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Parental therapy and psychomotor support in children with overweight or childhood obesity

Submission date
18/02/2024

Recruitment status
No longer recruiting

Registration date
14/03/2024

Overall study status
Completed

Last Edited
04/03/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Boys and girls diagnosed with overweight and obesity tend to have health consequences such as hypertension and metabolic syndrome; decreased physical performance; negative emotionality and binge eating disorder. In recent decades, prevention has focused on the environment since obesogenic behaviors and environments explain a good part of the growing rates of childhood and adolescent obesity. Research reports that interventions should include strengthening self-regulation and the family approach because they would present better results in weight loss. Furthermore, there is evidence of the effectiveness of family parenting therapy supported by clinical psychomotor therapy in infants diagnosed with attention deficit disorder, showing significant changes in self-regulatory capacity and it is relevant to study it in overweight and obese children.
This study aims to determine the effect of the family bonding therapy intervention accompanied by group clinical psychomotor therapy on the capacity for self-regulation, measured through physical-psychological-relational dimensions in children from 5 years months to 10 years 11 months with a diagnosis of overweight or obese. A repeated measures quasi-experimental design will be used to assess self-regulatory behavior. The intervention program will be through a group clinical psychomotor workshop for children in addition to a psychoeducation workshop aimed at direct caregivers in family bonding therapy. The families will receive care from the Choose Healthy Life Program framed within the primary health care of the Lo Prado commune, which offers health benefits proposed at the government level. Half of the recruited families will additionally receive the intervention program.
The measurement of self-regulation will be in three dimensions: Physical/Well-being, Psychosocial, and Relational. The results will allow the development of a practical guide of recommendations for the “Elije Vida Sana” and “Estrategia 3ª”, as well as publications in indexed journals. Finally, the new knowledge will be transferred to the educational and health environment to improve the quality of life and increase healthy habits.

Who can participate?
Children aged 5 years to 10 years 11 months old diagnosed with overweight or obesity.

What does the study involve?
This study aims to determine the effect of family bonding therapy accompanied by group clinical

psychomotor therapy on self-regulation capacity, measured through physical-psychological-relational dimensions. The intervention program will involve a group clinical psychomotor workshop for children in addition to a psychoeducation workshop for direct caregivers in family bonding therapy.

What are the potential benefits and risks of participating?
Benefits: As a participant in this research, the child and their parents will contribute globally to scientific development and collaborate in research aimed at reducing excess malnutrition through improved self-regulatory skills and the promotion of healthy habits. In addition, the parent will receive a preliminary report after each assessment process that includes the diagnostic opinion. Also, a second report on the progress of the process with implications and general suggestions for school and home will be provided, and the reports can be freely accessed.

Risks: No risks associated with the child's participation in this study are anticipated. However, if any of the assessments cause discomfort or unease to the parent or child, or if there are any questions during the process, they can inquire with the responsible person for the research and /or stop their participation at any time. If a health difficulty or condition that imminently affects the well-being of the parents or the child is identified, it will be reported to those in charge of the 3A strategy in the Lo Prado commune, to collaborate in their process as promptly as possible.

Where is the study run from?
Participant interventions take place within the Elije Vida Sana Program, part of the Tres A Communal Strategy in Lo Prado, Metropolitan Region, Chile.

When is the study starting and how long is it expected to run for?
September 2023 to November 2025

Who funds the study?
ANID of Chile (Project FONIS SA23I0167)

Who is the main contact?
Josefina Larraín-Valenzuela, josefinalarrain@udd.cl

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FONIS SA23I0167

Study information

Scientific Title
Effectiveness of parental therapy supported by clinical psychomotor skills in the self-regulation of children with overweight or childhood obesity to increase healthy habits

Study objectives
The intervention of family bonding therapy accompanied by group clinical psychomotor therapy increases self-regulatory capacity measured through physical-psychological-relational change in children diagnosed with overweight or obesity.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/11/2023, Institutional Research Ethics Committee (CEII) of the Universidad del Desarrollo (Av. Plaza 680, Las Condes, Santiago de Chile, Region metropolitana, Santiago, 7550000, Chile; +56 (0)2 2327 9110; lmelo@udd.cl), ref: SA23I0167

Study design
Randomized quasi-experimental repeated-measures design

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Childhood overweight or obesity

Interventions
The intervention will be carried out both for parents with a diagnosis of obesity or overweight called a Psychoeducation Workshop and for their children called a Child Psychomotor Workshop for girls and boys with a diagnosis of obesity or overweight. The age range of children is between 5 years and 10 years 11 months because there is already evidence of the effectiveness of both programs on other developmental problems.

A total of 72 families are recruited who receive the intervention of a health program “Choose a Healthy Life” within the Communal Strategy 3A of Lo Prado of the Metropolitan Region of the state of Chile. This is a primary health benefit within the educational field that addresses problems of obesity or overweight.

Participants will be randomised using Covariate Adaptive Randomization methods. Half of these families will receive an extra parental therapy intervention with group clinical psychomotor support for boys/girls. That is, the entire sample will be evaluated and half of it will receive an additional intervention. The assignment of whether or not they will receive complementary intervention is unknown to the participant. This is detailed in the informed consent. Once assigned, participants are informed if they will only receive the evaluations or the evaluations plus treatment for 4 months.

The entire sample will be distributed in three phases, and each phase will include 24 families - 12 of them receive the intervention - both groups will be evaluated three times: (1) before and at (2) the end of both interventions, (3) follow-up after 6 months of completing the programs. The duration of the intervention will be 4 months.

Intervention:
Comprehensive parental support program (family bonding therapy [FBT]) with group clinical psychomotor therapy as a solution to improve indicators of childhood overweight and obesity. This program will simultaneously offer the approach to parents and their children, in two different spaces and times within the same week. The frequency is weekly for both parents and their children for 75 minutes.
The part of the program aimed at parents considers the theoretical and practical alignments of Claudia Messing's family bonding therapy. This intervention guides the therapeutic process towards subjectivation with emotional reconnection, and the construction of new models of authority in the face of the failure of traditional models (e.g. linked to fear).
The intervention will be carried out by a clinical psychologist with training in family bonding therapy and eating behavior problems. The intervention will aim to address the most important aspects promoting awareness of the ties between mothers and fathers with their children and

with their own mothers and/or fathers. Identification of problems around food and possible psycho-affective transfers. Additionally, the excessive overload of family roles and their effects, the massive mimicry of their own fathers and mothers, the reproduction of experiences, and the difficulty in setting appropriate limits for their children and conflicts that affect the incorporation of healthy habits. The increase in self-regulation of mothers and fathers will be through the verbalization of different lived experiences of discomfort and/or pain with the ties with their own mothers, fathers and siblings. Forms of immediate gratification that they carry out at the family level will be identified and others that do not involve the connection with food will be sought. The effects on the body image and schema will be measured, looking for care strategies for both the family group and the child. The study team will work on the interpretation of the body as a component that affects self-concept and self-esteem. The topics will be addressed during 16 sessions that present a common general structure:
1. The time and place will be previously defined
2. The participants will be assigned in a circle to favor the gaze of the other participants
3. The need to respect the group and avoid punitive judgment among them will be pointed out
4. Each member of the group will be invited to intervene on a specific problem voluntarily, here a change of perspective on the situation and the possibility of solving the problem collectively will be sought
5. Each person's problem will serve as an example to improve the personal aspects of the entire group
6. Goals and resolution strategies will be proposed to implement at home to review them at the next meeting
7. The closing of the session will end with the evocation of “a word” that will refer to the emotional state for the end of the session

The part of the program aimed at children is clinical psychomotor therapy (CPT), which aims to trigger questions about the body, enhancing the transference with therapy and objects. Children will be encouraged to develop their subjective construction from the therapist's mirror to promote the expression of their corporality and symbolization as well as their motor development to achieve greater adjustment to their environment.

All sessions will be carried out by an expert in psychomotor skills, who will actively listen to the children through tonic empathy, which transmits a feeling of security, allowing the transition to the symbolic. The intervention will be carried out in a group with a maximum of four members to create collaboration and modulation of behavior, because there are previous reports of effectiveness with that number of participants. The physical space called “the psychomotor room” will meet the requirements of luminosity, space, warmth and low levels of exposure to danger for girls and boys. The material provided will consider the interests and needs of the participants since it will be the non-figurative polymorphic material necessary to promote imagination (e.g., ladder, mattresses, mirrors, fabrics), ropes, wood, sheets, pencils, etc). The general structure will be 16 clinical sessions on child psychomotor skills incorporating psychomotor practice principles.

All sessions will present the structure: a beginning called entry ritual, in which the psychomotor therapist will agree with the participants, the rules of the place associated with the care of one's own body, the body of companions and materials. Then, the moment of free play, where sensorimotor games will prevail. Subsequently, the children will be invited to the moment of representation associated with graphic-plastic expressive activities of free choice. Ended with the exit ritual that marked the passage “from the game” to “reality”.

Intervention Type
Behavioural

Primary outcome(s)
The following Primary outcome measures are assessed at baseline and follow-up:
1. Body composition measured using an Inbody device
2. Practice of physical activity in schoolchildren measured using the Physical Activity Questionnaire for older children (PAQ-C)
3. Adherence to the Mediterranean diet measured using the Mediterranean Diet Quality Index (KIDMED) test
4. Waist, brachial, and neck circumferences measured using a Lufkin inextensible metal measuring tape
5. Body weight measured using a SECA 813 Scale
6. Blood pressure measured using a Dynamap Pro 100 digital blood pressure monitor
7. Size (height) measured using a SECA 213 mobile stadiometer
8. Skin folds measured using a Harpenden calliper
9. Appendicular strength measured using a JAMAR hydraulic hand and thumb dynamometer
10. Sexual maturation measured using a photographic cardex
11. Executive function measured using the Behavioral Assessment of Executive Functions (BRIEF) Scale administered to parents to assess
12. Behavior measured using the Child and Adolescent Assessment System (Sistema de Evaluación de Niños y Adolescentes; SENA) Scale completed by parents to evaluate
13. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI)
14. Use of Screens measured using a screen-use survey
15. Childhood Eating Behavior measured using the Child Eating Behavior Questionnaire (CEBQ)
16. Risk of Eating Disorders of the responsible caregiver measured using the Eating Attitudes Test-26 Scale
17. Social Climate measured using the Family Environment Scale (FES)
18. Coping with stress measured using the Coping with Stress Questionnaire

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
20/11/2025

Eligibility

Key inclusion criteria
1. Families must participate in both programs and commit to the programming
2. The program is aimed at a low socioeconomic level
3. They must be referred for medical assistance with the diagnosis of overweight and obesity
4. Mothers and fathers must present a reason for consultation associated with the desire to change eating habits as caregivers and thus strengthen the development of their girls and boys

Participant type(s)
Patient, Carer, Population

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
11 years

Sex
All

Key exclusion criteria
1. Without involvement in neurological diseases
2. Diagnoses based on the problem being greater (e.g. Autism Spectrum Disorder)
3. They do not wish to participate in the evaluation process

Date of first enrolment
05/03/2024

Date of final enrolment
30/03/2025

Locations

Countries of recruitment
Chile

Study participating centre
Strategy 3A, Choose Healthy Life Program, Municipality of Lo Prado, Santiago, Chile
Colegio Golda Meir en Av. Dorsal 5699-5671, comuna de Lo Prado
Santiago
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Sponsor information

Organisation
Agencia Nacional de Investigación y Desarrollo

ROR
https://ror.org/02ap3w078

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Investigación en Salud (FONIS) SA23I0167

Results and Publications

Individual participant data (IPD) sharing plan
The information obtained will be confidential and access is limited to the team of researchers, owners of the project, who are responsible for safeguarding and handling all the information obtained under strict anonymity.
The data obtained will be used without any type of individual information, for this the names of the participants will be replaced by a code.
It is possible that the data collected within the framework of this research will be used in subsequent studies that benefit from the type of records obtained. If so, only anonymous and coded data will be available as indicated.
All families who make the decision to participate will sign a consent and informed assent in printed format about the research project before starting the first evaluation. Consent will be requested by whoever administers the tests. The following will be explained there:
1. Regarding the benefits, each family will participate in two programs carried out by experts for free and each family will receive a comprehensive report of the evaluations carried out. All exams and procedures will be free.
2. In relation to risks, we will work with families chosen at random, who are treated in different health centers, which will imply permanent contact for teamwork, and also for any eventuality in physical, psychological and social aspects.
3. Regarding confidentiality, although the results obtained are intended to be used for scientific publications, the identity will not appear published in any case, remaining anonymous and only assigned with codes and the date of the procedure; Anyone outside of this research lacks access to information that would identify the volunteers participating in this study.
4. The decision of the participants to enter this project will be completely voluntary and the rejection of consent will not have any type of economic, legal, or mandatory repercussion in the future. Likewise, families can abandon the study at any phase of it, if this is their wish. Non-participation in the study will not have any consequence on future medical management or on the relationship with the treating physicians of the child or his/her family. In addition, the participating children will sign an assent. The data will be available only to the team of principal investigator, alternate investigator and methodologist. The researchers will work with R and SPSS statistical analysis software. For any request please contact the main researcher Josefina Larraín (josefinalarrain@udd.cl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes