ISRCTN14864396 https://doi.org/10.1186/ISRCTN14864396

Preventing obesity through evidence-based recommendations and community-based, family-centric interventions

Submission date
06/08/2025

Recruitment status
Recruiting

Registration date
13/08/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Excess unhealthy body weight, defined as overweight (OV) or obesity (OB), affects around one third of children and adolescents worldwide, rendering it one of the most common paediatric chronic diseases. Obesity negatively impacts children's health, being associated with both physical and psychological morbidity that may persist into adulthood. The school environment has long been recognised as a unique setting for delivering interventions to prevent childhood OV/OB, in that first and foremost, schools encompass the majority of children within a geographical area, and children spend a large proportion of their time there. This study aims to develop and pilot-test a school-based, family-centric healthy lifestyle intervention incorporating digital tools for the prevention of OV/OB in children and adolescents.

Who can participate?
Schoolchildren aged 9-14 years.

What does the study involve?
Multi-component, school-based, family-centric intervention focusing on healthy lifestyle behaviours. The intervention will last for 6 months, will be delivered by experienced researchers with support from members of the school community (teachers), and will be based on established behaviour change techniques. Participants in both the IG and the CG will participate in 4 healthy lifestyle classroom workshops (each of approx. 90-minute duration), focusing on lifestyle habits/practices that have been identified as important for the prevention of childhood OV/OB (e.g., hydration, meal habits, physical activity and sleep). Participants in the IG will additionally be given access to digital tools, namely a mobile phone application (including a lifestyle recommendation engine feature), and a serious games suite, that will serve as complementary features of a family-centric approach to facilitate intervention delivery and adherence to the desired lifestyle habits/practices.

What are the possible benefits and risks of participating?
Possible benefits include improved health knowledge, the possibility to improve their health literacy and ultimately overall well-being.

Given the nature of the intervention applied, i.e., behaviour change towards a healthy lifestyle, no intervention-related harms or adverse effects are expected to occur in any participant.

Where is the study run from?
The Danish Committee for Health Education, Denmark.

When is the study starting and how long is it expected to run for?
May 2023 to December 2026

Who is funding the study?
The Horizon Europe Health program, European Commission.

Who is the main contact?
Not provided at time of registration

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Meropi Kontogianni

Contact details
El. Venizelou 70
Athens
Greece
17671
+302109549359
mkont@hua.gr

Type(s)
Public, Principal investigator

Contact name
Mr Charan Nelander

Contact details
Classensgade 71
København
Denmark
2100
+4525487661
cn@sundkom.dk

Type(s)
Scientific, Principal investigator

Contact name
Dr Izidor Mlakar

ORCID ID
https://orcid.org/0000-0002-4910-1879

Contact details
Slomškov trg 15
Maribor
Slovenia
2000
+386 2 220 7267
izidor.mlakar@um.si

Type(s)
Principal investigator

Contact name
Miss Sara Anjos

ORCID ID
https://orcid.org/0000-0002-8544-7471

Contact details
Largo dos Topazios 48-3 FTE
Sao Domingos de Rana
Portugal
2785817
+351 936679210
sara.anjos@nuclio.org

Type(s)
Principal investigator

Contact name
Miss Eszter Salamon

ORCID ID
https://orcid.org/0000-0001-9504-3641

Contact details
Herenstraat 35
Utrecht
Netherlands
3512 KB
+31 640912781
eszter.salamon@esha.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HORIZON EUROPE Health grant no: 101080718

Study information

Scientific Title
Preventing obesity through evidence-based recommendations and community-based, family-centric interventions: a randomised controlled trial

Study objectives
Primary aims/goals:
A1: To promote healthy eating and physical activity habits among children and adolescents.

Secondary aims/goals:
A2: To improve the knowledge, self-efficacy, attitudes and behaviours regarding nutrition and physical activity among children and adolescents.
A3: To contribute to the development of healthy habits in children and adolescents by increasing intake of fruits and vegetables, reducing intake of sweets and unhealthy snacks at home and in school, increasing exercise and reducing sedentary activities.

Primary research questions:
Q1: “Can BIO-STREAMS contribute to the development of healthy lifestyle habits in children and adolescents? What is the impact of a family-centric intervention incorporating digital tools on the change in dietary and physical activity habits?”
Secondary research questions:
Q2: “Can BIO-STREAMS contribute to improved self-efficacy and health engagement of children and adolescents and what impact does increased self-efficacy and increased knowledge have on the change towards healthy behaviour?”
Q3: “What impact will the use of BIO-STREAMS tools have on the change in anthropometric parameters?”
Q4: “What are the differences among pilot countries’ participants in primary (i.e., dietary and physical activity habits) and secondary outcomes (i.e., food/nutrition literacy, self-efficacy, self-perception, self-reported body weight and height, perception of suitability of the digital interventions) of the study in the baseline and follow-up assessments, and what are the differences in the change of these outcomes among pilot countries?”

Scientific hypotheses:
H1: We hypothesise that both study groups will achieve study aims/goals.
H2: We hypothesise that the IG will present a relevant advantage compared to the CG in meeting study aims/goals.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. submitted 26/05/2025, The Ethics Committee of Stichting International Parents Alliance (Snip 41, Sassenheim, 2171KT, Netherlands; +31 651639184; info@parentsinternational.org), ref: BIOSTREAMS ESHA

2. submitted 14/06/2025, Komisijo za etičnost raziskovanja na Filozofski fakulteti (KER FF) [Committee for Research Ethics at the Faculty of Arts] (Koroška cesta 16, Maribor, 2000, Slovenia; -; kerff@um.si), ref: Not yet recieved

3. approved 14/05/2025, Bioethics Committee of Harokopio University of Athens (El. Venizelou 70, Athens, 17676, Greece; +302109549337; atsiaf@hua.gr), ref: 1907/29-04-2025

4. submitted 20/06/2025, Monitoring School Surveys - Directorate-General for Education (DGE) (Av. 24 de Julho, Lisbon, 1399-025, Portugal; +351 21 393 45 00; mime@dge.mec.pt), ref: Nil known

5. notYetSubmitted

Study design
Parallel-group cluster pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life

Health condition(s) or problem(s) studied
Prevention of obesity in school children aged 9-14 years

Interventions
This is a parallel-group, cluster pilot randomised controlled trial (RCT) with a total duration of 1 school year, including a 6-month healthy lifestyle intervention. Clusters (schools) will be randomly assigned to either a control group (CG) or an intervention group (IG) with an allocation ratio of 1:1. Within each educational level strata group, schools will be randomised in one of the two study groups using a computerised random number generator. Participants' (students') characteristics will be evaluated at baseline and at the end of the intervention (6 months). The study will take place in 5 pilot sites across Europe, with each site representing one of the following countries: the Netherlands, Portugal, Greece, Slovenia and Denmark.

The intervention will last for 6 months and will be delivered by experienced researchers with support from members of the school community (teachers). The intervention will be based on behaviour change techniques, such as goal setting, self-monitoring, problem solving, stimulus control, relapse prevention and reinforcement. Such techniques are part of established theoretical frameworks/models of behaviour change (e.g., the social cognitive theory) that are considered crucial in the design of successful interventions for the promotion of a healthy lifestyle and the prevention of childhood overweight/obesity in community settings. Participants in both the IG and the CG will participate in 4 approx. 90-minute healthy lifestyle classroom workshops, focusing on lifestyle habits/practices that have been identified as important for the prevention of childhood OV/OB through high-quality scientific research (based on the systematic reviews of prospective epidemiological studies and RCTs performed within WP2 of the BIO-STREAMS project regarding lifestyle risk factors/interventions for the development/prevention of childhood OV/OB). The 4 workshops will be conducted in

classrooms, during school hours, throughout the 6-month intervention period, taking into consideration the established school curriculum and national holidays/vacations (e.g., 1 workshop every 4-6 weeks).

On top of the 4 healthy lifestyle workshops, participants in the IG will also be given access to digital tools. These tools will include a mobile phone application (including a lifestyle recommendation engine feature and micro-moments) and a serious games suite, and will serve as complementary features of a family-centric approach to facilitate intervention delivery and adherence to the desired lifestyle habits/practices. Researchers will present the digital tools to students and encourage their use throughout the intervention period.

Intervention Type
Behavioural

Primary outcome(s)
Dietary habits and physical activity habits measured using self-reported questionnaires at baseline and endline

Key secondary outcome(s))
The following secondary outcome measures were assessed using questionnaires at baseline and endline
1. Food/nutrition literacy
2. Self-efficacy
3. Self-perception
4. Self-reported body weight and height
5. Suitability of the digital interventions measured through:
5.1. Usability
5.2. User experience
5.3. Trust and acceptance

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Schoolchildren aged 9-14 years
2. Signed written consent by the student and their parent or legal guardian

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 years

Upper age limit
14 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Refusal or inability of the child or their parent/legal guardian to give informed consent (e.g., in case of intellectual disability)

Date of first enrolment
01/09/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
Denmark

Greece

Netherlands

Portugal

Slovenia

Study participating centre
Komiteen for Sundhedsoplysning
Classensgade 71, 5th floor
Copenhagen
Denmark
2100

Study participating centre
Harokopio University of Athens (HUA)
El. Venizelou 70
Athens
Greece
17671

Study participating centre
Univerza v Mariboru Faculty of Electrical Engineering and Computer Science
Slomskov 15
Maribor
Slovenia
2000

Study participating centre
Núcleo Interactivo de Astronomia Associacao
Largo dos Topazios 48-3 FTE
Sao Domingos de Rana
Portugal
2785817

Study participating centre
European School Heads Association
Herenstraat 35
Utrecht
Netherlands
3512

Sponsor information

Organisation
Harokopio University of Athens

ROR
https://ror.org/02k5gp281

Organisation
Komiteen for Sundhedsoplysning

Organisation
University of Maribor

ROR
https://ror.org/01d5jce07

Organisation
Núcleo Interactivo de Astronomia

ROR
https://ror.org/044qmzh69

Organisation
European School Heads Association

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Health

Alternative Name(s)
Health, Cluster 1: Health, Polo tematico 1: Salute, Salute, Cluster 1: Gesundheit, Gesundheit, Pôle 1: Santé, Santé, Zoskupenie 1: Zdravie, Zdravie

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Only anonymized data and synthetic data will be shared with third-party researchers outside the consortium under the Federated Data Storage paradigm (i.e. the BIO-STREAMS Citizen Node Bundle), hosted by Hetzner.

Personal data collected for the purpose of this study will be stored in a non-publicly available repository for up to 10 years after the study concludes, or until the data subjects (or their legal guardians) exercise their right to be forgotten or withdraw their consent.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes