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A family-based psychosocial intervention to prevent pediatric obesity and build up healthy lifestyles from preschool ages through the promotion of parents' social skills, self efficacy, and resilience: The PRESAFALIN study

Submission date
04/01/2024

Recruitment status
Recruiting

Registration date
08/01/2024

Overall study status
Ongoing

Last Edited
27/03/2024

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims.
Pediatric obesity presents a major global challenge. In 2020, over 38 million children under the age of 5 were living with excessive weight. Preschool age is a pivotal developmental stage with an impact on overall well-being and the prevention of diseases, including obesity. The etiology of pediatric obesity is multifaceted, involving biological, psychosocial, lifestyles, sociodemographic and environmental factors. In developed countries, a significant higher prevalence of pediatric obesity is observed among socioeconomically vulnerable populations. Promising interventions, focusing on parenting skills training and behavioral changes among adults, have shown potential in preventing pediatric obesity. However, there's a lack of evidence regarding the effectiveness of psychosocial approaches to prevent pediatric obesity during early childhood. The PRESAFALIN study aims to explore the effects of a family-based intervention addressed to promote parents' social skills, self efficacy and resilience in order to prevent pediatric obesity and build up healthy lifestyles from preschool ages.

Who can participate?
1,200 preschool children aged 0 to 5 years old and their parents who attend 1 of the 120 participant child day care centers (CDCC) and nursery schools (NS) in Barcelona and Madrid and who sign positively the study consent form.

What does the study involve?
The study will encompass 400 families per school year. Half of this sample, consisting of 200 families (children and adults), will form the intervention groups, and this composition will be replicated in the control groups. The allocation to intervention or control group will be assigned randomly. Each CDCC&NS will have at least 10 individuals in both the intervention and control groups with at least one adult and one child from each family unit. The sample will be distributed across three consecutive waves, spanning from 2024 to 2027, reaching a total of

1200 families. The study will start in 2024 after 3 years of pilot intervention (2021-2023) in which the study methodology and evaluation have been tested.
The PRESAFALIN project consists of two main phases. In the first phase, the intervention groups will participate in a 10-month program, comprising seven sessions, including two individual and five family workshops. CDCC&NS participating in the intervention group will be participating in meeting and training sessions to ensure project implementation. Additionally, tailored communication and educational materials will be provided based on participation groups. Level of satisfaction with the intervention will be continuously assessed during the project. In the second phase, we will track children aged 6 to 12 along with their parents from all the intervention and control CDCC&NS. For the intervention group, the follow-up comprises one family workshop per year with pedagogical materials, and individual activities such as telephone calls and text messaging. All the sessions will be led by the Gasol Foundation team with the support of the CDCCC&NS's educational team.
To study the intervention effects an evaluation protocol including control groups, has been designed. Both groups (intervention and control) participate in a baseline and a follow-up evaluation session after the 10-months intervention (phase I), such as long term follow up until children are 12 y.o. (phase II). During phase I, self-reported adult lifestyle variables will be recorded and parents zBMI and weight status. In the phase II, children's lifestyle variables will be reported by their parents when children will be 6 y.o. and will be self-reported when children will be 8, 10 and 12 y.o. For the whole evaluation period (phase I and II) zBMI and weight status of children will be registered as primary outcomes and adult self-reported questionnaires about parental skills, self efficacy and resilience will be assessed as secondary outcome measures. Also sociodemographic additional items will be registered.

What are the possible benefits and risks of participating?
The PRESAFALIN intervention study offers a range of significant benefits, including:
- Community engagement: Actively involving various stakeholders, such as community social and educational professionals, and families residing in the neighborhood, in a family-based intervention addressed to prevent pediatric obesity.
- Accessibility and inclusivity: Inviting families to join the program on a voluntary basis, to ensure accessibility to families living in socioeconomically vulnerable environments.
- Building trusting and supportive spaces: Cultivating nonjudgmental and understanding spaces within the community, allowing families to openly discuss and share their experiences in child rearing with fellow families and socio-educational professionals from the CDCC&NS.
- Promoting family bonding: Providing safe spaces for play and strengthening the connections between adults and children.
- Active participation and feedback: Encouraging active involvement and assessing the satisfaction and engagement levels of the CDCC&NS and families throughout the intervention.
- Providing resources: Distributing communication and educational materials to motivate and cultivate a sense of community within the entire group.
- Transferring study findings: communicating the study's impact results and findings to ensure knowledge transfer and understanding among the CDCC&NS and families.

The benefits for the intervention group are those of the study itself:
- Promotion of the necessary parental social skills, self-efficacy and resilience at short term to build up children's healthy eating, physical activity, sleep quality and psychological well being at mid term, leading to a reduced risk of pediatric obesity at long term (0 to 12 y.o.)

PRESAFALIN study carry no inherent risks.

Where is the study run from?
Grupo IFA.
Diputació de Barcelona (Spain)

When is the study starting and how long is it expected to run for?
November 2020 to December 2038

Who is funding the study?
Gasol Foundation (Europe)

Who is the main contact?
Dr Santiago Felipe Gómez Santos, sgomez@gasolfoundation.org
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Study website
https://gasolfoundation.org/es/presafalin/

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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
PRESAFALIN study protocol: A randomized controlled trial to evaluate the effects of a family-based psychosocial intervention to prevent pediatric obesity and build up healthy lifestyles from preschool ages through the promotion of parents' social skills, self efficacy and resilience

Acronym
PRESAFALIN

Study objectives
Family participation in the PRESAFALIN project promotes the necessary parental social skills, self-efficacy and resilience at short term to build up children’s healthy eating, physical activity, sleep quality and psychological well being at mid term, leading to a reduced risk of pediatric obesity at long term (0 to 12 y.o.)

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 11/11/2020, CEIm Fundació Sant Joan de Déu (Medical Research Ethics Committee) (Sant Joan de Déu Foundation, Santa Rosa, 39-57, Esplugues del Llobregat, Barcelona, 08950, Spain; +34 936 00 97 51; info@fsjd.org), ref: PIC-238-20

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Childcare/pre-school, Community

Study type(s)
Prevention, Quality of life

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Pediatric obesity

Interventions
The PRESAFALIN project will involve at baseline preschool children aged 0 to 5 years and their parents from 40 child day care centers (CDCC) and nursery schools (NS) situated across various regions of Spain (Catalonia and Madrid). The CDCC is a social and educational space specifically created to support families with pre-school and school-age children. Within this place, trained professionals collaborate with parents to strengthen family bonds. Priority is given to families that are exposed to the risk of social exclusion. A NS in Spain, provides the initial phase of non-compulsory early childhood education, tailored for children aged from four months to three years.

The study will be conducted in the child day Care Centers (CDCC) and nursery schools (NS) (CDCC&NS) and therefore will also serve as the units for assigning participants to either the intervention or control group. The allocation of the 40 CDCC&NS will be done randomly, following a 1:1 ratio. Participants in the control group will be offered to join the intervention group in the subsequent edition. The study will ensure the inclusion of at least one adult and one child of each participant family and 10 family units will be recruited for each CDCC&NS . In total, the study will include 400 families (400 children & 400 adults) per school year. Half of this sample will be assigned to the intervention groups, and the other half to the control groups. The sample will be distributed across three consecutive waves, spanning from 2024 to 2027. After the 3 waves, a total estimated 120 CDCC&NS and 1200 family units will participate.

PRESAFALIN project will comprise two main phases. In the first phase, the intervention groups will participate in a 10-month intervention that encompass seven workshops, including two individual and five familiar workshops. These workshops are focused on the promotion of parental social skills, self-efficacy and resilience to build up children’s healthy lifestyles, such as sleep quality, emotional well-being, healthy eating, and physical activity. The CDCC&NS’s

comprising the intervention group will be required to actively participate in scheduled meetings and training sessions, essential for the project implementation. Moreover, communication and educational materials will be provided based on the specific mode of participation, whether it is within the intervention group or the control group (each intervention component is further explained in detail). Concurrently, the control groups will continue to receive the standard care provided by the CDCC&NS, with the addition of a family workshop at the midpoint of the project, aimed at enhancing their engagement in the project and reducing potential drop outs at follow-up. Furthermore, both groups, intervention and control, will participate in two evaluation sessions, one before the intervention (baseline) and another after the 10-month intervention period (follow-up). Satisfaction related to the project's actions will also be evaluated throughout the intervention.

The second phase aims to follow children among the intervention and control groups of 120 CDCC&NS, from 6 to 12 years, along with their parents. Children will be reevaluated at 6, 8, 10 and 12 years old while parents will be evaluated every year since their children will be 6 years old and until 12 years old. It is expected to have an attrition rate of 20% during the full period of follow-up. Moreover, the follow-up comprises one familiar workshop with the delivery of pedagogical and communicative materials per each scholar year since the children will be 6 years old and until 12 years old. Additional supplementary activities will be available for each family unit, including individual telephone calls and text messaging.
The Gasol Foundation will oversee the entire project in partnership with the participating CDCC&NS.

Brief description of the intervention (phase I):
Addressed to family units:
1. Workshops:
- 7 family sessions per CDCC&NS participating in the intervention group, each lasting 1 hour and 15 minutes.
- 2 individual sessions for each intervention family, with each session lasting 1 hour.
- 1 family session for CDCC&NS participating as control groups, with each session lasting 1 hour and 15 minutes.

2. Evaluation & Dissemination.
- 1 baseline evaluation session per each CDCC&NS, both intervention and control groups, with each session lasting 2 hours.
- 1 follow-up evaluation session (40 weeks from baseline) per each CDCC&NS, both intervention and control group, with each session lasting 2 hours.
- 1 satisfaction evaluation after individual and grupal workshop per each family participating in the intervention group.
- 1 poster provided to each CDCC&NS displaying the results of the short-term PRESAFALIN study impact.
- 1 text message sent to each family participating in the intervention group to transfer the results of short-term PRESAFALIN study impact.

3. Communicative and Pedagogical material:
- 32 text messages for each family participating in the intervention groups.
- 4 packs of pedagogical material for each family participating in the intervention groups.
- 1 pack of communicative and pedagogical material for CDCC&NS participating in the intervention groups.

Addressed to CDCC&NS staff:
4. Training & meetings:

- 1 qualitative session for each CDCC&NS, with each session lasting 2 hours.
- 3 training sessions for all the CDCC&NS participating as intervention groups, with each session lasting 3 hours.
- 4 meetings sessions for CC&KS participating as an intervention group, with each session lasting 45 min.
- 1 meeting for all the CDCC&NS to transfer the results of short-term PRESAFALIN study impact.

Follow-up (phase II):
Addressed to family units:
1. Workshops:
- 3 familiars workshops for each CDCC&NS participating in the follow up, with each session lasting 3 hours.
- 2 Individual telephone call sessions for families participating in the follow up, with each session lasting 45 minutes.

2. Evaluation & Dissemination.
- 2 evaluation sessions for all the CDCC&NS participating in the follow-up, with each session lasting 2 hours.
- 1 meeting for all the CDCC&NS participating in the follow-up to transfer results of long-term PRESAFALIN study impact.
- 1 poster provided to each CDC&NS participating in the follow-up , displaying the results of long-term PRESAFALIN study impact.

3. Communicative and Pedagogical material:
- 4 text messages for each family participating in the follow-up intervention group .
- 3 packs of pedagogical material for each family unit participating in the follow-up intervention group.
- 1 pack of communicative and pedagogical material for each CDCC&NS participating in the follow-up.

Addressed to CDCC&NS staff:
4. Training & meetings:
- 1 meeting for each CDCC&NS participating in the follow-up, with each session lasting 1 hour.

Intervention Type
Behavioural

Primary outcome measure
zBMI (kg/m²) and weight status measured using body weight (kg), height (cm) and waist circumference (cm) of each participant. Body weight and height measurements will be taken with participants wearing a t-shirt and lightweight trousers, while waist circumference will be measured by lifting the t-shirt at the mid-torso. The measurements will be conducted without shoes. For children aged 2 to 12 years and adults, an electronic scale (SECA 899) will be used with an accuracy to the nearest 100 grams. For children aged 0 to 2 years, the SECA 384 electronic scale will be employed.
Height measurements will be carried out using a portable stadiometer (SECA 217) for children aged 2 to 12 years and adults, with an accuracy to the nearest 1 millimeter. For children aged 0 to 2 years, the SECA 417 stadiometer will be used. Additionally, a metric tape (SECA 201) with an accuracy to the nearest 1 millimeter will be utilized exclusively for children aged 6 to 12 years and adults. All measurements will be performed by trained field researchers.

Secondary outcome measures

Intervention (phase I):
Self-Reported adult variables:
1. Self-efficacy assessed by the 20 items Perceived Maternal Parenting Self- Efficacy (PMP S-E) questionnaire.
2. Resiliency evaluated by Connor-Davidson Resilience 10 items reduced scale.
3. Competencies and Abilities assessed by 20 items ad-hoc questionnaire.
4. Self- perceived stress, measured by the 10 items Perceived Stress Scale (PSS).
5. Sleep duration assessed by 4 questions from Sleep Survey for Adolescents (SHSA) Questionnaire.
6. Diet Quality evaluated by the 18 items short Diet Quality Screener (SDQ) questionnaire.
7. Physical activity (PA) level and sedentariness assessed by the 7 questions REGICOR Short PA questionnaire.
8. For adult demographics: date of birth, gender, birth country, number of years living in Spain, education level, work situation, annual income, and smoking habits using questionnaires.
9. For children's additional indicators: date of birth, gender, birth country, number of years living in Spain, home address, number of adults (under and older than18 y.o) living in the household, birth weight, weeks of pregnancy, birth typology (natural, vaginal, cesarean, others), and, breastfeeding months using questionnaires.

Follow-up (phase II):
Self-Reported adult variables:
1. Self-efficacy assessed by the 20 items Perceived Maternal Parenting Self- Efficacy (PMP S-E) questionnaire.
2. Resiliency evaluated by Connor-Davidson Resilience 10 items reduced scale.
3. Competencies and Abilities assessed by 20 items ad-hoc questionnaire.
4. Socioeconomic and environmental variables: education level, work situation, annual income, number of adults (under and older than18 y.o) living in the household and smoking habits.
Self-Reported children variables at 8, 10 and 12 years old*:
1. Quality of Diet and Adherence to Mediterranean Diet evaluated by 16 items KIDMED index questionnaire.
2. Sleep duration recorded by 4 questions from the Sleep Habit Survey for Adolescents (SHSA).
3. Sleep quality evaluated by 5 domains from the sleep screening tool (BEARS).
4. Physical activity (PA) assessed by the children's Physical Activity Unified- 7 items Screener (PAU-7S).
5. Physical condition evaluated by 5 items International Fitness Scale (IFIS).
6. Sedentary behavior measured by the 6 items Screen-time Sedentary Behavior Questionnaire (SSBQ).
7. Emotional well -being and Health status measured by one question of the self perceived health status from the questionnaire EQ-5D-Y-5L and 10 items KIDSCREEN.
8. Socioeconomic and environmental variables: gender, date of birth, home address, school home address, health card number, and identity card number.
*At age 6 years old, the variables will be reported through their parents.

Overall study start date
11/11/2023

Completion date
30/12/2038

Eligibility

Key inclusion criteria
1. Children aged 0 to 5 years and parents living in Spain (Catalonia & Madrid).
2. Enrollment in a selected CDCC&NS.
3. Informed consent signed positively by parents/legal guardians.

Participant type(s)
Population

Age group
Mixed

Lower age limit
0 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
1200

Key exclusion criteria
Intellectual or physical characteristics that incapacitate their enrollment in the evaluation procedures.

Date of first enrolment
10/01/2024

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Spain

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Study participating centre

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Funder(s)

Funder type
Charity

Funder Name
Gasol Foundation

Results and Publications

Publication and dissemination plan
The expected publication and dissemination plan of PRESAFALIN intervention study is the following:

PRESAFALIN intervention study protocol (2024).
PRESAFALIN short-term intervention effects (2025).
Differences in the short-term PRESAFALIN intervention effects according to socioeconomic and demographic variables (2026).
PRESAFALIN mid-term intervention effects (2027).

Other additional publications in high-impact peer-reviewed journal are expected but still not planned.

Intention to publish date

01/04/2039

Individual participant data (IPD) sharing plan

All dataset will be available for research organizations from the initial project edition without any data limitations. Interested organizations can request access by contacting the Gasol Foundation's research and programs global director:
- Contact name and surname: Santiago Felipe Gómez Santos
- E-mail contact: sgomez@gasolfoundation.org

The research organization will be asked to inform about: Name and legal status of the organization, contact name and email, main objective of using the dataset.

Upon reviewing this information, if the main objective uphold the ethical standards and align with the Gasol Foundation’s mission of the Gasol, the organization will sign a document outlining the following:
- Ethical use of the data.
- The dataset analysis objective.
- Commitment to share analysis details with the Gasol Foundation.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	01/09/2023	05/01/2024	No	Yes