure 2. The schedule of enrolment, interventions, and assessments

## Harms

There may be smaller inconveniences, at least for some, associated with the level of time consume from participating in a program such as GHAF. However, participation is entirely voluntary and will not affect access to other family services provided by the municipality or the region. Methodology is very participatory and respectful with the parents' needs and interests. Group meetings and home visits are held at the parents' convenience to minimize interference with families' working lives. For all these reasons, we expect the intervention to be associated with very low risk for participants.

## Registration numbers and name of trial registry

The project is registered with ISRCTN91206647 (registered in 02/12/2022).

## Protocol availability

This protocol will be made available at [www.madrid.es](http://www.madrid.es)

## **Discussion**

The protocol describes an experimental evaluation of a selective group- and home-based parenting support program that is planned to begin soon on a large scale and multi-site basis in the Municipality of Madrid, Spain. Such an evaluation has not been previously carried out in Spain or internationally. This evaluation study will provide evidence of what benefits are associated with the psychoeducational and social support component after making comparison with other two competitive control conditions. We hope that the program will help these families improve their early parenting, enhance child development, family wellbeing, social inclusion, and a more autonomous functioning, placing them outside the deleterious circle of poverty.

## **Declarations**

### **Ethics approval and consent to participate**

The project has been approved by the University Ethical Committee (University of La Laguna, Spain); registration number CEIBA2022-3194; date of approval: 18 November 2022.

### **Competing interests**

The authors declare that they have no competing interests.

### **Funding**

The European Commission for the National Plan for Recovery, Transformation and Resilience of Spain, which is transferred to the Ministry of Inclusion, Social Security and Migrations of Spain to perform an intervention study that will be carried out by the City Council of Madrid under a research contract with the University of La Laguna and the University of Las Palmas de Gran Canaria, Spain.

### **Authors' contributions**

MJR, JCM, SB, HC conceived the study idea, formulated the project description, drafted the study protocol. HC coordinate the funds administration, the recollection of participants, the hiring of professionals, and the contracts with supportive companies; SB, MA, SP coordinate the updating of the program didactic materials. MJR, JCM, SB performed the data analyses. The rest of authors collaborate in elaboration of didactic materials, participated in the design of and training sessions and the compilation of the instruments. All authors contributed to the final manuscript and all authors can be held accountable for the accuracy or integrity of any part of the work. All authors read and approved the final manuscript.

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## **References**

1. Morrison J, Pikhart H, Ruiz M, Goldblatt P. Systematic review of parenting interventions in European countries aiming to reduce social inequalities in children's health and development. *BMC Public Health*. 2014;14(1):1040. <https://doi.org/10.1186/1471-2458-14-1040>.
2. Rodrigo MJ, Almeida A, Reichle B. Evidence-based parent education programs: A European perspective. In Ponzetti J, editor. *Evidence-based parenting education*. Routledge; 2015. p. 111-130.
3. Rodrigo MJ, Byrne S, Álvarez M. Interventions to Promote Positive Parenting in Spain. In: Israelashvili M, Romano JL, editors. *The Cambridge Handbook of International Prevention Science*. Cambridge: Cambridge University Press; 2016. p. 929–56.
4. Rodrigo MJ. Promoting positive parenting in Europe: New challenges for the European Society of Developmental Psychology. *Eur J Dev Psychol*. 2010; 7:281–294.
5. Barth R P, Landsverk J, Chamberlain P, Reid J B, Rolls J A, Hurlburt M S, et al. Parent-training programs in child welfare services: Planning for a more evidence-based approach to serving biological parents. *Res Soc Work Pract*. 2005; 15: 353–371.
6. Rodrigo MJ, Byrne S, Álvarez M. Preventing child maltreatment through parenting programmes implemented at the local social services level. *Eur J Dev Psychol*. 2012; 9(1): 89-103.
7. Sandler I, Schoenfelder E, Wolchik S, MacKinnon D. Long-term impact of prevention programs to promote effective parenting: Lasting effects but uncertain processes. *Annu. Rev. Psychol*. 2011; 62: 299.
8. Webster-Stratton C, Reid M J. Adapting the Incredible Years, an evidence-based parenting programme, for families involved in the child welfare system. *J Child Serv*. 2010; 5: 25–42.
9. Collins WA, Maccoby EE, Steinberg L, Hetherington EM, Bornstein MH. Contemporary research on parenting. The case for nature and nurture. *Am Psychol*. 2000;55(2):218-32
10. Cooley C. Social networks, informal child care, and inadequate supervision by mothers. *Child Welfare*. 2007;86(6):53-66.
11. Coulton CJ, Crampton DS, Irwin M, Spilsbury JC, Korbin JE. How neighborhoods influence child maltreatment: a review of the literature and alternative pathways. *Child Abuse Negl*. 2007. 31(11-12): 1117–1142. <https://doi.org/10.1016/j.chiabu.2007.03.023>
12. Rodrigo MJ, Byrne S. Social support and personal agency in at-risk mothers. *Psychosocial Intervention*. 2011. 20, 13–24. <https://doi.org/10.5093/in2011v20n1a2>
13. Johnson M, Stone S, Lou C, Ling J, Claassen J, Austin MJ. Assessing parent education programs for families involved with child welfare services: Evidence and implications. In Austin MJ, editor. *Evidence for child welfare practice*. Routledge; 2010. p. 191–234.
14. Kaminski JW, Valle LA, Filene JH, Boyle CL. A meta-analytic review of components associated with parent training program effectiveness. *J Abnorm Child Psychol*. 2008;36(4):567-89. <https://doi.org/10.1007/s10802-007-9201-9>
15. Peacock, S., Konrad, S., Watson, E. *et al*. Effectiveness of home visiting programs on child outcomes: a systematic review. *BMC Public Health*. 2013;13-17. doi:10.1186/1471-2458-13-17



16. Rodrigo MJ, Almeida A, Spiel C, Koops W. Introduction: Evidence-based parent education programmes to promote positive parenting. *Eur J Dev Psychol.* 2012; 9: 2–10. doi:10.1080/17405629.2011.631282
17. Sandler IN, Schoenfelder EN, Wolchik SA, MacKinnon DP. Long-term impact of prevention programs to promote effective parenting: lasting effects but uncertain processes. *Annu Rev Psychol.* 2011; 62: 299-329. doi: 10.1146/annurev.psych.121208.131619.
18. Corkin MT, Peterson ER, Andrejic N, Waldie KE, Reese E, Morton SM. Predictors of mothers' self-identified challenges in parenting infants: Insights from a large, nationally diverse cohort. *J Child Fam Stud.* 2018; 27: 653–670. <https://doi.org/10.1007/s10826-017-0903-5>
19. Mulsow M, Caldera YM, Pursley M, Reifman A, Huston AC. Multilevel factors influencing maternal stress during the first three years. *J Marriage Fam.* 2002;64(4): 944–956 <https://doi.org/10.1111/j.1741-3737.2002.00944.x>
20. Glynn K, Maclean H, Forte T, Cohen M. The association between role overload and women's mental health. *J Womens Health (Larchmt).* 2009;18(2):217-23. <https://doi.org/10.1089/jwh.2007.0783>
21. Repetti RL, Wang SW. Employment and parenting. *Parenting.* 2014; 14: 121–132. <https://doi.org/10.1080/15295192.2014.914364>
22. Kluwer ES. From partnership to parenthood: A review of marital change across the transition to parenthood. *J. Fam. Theory Rev.* 2010; 2: 105–125. <https://doi.org/10.1111/j.1756-2589.2010.00045.x>
23. Rodrigo MJ, Martín, JC, Byrne, S., Álvarez, M., *et al.* Growing up Happily in the Family II (Crecer Felices en Familia II). Un programa psicoeducativo de parentalidad positiva para promover el desarrollo infantil y la convivencia familiar. Ayuntamiento de Madrid, España.
24. Bowlby J. Attachment and loss: Vol. 1. Attachment. New York: Basic Books; 1969.
25. De Wolff MS, van Ijzendoorn MH. Sensitivity and attachment: a meta-analysis on parental antecedents of infant attachment. *Child Dev.* 1997;68(4):571-591. doi:10.1111/j.1467-8624.1997.tb04218.x
26. Grusec JE, Goodnow JJ. Impact of parental discipline methods on the child's internalization of values: A reconceptualization of current points of view. *Developmental Psychology.* 1994; 30: 4–19. doi:10.1037/0012-1649.30. 1.4
27. Shonkoff JP, Phillips DA, editors. From neurons to neighborhoods: The science of early childhood development. Washington, DC: National Academies Press; 2000.
28. Coleman PK, Karraker KH. Maternal self-efficacy beliefs, competence in parenting, and toddlers' behavior and development status. *Infant Ment Health J.* 2003; 24: 126–148. doi:10.1002/imhj.10048
29. Jones TL, Prinz RJ. Potential roles of parental self-efficacy in parent and child adjustment: a review. *Clin Psychol Rev.* 2005;25(3):341-63. <https://doi.org/10.1016/j.cpr.2004.12.004>
30. Ceballo R, McLoyd VC. Social support and parenting in poor, dangerous neighborhoods. *Child Dev.* 2002 Jul-Aug;73(4):1310-21. <https://doi.org/10.1111/1467-8624.00473>
31. McCubbin H, McCubbin M, Thompson AI, Thompson E. Resiliency in ethnic families: A conceptual model for predicting family adjustment and adaptation. In McCubbin H, Thompson E, Thompson AI, Fromer JE, editors. *Resiliency in Native American and immigrant families.* Sage Publications; 1998. p.3-48.



32. Shah R, Kennedy S, Clark MD, Bauer SC, Schwartz A. Primary Care-Based Interventions to Promote Positive Parenting Behaviors: A Meta-analysis. *Pediatrics*. 2016;137(5):e20153393. doi: 10.1542/peds.2015-3393.
33. Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S, Mościcki EK, Schinke S, Valentine JC, Ji P. Standards of evidence: criteria for efficacy, effectiveness and dissemination. *Prev Sci*. 2005;6(3):151-75. doi: 10.1007/s11121-005-5553-y.
34. Gottfredson DC, Cook TD, Gardner FE, Gorman-Smith D, Howe GW, Sandler IN, Zafft KM. Standards of Evidence for Efficacy, Effectiveness, and Scale-up Research in Prevention Science: Next Generation. *Prev Sci*. 2015;16(7):893-926. doi: 10.1007/s11121-015-0555-x.
35. Rodrigo M J, Máiquez ML, Byrne S, Rodríguez B, Martín JC, Rodríguez G, Pérez L. *Crece Felices en Familia: Un programa de apoyo psicoeducativo para promover el desarrollo infantil*. Gerencia de Servicios Sociales de la Junta de Castilla y León; 2009.
36. Álvarez M, Rodrigo MJ, Byrne S. What implementation components predict positive outcomes in a parenting program? *Res Soc Work Pract*. 2018;28(2):173–87. <https://doi.org/10.1177/1049731516640903>.
37. Álvarez M, Byrne S, Rodrigo MJ. Patterns of individual change and program satisfaction in a positive parenting program for parents at psychosocial risk. *Child Fam Soc Work*. 2020; 25(2): 230-239.
38. Álvarez M, Byrne S, Rodrigo MJ. Social support dimensions predict parental outcomes in a Spanish early intervention program for positive parenting. *Child Youth Serv Rev*. 2021;121:105823.
39. Álvarez M, Padilla S, Máiquez ML. Home and group-based implementation of the “Growing up happily in the family” program in at-risk psychosocial contexts *Psychosocial Intervention*, 2016; 25: 69-78
40. Álvarez M, Padilla S, Rodrigo MJ. El apoyo social en los programas domiciliarios y grupales de educación parental. *Bordón: Revista de pedagogía*. 2021; 73(2): 9–24.
41. Byrne S, Rodrigo MJ, Máiquez ML. Patterns of individual change in a parenting program for child maltreatment and their relation to family and professional environments. *Child Abuse Negl*. 2014; 38(3): 457-467.
42. Berkel C, Mauricio AM, Schoenfelder E, Sandler IN. Putting the pieces together: an integrated model of program implementation. *Prev Sci*. 2011;12(1):23-33. doi: 10.1007/s11121-010-0186-1.
43. Barlow J, Smailagic N, Huband N, Roloff V, Bennett C. Group-based parent training programmes for improving parental psychosocial health. *Cochrane Database Syst Rev*. 2012;(6):CD002020. doi: 10.1002/14651858.CD002020.pub3.
44. Bloomfield L, Kendall S. Parenting self-efficacy, parenting stress and child behaviour before and after a parenting programme. *Prim Health Care Res Dev*. 2012;13(4):364-72. doi: 10.1017/S1463423612000060.