

An effectiveness study of Growing up Happily in the Family II Program aimed at promoting positive parenting in parents of young children at psychosocial risk

Submission date 02/12/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In the area of child maltreatment prevention in Europe, it is recognized that the parenting task needs psycho-educational and social support to be adequately performed. Attending parenting programs is especially crucial for families raising young children and experiencing negative psychosocial conditions. The "Growing Up Happily in the Family II" program combined group and home-based intervention targeted at such selective population. It is aimed at the promotion of parental capacities to enhance child development, encourage family wellbeing, resilience, and autonomous functioning in the family.

Who can participate?

The program is recommended for parents with children under eight years old in those families receiving the Minimum Vital Income with residence in the Municipality of Madrid, Spain, for at least a year.

What does the study involve?

Participants are randomly allocated to one of three conditions, following a factorial design 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 GHAF program 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. The time points for evaluation are at the beginning (all groups), intermediate (group 3 only), final (all groups) and 3-month follow up (all groups). Participants in the three conditions complete a range of questionnaires designed to measure their psychosocial risk, employment situation, family-work conciliation, child adjustment, childrearing attitudes and practices, confidence in the parental capacity, parenting stress, social support, family climate

and resilience facing adversities, and the responses are to be collected by external evaluators. Implementation measures during the program was also assessed by the practitioners during and at the end of the sessions.

What are the possible benefits and risks of participating?

Participants in the GHAF program may benefit from enjoying taking part in the group sessions learning new ways of childrearing and exchanging their experiences, having the support of the practitioner at home afterwards, and the opportunity to share their thoughts about the program at the end of the program. All participants will be offered a Thank You in the form of a city-travel voucher and a school kit at the initial, a tablet with a SIM card at their intermediate assessment. There are no risks.

Where is the study run from?

The study is run from the Government Area for Families, Equality and Social Welfare of the City Council of Madrid (Spain); by the Department of Developmental Psychology and Education. University of La Laguna (Spain) and by the Department of Education. University of Las Palmas de Gran Canaria (Spain).

When is the study starting and how long is it expected to run for?

January 2022 to January 2024

Who is funding the study?

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.

Who is the main contact?

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Contact information

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information**Scientific Title**

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.

Acronym

GHAF

Study objectives

The aim of this study is to investigate the effectiveness of the Growing up Happily in the Family II Program by conducting a large-scale, multi-site RCT trial for parents with young children who receive financial assistance for psychosocial risk conditions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/11/2022, Ethical Committee of Research and Animal Wellbeing of the University of La Laguna (Vicerrectorado de Investigación y Transferencia de Conocimiento. Universidad de La Laguna. 38071 La Laguna. Canary Islands. Spain; no telephone number provided; mejordan@ull.edu.es), ref: CEIBA2022-3194

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Selective prevention, families at psychosocial risk, parenting support, parental capacities, parents of young children, parental resilience, family climate

Interventions

Participants are randomised and assigned into three groups by two statistical experts from the Ministry of Inclusion, Social Security and Migrations, considering the uniform distribution of family type (one-parent / two-parent), years in social services (before 2018/ after 2018) and city zone habitat (north / south). Experts receive via internet the coded list of written informed acceptances collected by the practitioners via a previous letter/call followed by two rounds of interviews with the families. Then they proceed to randomly allocated participants into the three conditions with an equal number in each.

Intervention group: Participants of Intervention condition 3 receive the GHAF program plus training of socio-occupational skills, the latter as the other control conditions. The program consists of twenty weakly group sessions delivered in person (estimated over five months) designed to enhance the knowledge, skills, and confidence of parents. Sessions cover exercises on warmth and sensitive caring, positive expectations of child development, socialization strategies for the child's self-regulation, family-school partnership, and social support. Given the participants' low educational level and diverse cultural backgrounds, materials include vignettes, videos, case studies, guided fantasies, puzzles, games, and group discussions. Parents can bring their children who will be cared for by volunteer staff. The subsequent seven weakly sessions (estimated to be delivered over two month) are designed to be held at home. Sessions offers individualized information, guidance, advice, practical help, and emotional support to families. The program content involves interactive activities and stimulation sequences aimed at enriching the family learning scenario, strengthening the parent-child relationship, and improving child development. Total estimated duration is 47 hours

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.

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 work is contacted to provide assistants for this action. The provision of help 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 estimated duration is 44 hours.

Intervention Type

Behavioural

Primary outcome measure

1. Parental attitudes and child-rearing practices is measured using the Adult-Adolescent Parenting Inventory (APPI) at baseline, intermediate, and final testing reported by parents.
2. Parental confidence and competence is measured using Parental Sense of Confidence (PSOC) questionnaire at baseline, intermediate, and final testing reported by parents.
3. Parental stress is measured using Parenting Stress Index (PSI-Brief) at baseline, intermediate, and final test reported by parents.
4. Parental social support is measured using the Social Support Survey (MOS) at baseline and final testing reported by parents. Family risk profile is measured using the Protocol of Evaluation of the Psychosocial Risk at baseline reported by the practitioners.
5. 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.

Secondary outcome measures

1. Employment situation is measured using indicators drawn from the Sociodemographic Profile at baseline and 3 months follow-up testing reported by parents
2. Perceived financial difficulties is measured using the Economic Hardship Questionnaire (EHQ) at baseline and 3 months follow-up testing reported by parents.
3. 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.
4. 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.
5. 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.

Overall study start date

30/01/2022

Completion date

30/01/2024

Eligibility

Key inclusion criteria

1. Perceived the Minimum Vital Income (MVI) as residents in the Municipality of Madrid
2. Have at least one child aged up to seven years old who they care for.
3. Are able to comprehend and understand Spanish to provide consent to the study.
5. Are able to provide written informed consent.

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

3877 accepted was visited and received information about the study and the informed consent.

Total final enrolment

1551

Key exclusion criteria

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

Date of first enrolment

01/06/2022

Date of final enrolment

30/11/2022

Locations**Countries of recruitment**

Spain

Study participating centre**Social Services in the Municipality of Madrid**

There are eight centres located north and south in the Municipality of Madrid.

City Council Central site:

Palacio de Cibeles

Montalbán, 1

Madrid

Spain

28014

Study participating centre

University of La Laguna

Campus de Guajara

La Laguna

Spain

38205

Study participating centre

Campus University of las Palmas de Gran Canaria

Las Palmas de Gran Canarias

Spain

35004

Sponsor information

Organisation

Madrid City Council

Sponsor details

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dginnovacion@madrid.es

Sponsor type

Government

Website

<https://www.madrid.es>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan

A range of dissemination methods at a local, national, and international level. All reports will be presented following the CONSORT guidelines. Regular information will be sent to participants throughout the study and in the final months, in collaboration with service users. The study team aims to:

1. Publish a final report with the results of the study in compliance with the European Commission requirements and the Spanish Ministry of Social Inclusion, Social Security and Migrations regulations.
2. Publish scientific papers in peer-reviewed, academic, open-access journals for the professional academic and public health community
3. Disseminate information to the authorities and social agents in the Municipality of Madrid and relevant press office, radio/TV stations and community groups so that parents and their families (and the wider public) can understand the study’s potential benefits.
4. Disseminate scientific information to the academics of the University of La Laguna, the University of Las Palmas de Gran Canaria and other universities by means of conferences, workshops, etc. reporting about the study design, implementation, results and benefits.
5. Distribute reports to the Spanish official webpage familiasenpositivo.org that involves public and private agencies and social entities in the prevention field of child and family support and to the wider public audience.
6. Offer summaries to all participating parents to inform them of the outputs and acknowledged their valued contribution

Finally, in collaboration with our service user consultants, two events will be held out. The first event is a ‘Closing Event’ to officially acknowledge the families’ contribution to the project, in which authorities, a representation of the professionals and the families will address the audience sharing their experience and benefits obtained. The second event is a ‘Dissemination Event’ to inform stakeholder discussions with services and service users and their families, which will decide how to proceed with the future itinerary to encourage resilience and autonomous functioning in the family and further contribute to the promotion of equality, social inclusion, and the fight against poverty in at-risk families in the Municipality of Madrid.

Intention to publish date

20/11/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)			13/12/2023	No	No
Results article		01/01/2025	09/01/2025	Yes	No