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Childhood overweight and obesity intervention: Effectiveness of a programme based on parents as agents of change

Submission date
15/07/2020

Recruitment status
No longer recruiting

Registration date
29/07/2020

Overall study status
Completed

Last Edited
01/08/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Current plain English summary as of 10/02/2021:
Background and study aims
The rates of childhood overweight (OW) and obesity (OB) significantly increased in the past decades. The prevalence of OW/obese children in Portugal is one of the highest in the European Union. A comprehensive approach to prevent and treat childhood OW and OB is needed. Since parents have a crucial role in children's diet and physical activity, interventions should include the family's lifestyle and focus on parenting practices. Programmes targeting parents by increasing parents' awareness and responsibility in providing environments that lead children to healthy behaviours are imperative in treating childhood OW and OB. The purpose of this study is to evaluate the effectiveness of Group Lifestyle Triple P (GLTP) in a Portuguese sample of parents of OW/obese children. This is particularly relevant as, to date, there are no such structured interventions available in Portugal.

Who can participate?
Parents of OW/obese children, aged 5 to 10, currently being followed at the paediatrics appointment at the Nutrition Unit of the Paediatric Department (NUPD) of the University Hospital Centre of Porto (Centro Materno-Infantil do Norte, Portugal).

What does the study involve?
Participants will be randomly allocated to intervention or control conditions. Participants in the intervention condition receive clinical Treatment-As-Usual (TAU) along with Group Lifestyle Triple P (GLTP), whereas those in the control condition solely receive clinical TAU. TAU includes quarterly structured medical appointments delivered by paediatricians, following the guidelines defined by the ESPGHAN Committee on Nutrition, encouraging behavioural change to facilitate consistent and long-term follow-through.
GLTP is an evidence-based parenting intervention, underpinned by cognitive behavioural theory, that aims to reduce children’s risk of chronic weight problems by increasing parents’ skills and confidence in managing children’s weight-related behaviour. The programme addresses positive parenting and aims at helping parents develop strategies for managing their child’s weight and weight-related behaviours by introducing changes in the family’s lifestyle, mainly through

promoting healthy family eating and encouraging physical activity. The programme targets parents of OW/obese children aged 5 to 10. It consists of a 14-session intervention delivered in a hybrid format, where parents receive ten 90-minute group sessions (in-person) and four 20-min individual sessions (by phone or video call) over 17 weeks.
Participants take part in three assessment time points at the beginning of the study and 4 and 10 months after. The following outcomes are assessed at each time point: child's anthropometric measures, body composition, dietary behaviour and physical activity levels, behaviour problems and quality of life; parents' psychological symptoms, perception of child's weight-related problem behaviour and self-efficacy in managing such behaviours, general parenting practices, specific parenting practices regarding feeding and physical activity, and parents' perception of change and satisfaction following the GLTP intervention.

What are the possible benefits and risks of participating?
Participants have the opportunity to receive the GLTP intervention and with that learn strategies to deal with their child's weight-related problem behaviour effectively, increasing their self-efficacy in managing their child's behaviour, and their use of effective parenting practices. After completing all the assessment time points, participants in the control condition will have the opportunity to receive the GLTP intervention. All the participants receive a gift card (€30) as compensation for their travel expenses to participate in the different assessment time points. Participants from both conditions who receive the GLTP also receive the materials needed for programme implementation. No risks are foreseen for participants.

Where is the study run from?
University of Porto (Portugal)

When is the study starting and how long is it expected to run for?
July 2018 to July 2023

Who is funding the study?
Fundação para a Ciência e a Tecnologia (Portugal)

Who is the main contact?
Prof. Orlanda Cruz
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Previous plain English summary:
Background and study aims
The rates of childhood overweight (OW) and obesity (OB) significantly increased in the past decades. The prevalence of children with both OW and OB (OW/OB children) in Portugal is one of the highest in the European Union and the OECD area. A comprehensive approach to prevent and treat childhood OW and OB is needed. Since parents have a crucial role in children's diet and physical activity, interventions should include the family's lifestyle and focus on parenting practices. Programs targeting parents by increasing parents' awareness and responsibility in providing environments that lead children to healthy behaviours are imperative in the treatment of childhood OW and OB. The aim of this study is to evaluate the effectivess of Group Lifestyle Triple P (GLTP) in a Portuguese sample of parents of OW/OB children. This is particularly relevant as, to date, there are no such structured interventions available in Portugal.

Who can participate?
Parents of OW/OB children, aged 5 to 10, currently being followed at the paediatrics appointment at the Nutrition Unit of the Paediatric Department (NUPD) of Porto University Central Hospital (Centro Materno-Infantil do Norte, CMIN).

What does the study involve?
Participants will be randomly allocated to the intervention and control groups. The intervention group receives treatment-as-usual (TAU) along with Group Lifestyle Triple P (GLTP), whereas the control group receives only TAU. TAU includes quarterly structured medical appointments delivered by paediatricians, following the guidelines defined by the ESPGHAN Committee on Nutrition, encouraging behavioural change to facilitate consistent and long-term follow-through. GLTP is the only evidence-based program that teaches parents of children with OW (not only with OB) to use positive parenting to promote a healthy lifestyle in their families, through healthy eating and physical activity. It stems from the Triple P - Positive Parenting Program and is delivered in a 14-session intervention over 17 weeks. It aims to decrease the child's weight and weight-related problem behaviour by increasing parents' self-efficacy in managing the child's behaviour and by reducing the use of ineffective parenting practices. Participants take part in three assessment time points at the start of the study and 4 and 10 months after. The following are measured: the child’s body measurements, body composition, dietary behaviour and physical activity levels, behaviour problems and quality of life; the parents' psychological symptoms, parents’ perception of child's weight-related problem behaviour and self-efficacy in managing those problems, overall parenting practices, specific parenting practices regarding feeding and physical activity, and parents’ perception of change and satisfaction following GLTP intervention.

What are the possible benefits and risks of participating?
Participants have the opportunity to receive the GLTP intervention and with that learn strategies to deal with their child’s weight-related problem behaviour effectively, increasing their self-efficacy in managing their child's behaviour, and the use of effective parenting practices. After completing all the assessment time points, participants of the control group will have the opportunity to receive the GLTP intervention. All the participants receive a gift card (€30) as compensation for their travel expenses to participate in the assessment time points. Participants from both groups who receive the GLTP also receive all the materials needed for program implementation. No risks are foreseen for participants.

Where is the study run from?
University of Porto (Portugal)

When is the study starting and how long is it expected to run for?
July 2018 to June 2023

Who is funding the study?
Fundação para a Ciência e a Tecnologia (Portugal)

Who is the main contact?
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Study website
https://lifestyle.fpce.up.pt/en/home/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PTDC/SAU-NUT/30715/2017

Study information

Scientific Title

A randomized controlled trial comparing Treatment-As-Usual (TAU) and Group Lifestyle Triple P (GLTP) vs TAU only to evaluate the effectiveness of GLTP in a sample of parents of overweight /obese children aged 5 to 10 recruited from a university hospital: short and long-term (4 and 10 months after baseline) effects on child's anthropometric measures, body composition, dietary behaviour and physical activity levels, behaviour problems and quality of life; parents' psychological symptoms, perception of child weight-related problem behaviours, general parenting practices, specific parenting practices regarding feeding and physical activity, and perception of change

Acronym
LifeStyle

Study objectives
Group Lifestyle Triple P improves the clinical intervention outcomes provided to overweight /obese children followed at the Nutrition Unit of the Paediatric Department of the University Hospital Centre of Porto (Centro Materno-Infantil do Norte, Portugal).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/10/2016, Ethics Committee of the Faculty of Psychology and Education Science at the University of Porto (Rua Alfredo Allen, s/n, 4200-135 Porto, Portugal; +351 (0)220 400 647; comissao_etica@fpce.up.pt), ref: 13-10/2016
2. Approved 25/09/2019, Board of University Hospital Centre of Porto (Largo Professor Abel Salazar, s/n, 4099-001 Porto, Portugal; +351 (0)222 077 500; geral.investigacao.defi@chporto.min-saude.pt), ref: 2019.020(017-DEFI/018-CE)
3. Approved 06/02/2019, Data Protection Unit of the University of Porto (Praça Gomes Teixeira, 4099-002 Porto, Portugal; +351 (0)220 408 000; dados.pessoais@up.pt), ref: 2018091915006258

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Evidence-based parenting intervention (group format) in parents of overweight/obese children aged 5 to 10

Interventions

Current interventions as of 10/02/2021:
Recruited participants will complete the baseline assessment and be randomly assigned to one of two conditions, intervention or control. The randomisation process takes place after the baseline assessment. It is performed by an independent researcher not directly involved in data collection nor intervention delivery, using a list of computer-generated random numbers. Outcome assessors are not aware whether the participant received the Group Lifestyle Triple P (GLTP) intervention.

Participants in the intervention condition will receive GLTP intervention along with clinical Treatment-As-Usual (TAU). Participants in the control condition receive clinical TAU during the study and are given the opportunity to receive GLTP after the last assessment time point. The GLTP intervention is an evidence-based parenting intervention underpinned by cognitive behavioural theory with three core components, which address risk and protective factors for childhood OW and OB and translate into a range of specific parenting strategies. GLTP aims to reduce children's risk of chronic weight problems by increasing parents' skills and confidence in managing children's weight-related behaviour. The programme addresses positive parenting and aims at helping parents develop strategies for managing their child's weight and weight-related behaviours by introducing changes in the family's lifestyle, mainly through promoting healthy family eating and encouraging physical activity. The programme targets parents of OW/obese children aged 5 to 10. It consists of a 14-session intervention delivered in a hybrid format, where parents receive ten 90-minute group sessions (in-person) and four 20-min individual sessions (by phone or video call). Sessions 1 to 10 are delivered weekly, and sessions 11 to 14 biweekly, resulting in a programme duration of 17 weeks. The programme is delivered by two accredited practitioners (research team members) at the Faculty of Psychology and Education Science at the University of Porto.

TAU consists of structured medical appointments provided by two paediatricians (research team members) in a quarterly frequency at the Nutrition Unit of the Paediatric Department (NUPD) of the University Hospital Centre of Porto (Centro Materno-Infantil do Norte, Portugal). These medical appointments follow the ESPGHAN Committee on Nutrition guidelines, encourage behavioural change to facilitate consistent and long-term follow-through, target the promotion of healthy eating habits and physical activity and the reduction of risk/severity for obesity-related diseases.

Previous interventions:
Recruited participants will complete the baseline assessment and will then be randomly assigned to the two conditions, Group Lifestyle Triple P (GLTP) intervention along with clinical treatment as usual (intervention condition), or solely treatment as usual (control condition). The randomization process takes place after the baseline assessment and is performed by an independent researcher not directly involved in data collection nor intervention delivery, using a list of computer-generated random numbers. Outcome assessors are not aware whether the participant received or not GLTP intervention. Each of the conditions (intervention and control) will include eight groups of 20 parents.

The intervention condition includes the implementation of the program Group Lifestyle Triple P (GLTP), along with Treatment-As-Usual (TAU). GLTP is a cognitively behavioural intervention aimed at reducing children's risk of chronic weight problems by increasing parents' skills and confidence in managing children's weight-related behaviour. The program targets parents of

overweight or obese children aged 5 to 10 years and consists of a 14-session intervention, where parents receive ten 90-minute group sessions and four 20-minute individual sessions. The program is delivered by two accredited practitioners (research team members) at the Faculty of Psychology and Education Science at the University of Porto. TAU consists of structured medical appointments provided by two paediatricians (research team members) in a quarterly frequency at the Nutrition Unit of the Paediatric Department of the Porto University Central Hospital, targeting the promotion of healthy eating habits and physical activity, and the reduction of risk /severity for obesity-related diseases. These medical appointments follow the guidelines defined by the ESPGHAN Committee on Nutrition, encouraging behavioural change to facilitate consistent and long-term follow-through.

The control condition solely receives TAU.

Participants will take part in three assessment time points, at baseline, and 4 and 10 months following baseline.

Intervention Type
Behavioural

Primary outcome measure
The study includes three assessment time points for both intervention and control conditions at baseline, 4 and 10 months after baseline. The following primary outcomes will be assessed at each time point:
1. Child’s anthropometric measures including height, using a SECA stadiometer, weight, using an Inbody 270 scale, and waist and arm circumferences using a SECA measuring tape
2. Child's body composition, body fat percentage and lean body mass percentage, evaluated using an Inbody 270 scale
3. Child's dietary behaviour, obtained by parents’ report on a three-day food intake diary and by parent’s report on child’s intake frequency for specific foods and beverages
4. Child’s physical activity level, obtained by each child wearing a wGT3X-BT Actigraph Accelerometer for 5 days

Secondary outcome measures
The study includes three assessment time points for both intervention and control conditions at baseline, 4 and 10 months after baseline. The following secondary outcomes will be assessed at each time point:
1. Parents' perception of child's weight-related problem behaviours and self-efficacy in managing such behaviours, assessed using the Lifestyle Behaviour Checklist (LBC)
2. Parents’ comprehensive feeding practices, assessed using the Comprehensive Feeding Practices Questionnaire (CFPQ)
3. Physical activity parenting practices, assessed using the Physical Activity Parenting Practices (PAPP) questionnaire
4. Parenting styles and practices, assessed using the Alabama Parenting Questionnaire (APQ) and the Parenting Scale (PS)
5. Parents’ treatment self-regulation, assessed using the Treatment Self-Regulation Questionnaire (TSRQ)
6. Parents’ agreement or conflict on parenting practices, assessed using the Parent Problem Checklist (PPC)
7. Parents' perception of the child's quality of life, assessed using the EQ-5D-Y and the Kidscreen
8. Parents' perception of the child’s difficulties and strengths, assessed using the Strengths and Difficulties Questionnaire (SDQ)

9. Parents' recall on parents and child healthcare utilisation and productivity losses assessed using a questionnaire adapted from the TiC-P

The following data will be collected at baseline:
1. Family sociodemographic characteristics collected using a questionnaire
2. Parents' anxiety, depression, and stress, assessed using the Depression, Anxiety and Stress Scales (DASS-21)

Participants of the intervention condition will also provide information on the following:
1. Helpful aspects of the intervention, assessed using an adapted version of the Helpful Aspects of Therapy (HAT) interview, at the middle and the end of the GLTP intervention
2. Perception of family lifestyle changes, assessed using an interview developed for this purpose, at the end of the GLTP intervention
3. Perception of satisfaction with the intervention, assessed using the Triple P Client Satisfaction Questionnaire-Revised (CSQ), at the end of the GLTP intervention

Overall study start date
01/07/2018

Completion date
31/07/2023

Eligibility

Key inclusion criteria
Mothers and/or fathers of overweight and obese children (BMI for age >+1SD and BMI for age >+2SD according to the WHO Growth Reference 5-19 years) aged 5 to 10 years old, recruited at the Nutrition Unit of the Paediatric Department (NUPD) of the University Hospital Centre of Porto (Centro Materno-Infantil do Norte, Portugal)

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
120 participants

Total final enrolment
96

Key exclusion criteria
1. Parents not being able to commit to 6 months of regular contacts
2. Not being willing to make changes in their family's lifestyle
3. Presently participating in a program targeting childhood overweight and obesity
4. Parent of an overweight/obese child diagnosed with endocrine disease-causing overweight or

obesity, or diagnosed with cognitive, motor or development delays, or with physical limitations, or currently under medication known to cause overweight or obesity

Date of first enrolment
01/05/2019

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
Portugal

Study participating centre
University of Porto
Faculty of Psychology and Education Science
Rua Alfredo Allen
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Sponsor information

Organisation
University of Porto

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Sponsor type
University/education

Website
https://sigarra.up.pt/fpceup/pt/web_page.Inicial

ROR
https://ror.org/043pwc612

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

Results and Publications

Publication and dissemination plan
The study protocol is currently being prepared and will be available when published.
According to the target population, different dissemination outcomes are planned, following the Open Science guidelines (European Commission).
For researchers and the scientific community, expected scientific outputs include submitting six papers in indexed scientific journals, at least two of which in Open Access International Journals.
Regarding Open Research Data, access to datasets will be provided after rigorously screening the datasets and removing every data that can potentially jeopardise participants' anonymity and data confidentiality. Thus, the research's partial datasets will be uploaded into Open Research Data Repositories after undergoing a process of data curation.
Regarding Open Scholarly Communication, different actions are proposed.
Aiming at researchers and the scientific community: the study's results will be presented in National and International Conferences.
Aiming at specified (policymakers and stakeholders), and general audience, a seminar regarding the presentation of the results will be organised at the University of Porto.
For practitioners, a workshop focused on the effectiveness and dissemination of the program will be held. The results of this workshop will be compiled and fed back to professionals through the project website.
For parents, flyers and posters informing about Group Lifestyle Triple P as an available resource will be delivered in schools, primary health care centres, and other community centres where parents are often present and search for advice on child-rearing and health issues.

Intention to publish date

30/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Data to be shared regards primary and secondary outcomes evaluated at baseline, 4 and 10 months after, for participants in both conditions. Data will be available indeterminately at the end of the study, after results publication. Participants give their informed consent regarding data sharing. From ethical and data protection points of view, the research team entitles participants to the right of consulting, rectifying or deleting their personal data until the last assessment time point of the study, from that point onwards data are anonymised. Data from participants who do not consent to data sharing will not be included in the raw data datasets shared among the scientific community. The curated and anonymised datasets will be available for download and will have a reference and URL, for those who use them to cite them. Also, the manuscripts published on the current study results will include anonymised datasets as supplementary materials, in line with the open science guidelines to foster results reproducibility.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			01/08/2023	No	No