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Using electronic health records and AI to improve health outcomes for children with obesity across Europe

Submission date
23/09/2024

Recruitment status
No longer recruiting

Registration date
15/10/2024

Overall study status
Ongoing

Last Edited
14/11/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Childhood obesity is a growing health concern across Europe. This study aims to create a large database of information about childhood obesity from several European countries. We want to understand what factors contribute to obesity in children and use advanced computer programs (artificial intelligence or AI) to predict which children might be at risk. We also want to test if these AI programs can help doctors make better decisions about preventing and treating childhood obesity.

Who can participate?
This study will use existing medical records of children aged 5-18 years from seven hospitals across Europe. This includes records of children who are overweight or obese, as well as those with normal weight. While we are not recruiting children for this study, we are looking for two groups of professionals to help evaluate our new system:

Healthcare professionals: we need doctors and other healthcare workers who:
1. Work with children who have obesity
2. Are familiar with electronic health records and computer systems that help make medical decisions
3. Are willing to test our new EU Childhood Obesity Platform
4. Can judge how well AI systems might work in real medical situations

Researchers: we're also looking for researchers who:
1. Have experience studying obesity, especially in children
2. Work with large amounts of health data
3. Understand how AI is used in healthcare
4. Can evaluate how useful our AI system might be for studying and managing childhood obesity

Both groups will be asked to participate in two rounds of testing and evaluation.

What does the study involve?
The study involves collecting and analyzing information from children's medical records. This includes details about their health, lifestyle, and family history. We will use this information to create computer models that can predict obesity risks. The healthcare professionals and researchers we recruit will then test these models to see how well they work and how useful they might be in real-world situations.

What are the possible benefits and risks of participating?
For the healthcare professionals and researchers, the main benefit is the opportunity to contribute to cutting-edge research that could improve childhood obesity management. There are no significant risks, but participants will need to commit time to the evaluation process. The children whose records are used won't face any direct risks or benefits, as we're using existing medical information.

Where is the study run from?
The study is coordinated by the University of Maribor in Slovenia, but involves seven hospitals in six different European countries.

When is the study starting and how long is it expected to run for?
The study started in August 2024 and is expected to run until April 2027. The Recruitment for Blind Experiments will start in April 2025. The first round (the Inital AI Models) of the Blind Test Experiments will be carried out October 2025 and the second round (the Improved AI models) in October 2026.

Who is funding the study?
This study is part of the BIO-STREAMS European Project, funded by the Horizon Europe research and innovation program (Grant No. 101080718)

Who is the main contact?
While each study site has its own principal investigator, the main coordinator for this study is Dr Izidor Mlakar from the University of Maribor, who is coordinating the clinical aspects of the study. His email is izidor.mlakar@um.si.

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
101080718-observatonal-study, GA No. 101080718

Study information

Scientific Title
Childhood Obesity Research and AI anaLysis on an EU-wide cohort (CORAL): an observational cohort study

Acronym
CORAL

Study objectives
H1: There exist sets of clinical, biochemical and lifestyle/behavioral variables that can be associated with the different risks for - and health outcomes of -- obesity/overweight in children.
H2: There exists a (minimal) set of these variables that can be used to train predictive AI models to project clinical pathways and relevant health outcomes of childhood obesity.

Research Questions:
RQ1: What are the clinical, biochemical, and lifestyle/behavioral predictors of obesity?
RQ2: What is the minimal set of variables required to train AI models that can accurately predict clinical pathways in childhood obesity?
RQ3: Can the different interactions create new cohorts underlining more efficient and patient-centered interventions?
RQ4: How do clinicians evaluate the feasibility of using the system in clinical routine, by evaluating the usability, trust and acceptance, and user experience while using the EU Childhood Obesity Platform?

Ethics approval required
Ethics approval required

Ethics approval(s)

1. approved 25/04/2024, 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-2024-001

2. approved 12/03/2024, 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: 2024/82

3. approved 22/05/2024, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2024-02377-01

4. approved 01/05/2024, Scinetific Council of Athens Children's General Hosptial "Agia Sofia" (Thivon & Papadiamantopoulou, Athens, 11522, Greece; +30 (0)2132013099; a.tsola@paidon-agiasofia.gr), ref: 15593/01-03-2024

5. approved 14/03/2024, Scientific Council of Children's Hospital PENTELI (Hippocrates 8, Penteli, 15236, Greece; +30 (0)213-2052315; esgnpp@paidon-pentelis.gr), ref: 3143/12-03-24

6. approved 28/03/2024, Medical Ethics Committee of University Medical Center Maribor (Ljubljanska cesta 5, Maribor, 2000, Slovenia; +386 (0)23212489; eticna.komisija@ukc-mb.si), ref: UKC-MB-KME-17/24

7. approved 30/05/2024, 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: (AG) 127/2024

Study design
Multi-centre observational retrospective cohort study with randomized blind tests for AI model validation

Primary study design
Observational

Study type(s)
Other, Prevention

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

Interventions
No direct interventions are performed; the study focuses on analyzing existing data to generate insights and predictive models for childhood obesity.
This observational study involves the following key methodological components:

Data Collection:
Retrospective data extraction from Electronic Health Records of 7 European clinical sites, including demographic, clinical, biochemical, and lifestyle/behavioral variables for children aged 5-18 years.

Data Harmonization:
Transformation of collected data into a unified format using a common data model and ontology to create a standardized EU-wide childhood obesity biobank.

Data Analysis:
Application of statistical analyses and machine learning techniques to identify risk factors associated with childhood obesity and its health-related outcomes.

AI Model Development:
Creation of predictive/prognostic AI systems using the harmonized dataset to identify obesity risk factors and project clinical pathways.

Model Validation:
Randomized blind tests using 5-10% of the data to validate the sensitivity and specificity of the AI models in predicting obesity risks and outcomes. Blind tests are conducted to compare AI algorithm results with detailed clinical assessments. 30 clinicians and 30 researchers will participate.

Platform Evaluation:
Assessment of the EU Childhood Obesity Platform's feasibility, usability, and economic impact through evaluations by clinicians and researchers.

Cohort Comparison:
Analysis of data from both overweight/obese (n = 5600) and normal weight (n = 3200) children to identify distinguishing factors and potential intervention points.

Intervention Type
Other

Primary outcome(s)
1. Number of new obesity pathways discovered, as identified through machine learning analysis of the BIO-STREAMS dataset, measured at the end of the data analysis phase, evaluated at M30 (October 2025) and M42 (October 2026)
2. Sensitivity and specificity of the AI models for prediction of risks for obesity, compared to detailed clinical assessment, measured through blind tests on a 5-10% subset of the data at the end of the model validation phase, evaluated at M32 (December 2025), M44 (December 2026)

Key secondary outcome(s))
1. Usability of the EU Childhood Obesity Platform, measured using the System Usability Scale (SUS) completed by participating healthcare professionals and researchers at the end of each evaluation round, evaluated at M32 (December 2025), M44 (December 2026)
2. User acceptance of the EU Childhood Obesity Platform, assessed using a custom questionnaire based on the Technology Acceptance Model (TAM), completed by participating healthcare professionals and researchers at the end of each evaluation round, evaluated at M32 (December 2025), M44 (December 2026)
3. Quality and completeness of the homogenized retrospective BIO-STREAMS dataset, assessed using custom data quality metrics at the end of the data harmonization at M30 (October 2025)
4. Trust in AI predictions, measured using the Trust between People and Automation scale, completed by participating healthcare professionals and researchers at the end of each evaluation round, evaluated at M32 (December 2025), M44 (December 2026)
5. Cost-effectiveness of the EU Childhood Obesity Platform, calculated as the ratio of platform implementation costs to potential healthcare savings, estimated at the end of the study (April 2027, M48)

Completion date

30/04/2027

Eligibility

Key inclusion criteria
Inclusion criteria for the retrospective subjects:
1. Age of diagnosis between 5 and 18 years
2. (Overweight Cohort) BMI more than 1 SD to 2 SD above the median of the WHO growth reference for children and adolescents
3. (Obese Cohort): BMI more than 2 SD above the median of the WHO growth reference for children and adolescents
4. (Normal Weight Cohort) BMI up to 1 SD above the median of the WHO growth reference for children and adolescents

Inclusion criteria for the healthcare professionals involved in the blind tests:
1. Must be professionally involved in the management of childhood obesity
2. Familiar with electronic health records and clinical decision support systems
3. Willingness to participate in the evaluation of the EU Childhood Obesity Platform
4. Ability to assess the feasibility, usability, and predictive power of AI/ML algorithms in clinical settings in two rounds

Inclusion criteria for the researchers involved in the blind tests:
1. Experience in epidemiology of obesity, obesity research, or related fields
2. Must be engaged in clinical research on Big Data and/or obesity
3. Familiarity with AI/ML methodologies in healthcare applications
4. Ability to assess the feasibility, usability, and predictive power of AI/ML algorithms in clinical settings in two rounds

Participant type(s)
Patient, Health professional, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria for blind test participants (healthcare professionals and researchers):
1. Unwillingness/inability to sign and Informed Consent
2. Participation in competing childhood obesity prediction or management platforms within the last 12 months
3. No current active involvement in clinical practice or research related to paediatrics or obesity management
4. Lack of basic digital literacy skills necessary to interact with the platform

Date of first enrolment
01/04/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Belgium

Bulgaria

Greece

Slovenia

Spain

Sweden

Study participating centre
University Clinical Centre Maribor, University division of Paediatrics
Ljubljanska 5
Maribor
Slovenia
2000

Study participating centre
National and Kapodistrian University of Athens, Center for the Prevention and Management of Overweight and Obesity in Childhood and Adolescence
Thivon and Levadias
Athens
Greece
11527

Study participating centre
Karolinska Institute, Department of Biosciences and Nutrition (BioNut)
Alfred Nobels allé 8
Stockholm
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141 52

Study participating centre
Blocks Health and Social Care EOOD, Deaprtment of Phsiotherapy and rehabilitation for children
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Study participating centre
Hospital Universitari Vall d'Hebron, Vall d'Hebron Institut de Recerca
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Study participating centre
Centre Hospitalier Universitaire de Liège, Department of Pediatrics
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Study participating centre
Penteli General Children's Hospital, Penteli General Children's Hospital
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Sponsor information

Organisation
University Medical Center Maribor

Organisation
University of Maribor

ROR
https://ror.org/01d5jce07

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 not expected to be made available to a wider due to ethical and privacy restrictions.

IPD sharing plan summary
Not expected to be made available

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