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Feasibility study of a personalized recommendation system for obesity prevention: a mixed methods approach

Submission date
12/03/2025

Recruitment status
Recruiting

Registration date
23/04/2025

Overall study status
Ongoing

Last Edited
20/06/2025

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
Childhood obesity is a growing health challenge worldwide. The BIO-STREAMS project aims to tackle this by testing a personalized digital program designed to help children and families adopt healthier lifestyles. The digital intervention includes a mobile app, serious games, and tailored advice based on each child's habits, genetic background, and metabolism. The study will also understand how genes and environmental factors influence how well these lifestyle and behavioral changes work.

Who can participate?
Children and adolescents aged 5–18 years old from six European countries (Slovenia, Spain, Greece, Sweden, Belgium, Bulgaria). Parents of younger children (5–12 years) will also take part.

What does the study involve?
Participants are divided into three groups:
1. Children without overweight/obesity (CWO)
2. Children with overweight/obesity but normal metabolism (CONM)
3. Children with overweight/obesity and metabolic health issues (e.g., high blood sugar or cholesterol) (COMA)

Co-creation workshops: Children help design the app and games by sharing feedback on features from the mobile application, study design and concepts such as avatars, quizzes, and exercise plans.

6-month intervention: The participants undergo a 6-month intervention with personalized lifestyle recommendations delivered through digital tools, without randomization or masking, and no control group in the traditional sense, but rather a comparison across different participant groups.

First 2 months: Baseline assessment, including body measurements, lifestyle questionnaires, and saliva collection for genetic testing, and education and training activities.

Next 1 month: Supervised use of the BIO-STREAMS digital interventions. Participants will use the BIO-STREAMS mobile app under clinical supervision to track their activities and receive personalized health recommendations.

Next 3 months: Unsupervised use of BIO-STREAMS digital interventions and using the app independently.

Final check-up: Saliva samples (for genetic testing), body measurements, and questionnaires about user experience, usability, acceptance, health and food literacy, and trust and health habits and well-being.

What are the possible benefits and risks of participating?
Benefits: Participants will gain access to personalized health recommendations and digital tools designed to promote healthy living. They will also contribute to important research that may help prevent childhood obesity for future generations.

Risks: The study involves minimal risks. Collection of saliva samples may cause slight discomfort. There is also a small risk related to data privacy, but strict security measures are in place to protect all personal information. Psychological support will be available if needed, and participants can withdraw at any time.

Where is the study run from?
The study is run from clinical sites across six European countries:
University Medical Centre Maribor (Slovenia)
National and Kapodistrian University of Athens (Greece)
Karolinska Institute (Sweden)
Blocks Health and Social Care EOOD (Bulgaria)
Hospital Universitari Vall d'Hebron (Spain)
Centre Hospitalier Universitaire de Liège (Belgium)
Penteli General Children's Hospital (Greece)

When is the study starting and how long is it expected to run for?
September 2024 to February 2027. Co-creation workshops will begin in 2024. The main intervention study is planned to start in early 2025, with the first participants completing the study by late 2025. The final results are expected by early 2026.

Who is funding the study?
The European Union's HORIZON EUROPE HEALTH

Who is the main contact?
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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HORIZON EUROPE Health GA No. 101080718

Study information

Scientific Title
BIO-STREAMS: a multi-center mixed method trial evaluating personalized digital interventions for prevention of childhood and adolescent obesity based on genetic, epigenetic, and behavioral factors

Acronym
PERSOM

Study objectives
H1: The personalized lifestyle modification interventions delivered through the BIO-STREAMS platform will identify novel biological pathways that enhance the efficacy of preventive behaviors among children and adolescents, thereby contributing to improved health outcomes.

H2: BIO-STREAMS: A Multi-Center Mixed Method Trial Evaluating Personalized Digital Interventions for Prevention of Childhood and Adolescent Obesity Based on Genetic, Epigenetic, and Behavioral Factors

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 16/10/2024, Komisija Republike Slovenije za medcinsko etiko (Štefanova ulica 5, Ljubljana, 2000, Slovenia; +386 (0)14786906; kme.mz@gov.si), ref: 0120-410/2024-2711-3

2. approved 27/09/2024, Scinetific Council of Athens Children's General Hosptial "Agia Sofia" (Thivon & Papadiamantopoulou, Athens, 11522, Greece; +30 (0)2132013099; a.tsola@paidon-agiasofia.gr), ref: 23716/27.09.2024

3. submitted 03/03/2025, Ethics Committee of the Specialized Hospital for Rehabilitation and Long-Term Treatment BLOCKS (SBRPL BLOCKS) (Konstantin Pomyanov St., 1, Sofia, 1415, Bulgaria; +359 (0)888061383; research@blocks.care), ref: BLOCKS-2024-19

4. notYetSubmitted, Ethics Committee of the CHU Liege (707) (Avenue de l'Hôpital, 1, Liege,, 4000, Belgium; +32 (0) 4.323.00.00; ethique@chuliege.be), ref: To be submittted when approved

5. approved 13/11/2024, Swedish Ethical Review Authority (Box 2110,, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2024-05917-01

6. approved 19/09/2024, Scientific Council of Children's Hospital PENTELI (Hippocrates 8, Penteli, 15236, Greece; +30 (0)213-2052315; sgnpp@paidon-pentelis.gr), ref: 10917/19-9-24

7. submitted 10/12/2024, Clinical Research Ethics Committee of University Hospital VALL D'HEBRON (Paseo de la Vall d'Hebron, 119-129, Barcelona, 08035, Spain; +34 (0)934 89 30 00; ceic@vhir.org), ref: To be submittted when approved

Study design
Mixed-methods non-randomized study

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
The study compared children without overweight/obesity, those with overweight/obesity and normal metabolic parameters, and those with overweight/obesity and metabolic abnormalities.

Interventions
This is a mixed-methods study that includes both co-creation workshops and an interventional component. The interventional part is a multicentre study conducted across six EU countries, involving a within-subject design where participants are stratified into three groups:
Children without overweight/obesity (CWO)
Children with overweight/obesity but normal metabolism (CONM)
Children with overweight/obesity and metabolic health issues (e.g., high blood sugar or cholesterol) (COMA)
The participants undergo a 6-month intervention with personalized lifestyle recommendations delivered through digital tools, without randomization or masking, and no control group in the traditional sense, but rather a comparison across different participant groups.

Co-creation workshops with an open discussion on the topics related to the aims of the co-creation led by moderators. Group activity with similarly aged 6-8 children in each group: minimum 144 participants in total, from different age groups (minimum 36 participants per age-group in total; (i) up to 8 years, (ii) 8-10 years, (iii) 10-14 years, (iv) 14-18 years) and cultural settings (minimum 24 participants per piloting county).

The clinical intervention will involve the validation of the digital solutions (The ActiveHealth app, Serious Games, Micro-moments, Open Toolkit services, Risk Assessment Tool and Recommendation Engine) in a prospective study, where the user experience (engagement,

acceptance, adherence) will be assessed, as well as the impact of the solution on targeted health outcomes. To this end, participants will then enter a 4-month intervention program supported by an internet-based application where individual-centric and family-centric recommendations, based on micro-moments, for physical activity and changes in dietary intake will be generated using the BIO-STREAMS EU Childhood Obesity Platform recommendation toolsets. The intervention will have 6 measurement points, with 2 times saliva sampling and centralized analysis (saliva-centrally) and 1-time blood (in case no data not older than 1 year is already available).

Intervention Type
Behavioural

Primary outcome(s)
1. The number of new biological pathways conferring efficacy of preventive behavior measured using an epigenomic analysis of saliva collected at baseline and final check-up
2. Acceptability and usability of the mobile application and interventions measured through affective attitude (user experience) and participant engagement, trust and acceptance, the perceived burden of the behavior modifications and adherence using the Short Version of the User Experience Questionnaire (UEQ-S), the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) and the System Usability Scale (SUS) at T4 (during the first follow-up at the end of the supervised stage) and T5 (after the intervention ends)

Key secondary outcome(s))
1. Sensitivity and specificity of defining the subsets of patients at risk for metabolic dysfunction measured using statistical analysis (ROC, AUC and k-fold cross-validation) comparing two classification approaches: (1) the computational classification generated by our Risk Assessment System and (2) the expert-determined metabolic status defined after T2 (stratification). The comparison will be performed after the last participant completes the study (after December 2026), establishing how accurately our computational model identifies at-risk patients relative to expert clinical assessment.

The following assessments are made at baseline (T1) - Before the start of the interventions and at Final follow-up (T6) - 6 months after the participant entered the study:
2. Reduction in body weight of 5% or centiles of BMI by 5 percentile points or z-score BMI change by 0,25, reduction in body fat, reduction in other anthropometric parameters. The measurements will be taken in a controlled environment at clinical sites: Body weight measures using a calibrated scale; BMI calculated from height and weight measurements; body fat percentage using bioelectrical impedance analysis (BIA); waist and neck circumference using a measuring tape; and, height using Stadiometer.
3. Improvement of health/food literacy measured using a Food and Nutrition Literacy (FNLIT)
4. Improvement in quality of life measured using the KIDSCREEN-10 instrument
5. Improvement in well-being measured using the Child Well-being Index (WHO-5)
6. Increase in self-regulation measured using the Exercise Self-Regulation Questionnaire (SRQ-E), and the Self-Regulation of Eating Behaviour Questionnaire (SREBQ)
7. Decreased mental distress, including anxiety, depression, and self-perceived stigma measured using the Penn State Worry Questionnaire for Children (PSWQ-C), the Center for Epidemiological Studies Depression Scale for Children (CES-DC), and the Weight Self-Stigma Questionnaire (WSSQ)

The following is assessed at final follow-up (T6) - 6 months after the participant entered the study

8. Medical costs related to overweight/obesity management measured using a custom self-defined questionnaire

Completion date
28/02/2027

Eligibility

Key inclusion criteria
Inclusion criteria:
1. Ability to give informed consent
2. Owning a smartphone or tablet (available in the home environment, not necessarily a personal device of the participant) OR a parent owning a smartphone (for younger children)
3. Age: 5-18 years old
4. For the age group of 5-12 years old, parents will need to be involved, together with the children

Inclusion into groups:
For the study aims, children with overweight or obesity will be recruited based on criteria below:
1. Overweight: BMI more than 1 SD to 2 SD above the median of the WHO growth reference for children and adolescents
2. Obesity: BMI more than 2 SD above the median of the WHO growth reference for children and adolescents

Further, the group will be stratified with children with overweight or obesity into two groups based on the IDF criteria:
Children with overweight/obesity with normal metabolic parameters (CONM)
Children with overweight/obesity with metabolic abnormalities (COMA)

For children below 16 years old, one criterion needs to be fulfilled to classify for COMA group, for children 16 and above, two criteria need to be applied. The third, control group, will consist of children also recruited in a clinical setting, but with normal weight:
Children without overweight/obesity (CWO): BMI up to 1 SD above the median of the WHO growth reference for children and adolescents

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
18 years

Sex

All

Key exclusion criteria
1. Age under 5 years or above 18 years old
2. Severe mental disorder (schizophrenia, bipolar disorder, severe depressive disorder)
3. Inability to give informed consent and/or assent (e.g., in case of intellectual disability), by parents or children (age depending on the local legislation)
4. Severe cognitive disorder that would prevent following up on recommendations, and epileptic disorders
5. Children with severe chronic medical conditions
6. Orthopedic affliction limiting physical activity
7. Use of medication known to affect body weight
8. Known family issues that would affect general compliance and attendance at follow-up visits
9. Diagnosis of clinical condition that requires a specific diet (e.g. Coeliac disease, allergies,…)

Date of first enrolment
31/05/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
Belgium

Bulgaria

Greece

Slovenia

Spain

Sweden

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University Clinical Centre Maribor, University division of Paediatrics
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https://ror.org/01d5jce07

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Organisation
National and Kapodistrian University of Athens

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ROR
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Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Health

Alternative Name(s)
Health

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 from Izidor Mlakar (Clinical Coordinator of BIO-STREAMS Studies, izidor.mlakar@um.si). Only anonymized data and synthetic data will be shared with 3rd party researchers outside the consortium under the Federated Data Storage paradigm (i.e. the BIO-STREAMS Node Bundle), hosted by the BIO-STREAMS Information Management System.

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

• The type of data that will be shared
anonymized data (e.g. cohort data) and synthetic data
• Timing for availability
Not before April 2027
• Whether consent from participants was required and obtained
Written Informed consent was required and obtained
• Comments on data anonymization
Data shared under the Federated Data Storage paradigm (i.e. the BIO-STREAMS Node Bundle)

IPD sharing plan summary

Stored in non-publicly available repository, 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
Study website	Study website	11/11/2025	11/11/2025	No	Yes