ISRCTN91206647 https://doi.org/10.1186/ISRCTN91206647

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

Registration date
07/12/2022

Overall study status
Completed

Last Edited
09/01/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex

All

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

Funder(s)

Funder type
Government

Funder Name
Ministry of Social Inclusion, Social Security, and Migrations of Spain

Results and Publications

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?
Results article		01/01/2025	09/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)			13/12/2023	No	No