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

**Submission date**
06/08/2025

**Recruitment status**
No longer recruiting

**Registration date**
13/08/2025

**Overall study status**
Ongoing

**Last Edited**
07/05/2026

**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

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# Additional identifiers

**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. Approved 12/11/2025, (Conditionally), The Ethics Committee of Stichting International Parents Alliance (Snip 41, Sassenheim, 2171KT, Netherlands; +31 651639184; info@parentsinternational.org), ref: BIOSTREAMS ESHA

2. Approved 15/12/2025, 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: 038-15-217/2024/12/FF/UM-2

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. Approved 08/10/2025, 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: 1312600001

5. Approved 11/02/2026, The Scientific Ethics Committees for the Capital Region of Denmark (Borgervænget 3, ground floor, Copenhagen, 2100, Denmark; +45 38666395; vek@regionh.dk), ref: H-25062899

## Primary study design
Interventional

## Study design
Parallel-group cluster pilot randomized controlled trial

## 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**
18/05/2026

# 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
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**Study participating centre**
**European School Heads Association**
Herenstraat 35
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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 |