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AI-based long-term health risk evaluation for driving behaviour change strategies in children and youth

Submission date 30/10/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/12/2024	**Overall study status** Ongoing	
Last Edited 03/09/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The study aims to reduce the risk of non-communicable diseases in children and adolescents through AI-driven health risk assessments and behavioral change interventions.

Who can participate?
Children aged 6-10 years and adolescents aged 11-14 years, along with their families, will be recruited from healthcare settings and schools. Healthcare professionals will also be included in the behavioural change process of those at high health risk.

What does the study involve?
Participants will use a web application for healthcare professionals and a mobile app for adolescents and families, receiving health assessments and tailored interventions over 7-9 months.

What are the possible benefits and risks of participating?
Benefits include increased awareness of health risks and access to support for healthier behaviors. Risks may involve data privacy concerns, although all information will be anonymized.

Where is the study run from?
The study will be led by Jožef Stefan Institute (Slovenia) and conducted in Slovenia, Portugal, Finland, the Netherlands, and Taiwan.

When is the study starting and how long is it expected to run for?
January 2024 to June 2026

Who is funding the study?
Horizon Europe Research and Innovation program

Who is the main contact?
Dr Maroje Sorić, maroje.soric@fsp.uni-lj.si

Study website
https://smart-change.eu/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
101080965

Study information

Scientific Title
AI-based long-term health risk evaluation for driving behaviour change strategies in children and youth - a feasibility trial

Acronym
SmartCHANGE

Study objectives
This study seeks to address the growing prevalence of non-communicable diseases (NCDs) by targeting children and adolescents, as early lifestyle interventions can significantly lower lifelong disease risk. Current tools for predicting disease risk focus on adults and often require invasive tests, making them unsuitable for preventive care in young populations. SmartCHANGE

aims to fill this gap by providing a user-friendly e-health tool that uses lifestyle and biological data to assess NCD risk in youth. The goal is to empower healthcare providers and families to implement timely, personalized risk-lowering strategies that foster the long-term health of children and adolescents.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 23/04/2025, JAMK's ethics committee (Rajakatu 35, Jyväskylä, 40200, Finland; +358 (0)20 743 8100; elina.kirjalainen@jamk.fi), ref: JAMK/73/13.02/2024/59876

2. Approved 13/01/2025, CEUP - Ethics Committee of University of Porto (Rua do Dr. Plácido Costa, 91, Porto, 4200 450, Portugal; +351 220425204; cefade@fade.up.pt), ref: CEFADE38_2024

3. Not yet submitted 30/11/2024, VUMC - Medical Ethical Committee (Address not provided, City not provided, Zip/postal code not provided, Netherlands; +31 (0)20 444 4444; not@provided), ref: Reference number not provided

4. Approved 28/02/2025, The National Medical Ethics Committee of the Republic of Slovenia (Address not provided, Ljubljana, 1000, Slovenia; +386 (0)1 478 60 01; gp.mz@gov.si), ref: 0120-493/2024-2711-6

Study design
Multicenter non-randomized study with control group (across five culturally diverse sites)

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Home, Hospital, Medical and other records, School

Study type(s)
Other, Prevention

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
Risk of developing cardiovascular and metabolic disease in children and adolescents based on their lifestyle

Interventions
The intervention will be implemented during one school year (i.e., about 6-9 months) and involves an e-Health tool that consists of two parts: 1) a web-based application intended for healthcare professionals; 2) a mobile application for families or adolescents (depending on the study site). After recruitment, adolescents (or their parents in the case of younger children) will

download the SmartCHANGE mobile app and will be equipped with wearable PA monitors (Garmin Vivosmart 5). After 7 days, depending on the calculated risk level, the participants with a medium- or high-risk level will receive a message from the application advising them to engage with the healthcare practitioners; participants with a low-risk level will be encouraged to keep using the application on their own. For the medium and high-risk participants, at the first visit to the healthcare professional's office, the details of the initial risk assessment will be delivered by SmartCHANGE health calculator to the leading healthcare professional via the SmartCHANGE web application. Based on the risk distribution, priorities for behaviour change will be outlined. After this, one behaviour will be selected through discussions with children (and their families in some instances), inspired by motivational interviewing techniques (These discussions will be facilitated by the web app for healthcare professionals). This behaviour will be entered into the web application and translated into prioritization of this behaviour of the mobile app. In the next step, healthcare professionals and patients will jointly set SMART goals for the period leading to the next appointment (typically after 4 months). After 4 months, children will return to the healthcare professional's office for interim assessments. During this visit, the behaviour change process will be discussed, and goals will be refined if needed. Again, the process of goal setting will be facilitated by the web app for healthcare professionals. During the next months, children will continuously use the mobile app to support behaviour change, while healthcare professionals will have the opportunity to communicate with them through the app, monitor their progress, offer support, and adjust goals. It is important to highlight that, despite giving priority to the behaviour change selected during doctor-patient discussions, the mobile app will maintain the holistic approach and promote several healthy behaviors (diet, physical activity, moderate screen use, optimal sleep). After 6-9 months from the start of the intervention, children will return to the healthcare professional's office for the final assessment of primary and secondary outcomes. The intervention will be compared to the usual care, specific to different settings across pilot sites. In addition to usual care the control group will also be equipped with a wearable physical activity tracker which they will be able to use with a designated proprietary mobile app.

Intervention Type
Behavioural

Primary outcome measure
The following seven aspects of feasibility of SmartCHANGE applications across different settings will be assessed at 9 months after baseline:
1. Acceptability measured using interviews inquiring about satisfaction with the overall intervention, perceived appropriateness and fit within the daily schedule or clinical routine
2. Demand will be measured through:
2.1. Uptake (number of participants approached, consented, and completed)
2.2. Adherence and actual use assessed via application use data
2.3. Likelihood of continued use, perceived demand, and perceived positive or negative effects on other aspects of life/work assessed via interviews
3. Implementation will be measured via interviews inquiring about how the intervention was implemented (e.g., amount of time used, amount of conversations with child), the success or failure of execution of different elements of the intervention
4. Practicality will be measured via interviews inquiring about factors affecting implementation ease or difficulty, efficiency and quality of implementation and the ability of participants to perform intervention activities
5. Adaptation, efficiency and quality of implementation comparison between five clinical settings
6. Integration will be measured via interviews inquiring about the ease of integration into the protocols and procedures within the specific healthcare setting, perceived fit with existing

infrastructure and perceived costs of full integration
7. Expansion will be measured via interviews inquiring about the perceived potential for expansion and perceived barriers to expansion

Secondary outcome measures
1. Usability and user satisfaction assessed 9 months after baseline
2. User impressions and feedback on their experience with the two applications will be gathered using focus group interviews with families and adolescents and semi-structured interviews with healthcare professionals. Unmoderated usability testing scenarios will be used.
3. Explainability of the AI-based models, assessed 9 months after baseline only in healthcare professionals using semi-structured interviews accompanied by interactive tasks. This group of outcomes will include:
3.1. Transparency
3.2. Scrutability
3.3 Trust
3.4. Effectiveness
3.5. Satisfaction
4. Lifestyle behaviours, measured at baseline and 4- and 9-months post baseline:
4.1. Physical activity, activity-related energy expenditure, and duration of moderate-to-vigorous physical activity during one week measured by Garmin Vivosmart 5 fitness tracker
4.2. Sleep, duration of nocturnal sleep during one week, measured by Garmin Vivosmart 5 fitness tracker
4.3. Diet, measured by the Mediterranean Eating Pattern for Americans (MEPA) Questionnaire
4.4. Screen time, measured by self-report on recreational screen use during one typical day
5. Cardiometabolic risk and biological risk factors for chronic non-communicable disease, assessed at baseline and 4-, and 9-months post baseline:
5.1. Blood pressure, measured using standard equipment and procedures in clinical settings involved in the study
5.2. Body Mass Index – calculated from weight and height, measured using standard procedures
5.3. Resting heart rate, measured by Garmin Vivosmart 5 fitness tracker and averaged over one week
5.4. Heart rate variability, measured by Garmin Vivosmart 5 fitness tracker and averaged over one week
5.5. Risk of cardiometabolic disease, measured at baseline and 9 months post-baseline, calculated by the custom-made SmartCHANGE risk calculator

Overall study start date
01/01/2024

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Participants from Portugal:
1. Family physician or paediatrician willing to participate
2. Children aged 6-10 years under the care of a family physician or paediatrician

Participants from Slovenia:
1. A functional multidisciplinary team at the community centre

2. Multidisciplinary team members are registered users of the MySLOfit app that supports access to data obtained in SLOfit – Slovenian physical fitness surveillance system in the schooling period
3. At least 50 children aged 6-10 years under the care of primary members of the team.

Participants from Nederlands:
1. Aged 11-14 years
2. Attending schools connected to the participating child public health care facilities

Updated 20/12/2024:
Participants from Finland:
1. School nurses willing to participate
2. Children aged 11 and 14 years from schools under the care of school nurses

Updated 03/09/2025:
Participants from Taiwan:
1. Family physician or paediatrician willing to participate
2. Children aged 13-14 years under the care of a family physician or paediatrician

Previous inclusion criteria:
Participants from Finland:
1. Family physician or paediatrician willing to participate
2. Children aged 6-10 years under the care of a family physician or paediatrician

Participants from Taiwan:
1. Family physician or paediatrician willing to participate
2. Children aged 6-10 years under the care of a family physician or paediatrician

Participant type(s)
Health professional, Learner/student

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Simultaneous participation in another study that might affect the findings of both studies

Date of first enrolment
15/02/2025

Date of final enrolment
15/12/2025

Locations

Countries of recruitment
Finland

Netherlands

Portugal

Slovenia

Taiwan

Study participating centre
University of Ljubljana
Faculty of Sport
Gortanova ulica 22
Ljubljana
Slovenia
1000

Study participating centre
Amsterdam UMC
Meibergdreef 9
Amsterdam
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Study participating centre
University of Porto
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Study participating centre
Taipei Medical University - TMU
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Study participating centre
Jamk University of Applied Sciences
PO Box 207
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Sponsor information

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Jožef Stefan Institute

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Sponsor type
Research organisation

Website
http://www.ijs.si/ijsw

ROR
https://ror.org/05060sz93

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

Publication and dissemination plan
Results to be published in scientific peer-reviewed journals and disseminated through conferences and the project website.

Intention to publish date
01/04/2027

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be anonymised and stored on local servers. The data will be available only at the project repository to those members of the consortium who are directly involved in the feasibility study.

IPD sharing plan summary
Stored in non-publicly available repository