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Abstract:	This document provides information on procedures that will be used for the feasibility study, including details on recruitment strategies, intervention description, outcomes assessed and timing of the study.
Keyword List:	Artificial Intelligence & Decision support, chronic diseases, risk assessment, children, youth, long-term risk prediction, chronic NCD, behaviour change, artificial intelligence, federated learning, explainable AI, robustness, bias, participatory design, feasibilty study
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Table of contents

Executive summary 6

List of abbreviations 7

1 Introduction 8

2 Study rationale 9

3 Objectives of the study 11

4 Design of the study 12

5 Participants 13

5.1 Recruitment strategies and scenarios 15

5.2 Strategies for underperformance in recruitment 19

5.3 Sample size and power calculations 20

6 Intervention 21

7 Description of SmartCHANGE tools 22

7.1 Web application for HCP 22

7.2 Mobile application for citizens 23

8 Outcomes 25

8.1 Feasibility outcomes 25

8.2 Usability outcomes and user experience 27

8.3 Explainability outcomes 28

8.4 Clinical outcomes 30

9 Data management plan 32

10 Comparison 48

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11 Blinding. 51

12 Intervention fidelity promotion 52

13 Ethical considerations 53

14 Timing of study procedures 54

List of figures

FIGURE 1 – TWO SCENARIOS FOR RECRUITMENT OF CHILDREN AND FAMILIES FOR THE FEASIBILITY STUDY 17
FIGURE 2 - MOBILE APPLICATION HAPPYPLANT 23
FIGURE 3 - EMPOWERMENT JOURNEY MAP (ADAPTED FROM MCCARTY ET AL, 2016, AND CHRIFOU ET AL. 2024) [18,19] 27

List of tables

TABLE 1: LIST OF ABBREVIATIONS 7
TABLE 2 - SEVEN AREAS OF FOCUS FOR THE FEASIBILITY ASSESSMENT WITH RELATED OUTCOMES AND METHODS OF ASSESSMENT (ADAPTED FORM BOWEN ET AL., 2009[17]) 26
TABLE 3 - FIVE PARAMETERS, THEIR DESIRED OUTCOMES AND METHODS OF ASSESSMENT FOR EVALUATING EXPLAINABILITY OUTCOMES 29
TABLE 4 - UPORTO: FEASIBILITY STUDY RELATED DATA 33
TABLE 5 - VUMC (AMC): FEASIBILITY STUDY RELATED DATA 34
TABLE 6 - JAMK: FEASIBILITY STUDY RELATED DATA 37

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Executive summary

This document details the procedures of the feasibility study that is meant to explore the use of the SmartCHANGE tools in different real-world health care contexts and identify possible problems with its acceptability and delivery. The primary objective is to examine the feasibility of the SmartCHANGE web and mobile applications in risk identification, stratification and primary prevention of cardiovascular and metabolic disease through five real-world scenarios, four set in different European regions in terms of demographics and socio-cultural environment, and the fifth located in Taiwan to test the potential for transferability to diverse global socio-cultural environments and healthcare settings.

A non-randomised trial design with a control group will be used at all five sites (clustered at the level of healthcare professionals). In Portugal, Slovenia and Taiwan the participants will be families with 6-10-year-old children, while Finland and the Netherlands will involve 11-14-year-old adolescents. About 100 participants of both genders will be enrolled in each site and assigned to experimental or control group in balanced way, while between 2 and 10 health professionals per study arm will be included depending on health care setting. In total we expect to engage about 25-35 health-care professionals distributed across 5 health care settings, and around 500 families/adolescents under their care.

The intervention will be implemented during one school year (between September 2025 and June 2026) and involve a web-based application intended for healthcare professionals and a mobile application for families or adolescents (depending on the study site). Based on the risk distribution delivered by the SmartCHANGE health calculator through the applications, priorities for behaviour change will be outlined and one behaviour will be selected for behaviour change intervention. This choice will be translated into prioritization of this behaviour by the mobile application. 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.

A priority set of outcomes will be focused on the feasibility, usability, and explainability of the SmartCHANGE tools. A secondary set of outcomes will enable limited efficacy testing through several clinical outcomes, i.e., estimates of the aggregated risk together with data on individual behavioural and biological risk factors for CVD as well as other relevant health outcomes.

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List of abbreviations

Table 1: List of abbreviations

Abbreviation	*Definition*
AI	Artificial Intelligence
BP	Blood pressure
CONSORT	Consolidated Standards of Reporting Trials
CVD	Cardiovascular disease
DMP	Data Management Plan
DPO	Data Protection Officer
EC	European Commission
EU	European Union
HCP	Health care professional
ISRCTN	International Standard Randomised Controlled Trial Number
NCD	non-communicable diseases
SMART	Specific, Measurable, Achievable, Relevant, and Time-Bound

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1 Introduction

The feasibility of the SmartCHANGE web and mobile applications in risk identification, stratification and primary prevention of cardiovascular and metabolic disease will be tested through five real-world scenarios, four set in different European regions in terms of demographics and socio-cultural environment, and the fifth located in Taiwan to test the potential for transferability to diverse global socio-cultural environments and healthcare settings. The main tools used in the feasibility study, the SmartCHANGE web and mobile applications, were developed in cooperation with children, adolescents, parents and health care professionals during a systematic co-design process (more details are available in D3.1). Four out of the five participating countries were involved in this exercise (Portugal, Slovenia, Finland, the Netherlands). All four countries engaged with health care professionals, Finland and the Netherlands focused on adolescents, while Portugal and Slovenia involved families with young children. Brief outline of study settings across sites is given below:

(1) In Portugal we will centre the study on a family setting, facilitated by paediatricians. We will involve paediatricians from Porto and families under their care with at least one child aged 6–10 years.

(2) The Slovenian pilot site will also be focused on families with younger children (6-10 years) but will involve a community approach through an integrated primary care setting, delivered by health care professionals in a continuum of care (school doctor, paediatrician, exercise specialist, psychologist, dietitian, physiotherapist, nurse, physical education teacher).

(3) Finland will host a study set in schools and performed by school nurses, and involve youth enrolled in the 5th and 8th grade of primary school (11 and 14-yr-olds), when regular health assessments are typically scheduled in the Finnish healthcare system.

(4) The Netherlands will include public health care facilities linked to secondary schools in the Amsterdam Metropolitan area and involve 11-14-year-old children at the time of their regular health assessments.

(5) The Taiwanese site will mimic the procedures of Portugal.

The study has been registered at ISRCTN database under the reference number 4631 and title: AI-based, long-term health risk evaluation for driving behaviour change strategies in children and youth - a feasibility trial; SmartCHANGE). It is currently being processed by the Editorial team and will receive the registration number and doi upon completion of the editorial process and payment of the fee.

2 Study rationale

The World Health Organization estimates that more than 70% of deaths worldwide and up to 90% in the European region are caused by non-communicable diseases (NCDs)[1]. The total cost of NCDs was estimated at €5.5 trillion in 2010 and projected to rise to more than €12 trillion by 2030[2]. Primary prevention that targets healthy individuals is typically more cost-effective compared to the treatment of early or fully developed disease[3]. Hence, identifying high risk individuals early in life and ensuring they receive access to timely risk lowering strategies is highly important. Most NCDs share predisposing risk factors such as obesity and low levels of physical fitness resulting from unhealthy lifestyle including insufficient physical activity, prolonged time spent in sedentary pursuits, poor nutrition, inappropriate sleep duration, cigarette smoking and abusive alcohol consumption[4].

Targeting children and youth for lifestyle interventions has been suggested for several reasons: (a) Although NCDs are not yet evident in this period of life, early precursors of most of the NCDs are already present[5]; (b) Childhood and adolescence are critical periods for the acquisition of healthy lifestyle habits, especially since risk factors for NCDs tend to spill into adulthood[6]; (c) Adolescent health risk burden has risen dramatically during the past decades and contributes to key global problems with NCDs. Available data suggest that a healthy lifestyle is not prevalent among children and adolescents, showing that less than 5% of European 11-year-olds rate perfectly on the healthy lifestyle, and this proportion is even lower in older adolescents[7]. However, lifestyle risk factors are many, some of them are quite complex, and they can cluster and interact to exponentially elevate the risk of NCDs. Besides, misperceptions of the adequate levels of lifestyle behaviours are particularly large and lead to incorrectly classifying a lot of individuals as low risk, particularly individuals with healthy weight[8,9]. All this makes identifying children and adolescents at risk from future NCDs in routine clinical practice very challenging.

Over the past few decades, over 300 models predicting risk for diabetes[10] or cardiovascular disease[11] in the general population have been developed. Some of these prediction models have been converted into tools and are included in clinical guidelines for therapeutic management[12]. Risk prediction tools have been repeatedly emphasised as agents in engaging people in risk lowering strategies. The little evidence that is available has shown that risk scoring in general population has proved to be largely unsuccessful for primary prevention of cardiovascular or metabolic disease[10,13]. However, a large majority of existing tools are used in adults, mostly after 35-40 years of age, when lifestyle risk factors have already been formed. Unfortunately, most of the available risk prediction tools even when meant for

children require information from biochemical essays which makes them unsuitable for use in preventive setting. Moreover, even when data on lifestyle behaviours are included in the risk prediction models, they are very generic, and lack the necessary level of detail that would make them more actionable and more personalised. In addition to this, they typically reduce complex continuous exposures to binary categories, thus reducing the accuracy of predictions. As current tools are inappropriate for children and adolescents, creating similar models that could be used in children and youth could have more potential for primary prevention as this is the time when lifestyle habits are shaped. Early behavioural interventions have the potential to markedly reduce the risk of developing cardiovascular or metabolic diseases[14]. At the same time, unhealthy lifestyle is almost universally present among todays' children and adolescents[6], but this largely remains unnoticed leading to low coverage of risk lowering strategies in this age group. The usefulness and the efficacy of risk prediction tools tailored for children and adolescents remains to be studied.

Through SmartCHANGE we aim to bridge this gap by providing health professionals and citizens an e-Health tool for the assessment of future risk of cardiovascular and metabolic disease in children and youth and based on readily available data. This will be done by integrating data on multiple health behaviours with available data on biological risk factors and using custom AI-driven models developed on a unique set of long-lasting cohort data. Consequently, by producing a single risk estimate, and evaluating the contribution of individual behaviours to this risk, we plan to offer support in decisions about risk lowering strategies, and at the same time raise awareness about the importance of healthy lifestyle among both citizens and medical professionals.

3 Objectives of the study

SmartCHANGE aims to provide healthcare professionals and citizens an e-Health tool for the assessment of future risk from cardiovascular and metabolic disease in children and adolescents. Alongside producing an aggregated risk estimate, the tool will describe the contribution of individual behaviours to the risk and offer support in prioritising behaviours for lifestyle interventions and decisions about the optimal risk lowering strategies. The details on the SmartCHANGE tools for citizens and healthcare professionals are provided in the designated chapter.

As this is a feasibility study, it is not focused on efficacy or effectiveness. Instead, it is meant to explore the use of the SmartCHANGE tools in different real-world health care contexts and identify problems which might undermine its acceptability and delivery of the related risk lowering strategies. In addition, the feasibility study is designed to inform the development of a future full-scale intervention study that will provide robust evidence on the effectiveness of the SmartCHANGE tools in cardiovascular risk lowering among children and/or adolescents.

Primary objective: to examine the feasibility of the SmartCHANGE tool in four different healthcare settings across five socio-culturally different sites.

Secondary objectives: a) to examine user experiences of the SmartCHANGE web and mobile applications; b) to increase understanding of how to make complex AI-based risk predictions more explainable to healthcare professionals; c) to provide preliminary data that can inform the potential efficacy of the SmartCHANGE tools in primary prevention of CVD and metabolic disease among children and adolescents by examining changes in individual lifestyle behaviours that were targeted and the related estimated aggregated risk; d) to inform the design of a future full-scaled intervention study.

4 Design of the study

A non-randomised trial design with a control group will be used at all five sites (clustered at the level of healthcare professionals). Control and experimental groups will be of equal size, and efforts will be made to achieve balance in respect to age, gender and socio-economic position. In addition, gender balance in respect to healthcare professionals will also be aimed for, but this will be done across all sites (and not necessarily within sites), due to low number of participating healthcare professionals.

The main study will be preceded by a small pilot study to ensure that recruitment, intervention delivery and follow-up run smoothly. In addition, we will use this small pilot to check the deployment of the SmartCHANGE tools, detect technical problems and solve bugs. The pilot study will mimic the procedures used in the main study during a shorter timeframe, and will engage participants during 2 months. The period between the pilot study and the main study will serve for improvement of the technical elements of the SmartCHANGE tools, accompanied by possible minor changes in the design of some elements of the tool for healthcare professionals.

While conducting the study, analysing outcomes, and reporting results we will follow methodological guidance for qualitative research in feasibility studies[15], or extension of the CONSORT 2010 statement to randomised pilot and feasibility trials[16], as appropriate.

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5 Participants

We are planning a multi-centre study involving five sites where SmartCHANGE tools will be used in different healthcare settings in real-world scenarios. The characteristics of the population are driven by the standard of care related to primary prevention in children and adolescents across the four EU countries involved (Portugal, Slovenia, the Netherlands, Finland), while the Taiwanese site will mimic the procedures used in Portugal to ensure EU-level ethical standards are followed.

1. In Portugal we will collaborate with hospital-based (CUF Hospital) paediatricians that will assist in recruitment of families with at least one child 6-10 years old. The tool for professionals will be used in conjunction with the family application. Principal users of the SmartCHANGE family app will be the parents. Convenience sampling will be used to recruit the children taking into consideration balanced gender distribution. In total, we expect to recruit 2-3 paediatricians and at least 50 children (and their parents) in the experimental arm. All children in the family of similar age to the main child (+/- 3 years) will be offered to use the family app, although only the main child will participate with data. A control group of the same size will be recruited following same procedures.
2. In Slovenia we will recruit 4 interdisciplinary teams from primary care community health centres by convenience and assign them to experimental and control arms in balanced design. At the same time, we will recruit fifty 6-10-year-old students and their parents through schools linked to the interdisciplinary teams. The tool for professionals will be used in conjunction with the family application. Principal users of the web-based tool will be several health-care professionals involved in the existing multi-disciplinary team in a health centre (paediatrician – school doctor, kinesiologist, dietitian, psychologist, physiotherapist, nurse), assisted by the Physical Education teachers from nearby schools. The tool for professionals will be used in combination with the family application. Principal users of the SmartCHANGE family app will be the parents. Same as in Portugal, all children in the family of similar age to the main child will be will be offered to use the family app, although only the main child will participate with data
3. In the Netherlands, we will recruit child public health care facilities who are linked to schools. These facilities provide usual care to children 0-19 years old. The tool for professionals will be used in conjunction with the SmartCHANGE application for adolescents, for which agreement from adolescents will be required. Inclusion criteria of the children are: 1) aged 11-14 years; 2) attending schools connected to the participating child public health care facilities. In total, we expect to recruit 2 schools with different child

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public health care physicians and about 50 children/adolescents in the experimental group and the same number of participants in the control group.

4. In Finland we will collaborate with school nurses. We will recruit 3 school nurses and a total of 50 boys and girls from grade 5 and 8 (aged 11 and 14 years) into the experimental group. The tool for professionals will be used in conjunction with the SmartCHANGE application for adolescents. In addition, a group of same size (3 school nurses and 50 children and adolescents) will be recruited to act as a control group. Convenience sampling will be used to recruit school nurses. The process will be linked to the national physical fitness testing (Move! measurements) and health check-ups in schools. Move! monitoring system for physical functional capacity in Finland is an educational tool that provides feedback to an individual and encourages pupils to take care of their physical functional capacity (https://www.oph.fi/en/move). In Finland approximately 100 000 students aged 11 and 14 participate in Move! measurements each year.
5. In Taiwan we will follow the identical protocols as in Portugal. We collaborate with hospital-based paediatricians that will assist in recruitment of families with at least one child 6-18 years old. The tool for professionals will be used in conjunction with the family application. Principal users of the SmartCHANGE family app will be the parents. Convenience sampling will be used to recruit the children taking into consideration the child´s balanced gender distribution. In total, we expect to recruit 2-3 paediatricians and at least 80 children (40 case and 40 control) in the experimental arm. All children in the family of similar age to the main child (+/- 3 years) will be invited to participate, although only the main child will participate with data. A control group of the same size will be recruited following same procedures.

In total we expect to engage about 25-35 health-care professionals distributed across 5 health care settings, and around 500 families/adolescents under their care. Between 2 and 10 health professionals per study arm will be included depending on the health care setting. In addition, about 50 children/adolescents - including both genders - will be engaged in both experimental and control group in each study site. The feasibility study conducted in the family settings will attempt to include disadvantaged population and provide them with free technology needed to use SmartCHANGE risk-prediction and behaviour change tool. Similarly, appropriate sampling will be used to ensure equal enrolment of genders, ethnicities and socio-economic categories in other settings. Several initial strategies include: 1) Schools to participate will be chosen based on having a mixed education levels, rather than only grammar school level; 2) Schools will be recruited in areas known for having diverse populations; 3) We will attempt to engage with potential users from disadvantaged populations to enquire what would be required to enable or motivate them to participate in the program, given that people from

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disadvantaged populations are more likely to refuse to participate even when they are within the sampling group. These strategies will be continuously adapted and supplemented during the recruitment process in line with evolving challenges in engaging vulnerable groups.

5.1 Recruitment strategies and scenarios

At each pilot site, healthcare professionals will be recruited by convenience sampling following the predefined inclusion criteria per study site and assigned to experimental and control group in a balanced design. General exclusion criterium across all sites will be simultaneous participation in another study that might affect the findings of both studies. This criterium will be applied both on the healthcare professional and the child/family/adolescent level.

Two scenarios for the recruitment of children and families are depicted in Figure 1. Scenario A is foreseen for sites in Slovenia and the Netherlands, while Portugal will use scenario B. Finland will be following both scenarios (A and B) and recruit about equal number of adolescents through each of the scenarios.

Scenario A) Recruitment at participant level will follow community approach and will be conducted through schools linked to the recruited healthcare professionals. In this path, families and adolescents will start using the mobile application on their own and will be prompted to seek the support of a healthcare professional if the AI models recognize a moderate to high risk. The system will allow the family or adolescent to decide whether to be supported by a healthcare professional or not. This choice was made because representatives of these target groups expressed privacy concerns in sharing data in the co-design phase, and indicated they would want control on sharing data with others (including healthcare professionals).

Scenario B) Recruitment at participant level will go through regular check-ups at the HCP office. HCP will collect data needed for initial risk assessment, and based on the outcome, will suggest unsupervised use of SmartCHANGE family app to reinforce healthy lifestyle in low-risk children, or will offer to support behaviour change process driven by SmartCHANGE app for medium to high-risk children.

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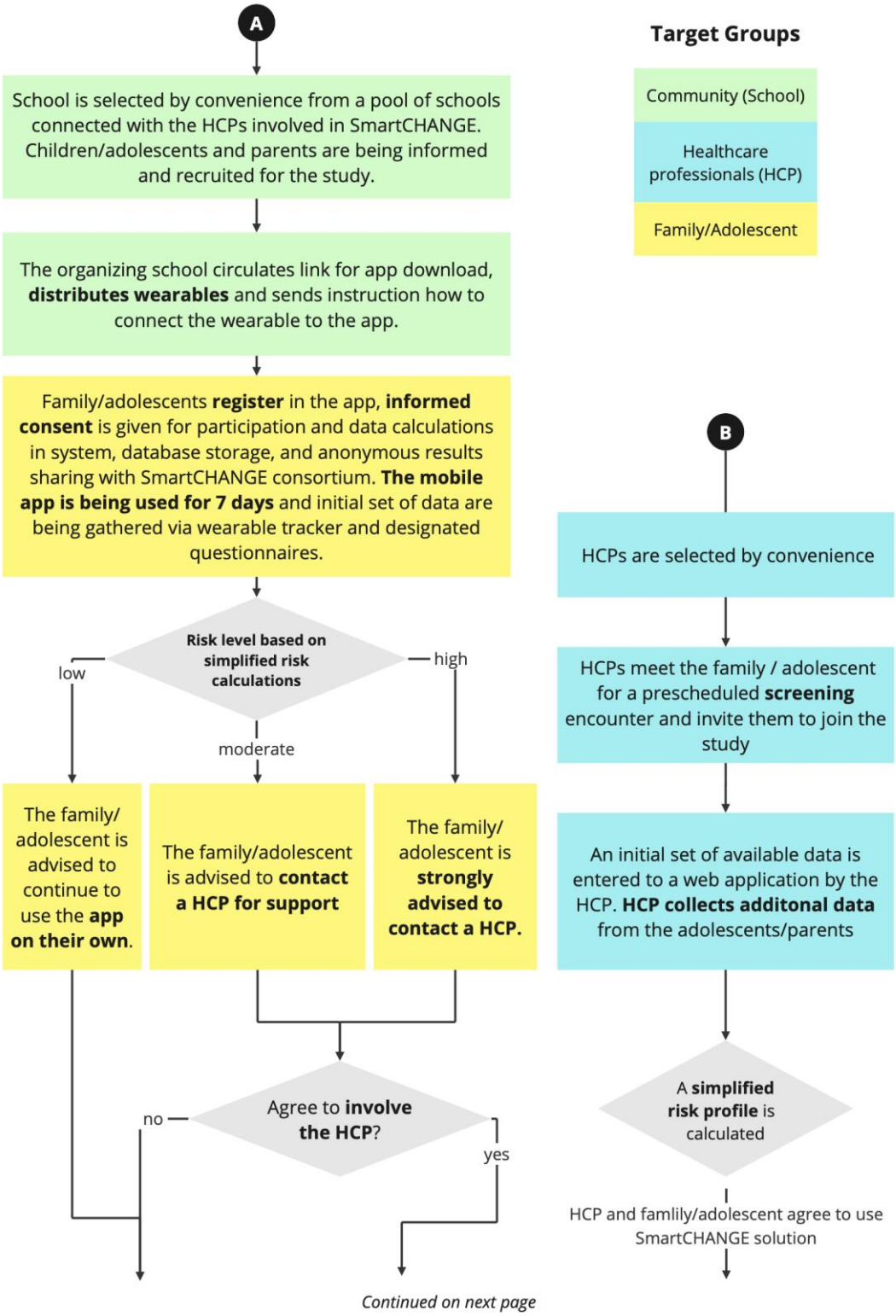

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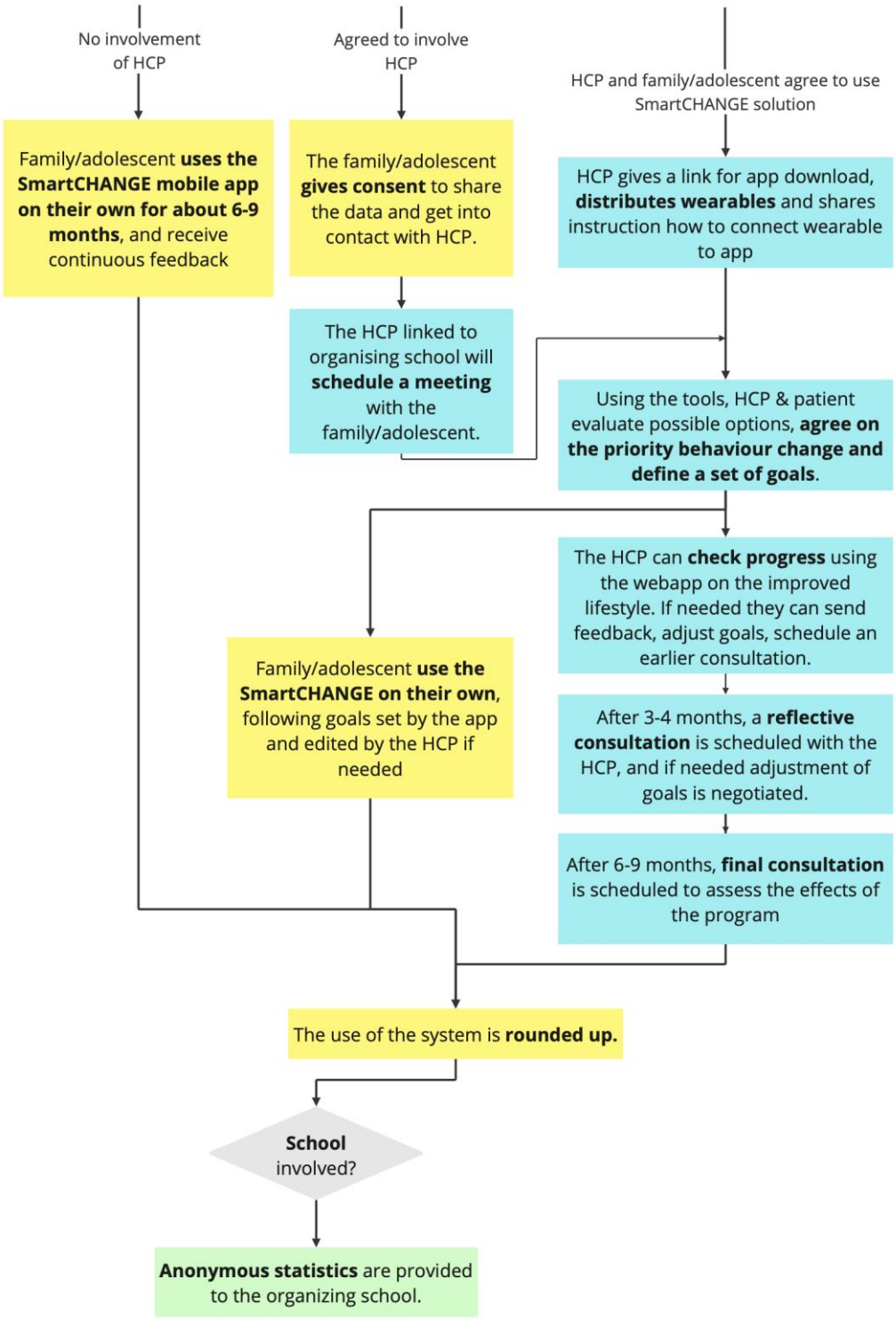

Figure 1 – Two scenarios for recruitment of children and families for the feasibility study

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An extensive time period for recruitment is foreseen (12 months), to ensure the success of recruitment. For a small pilot study which will precede the main study, 5-10 children/adolescents under the care of one healthcare professional in each of the 5 participating sites will be approached during regular visits and invited to participate based on convenience.

1. In Portugal, eligible participants will be contacted via telephone calls or information letters from the Units of Paediatrics of the "CUF Private Hospital" and "Cluster of Health Centres Eastern Porto" in Porto, and "Family Health Care Unit of Amarante" of Amarante. A short study information brochure will be used in routine check-ups. A meeting will be held with potential participants and parents/tutors to carefully inform about the benefits and risks of the study, and researchers will answer any question that they may have. Then, informed consents will be given, and participants will have 15 days to send it to the researchers. A hotline will be available to clarify remaining questions about the study. Those who do not react to the study invitation will be followed up via phone call at the end of these 15 days in order to check if they wish to participate. All participants will sign the informed written consent before enrolling in the study Inclusion criteria will include: 1) family physician or paediatrician willing to participate; 2) children aged 6-10 years under the care of a family physician or paediatricians.
2. In Slovenia, we will leverage a national registry to create a list of multidisciplinary teams in several convenient regions. Convenience sampling will be used to recruit health-care professionals, taking care about the balanced gender distribution. We will start from the regions where we have longstanding research cooperation with primary healthcare facilities, and move down along the list in case of low acceptance rate. These multidisciplinary teams are usually coordinated by a paediatrician or a family medicine specialist. One of these team members will be responsible for enrolling whole families with at least one 6-10-year-old child that are under their care. In case of slow recruitment of patients, we will include more health professionals from the compiled list and assign them to control or experimental arm as needed. Families will be selected based on First come first served basis, taking care to ensure diversity in gender and socio-economic position. Inclusion criteria will include: 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 schooling period; 3) at least 50 children aged 6-10 years under the care of primary members of the team. One of the teams in the experimental group will include a school doctor - paediatrician who had been involved in the participatory design process in the SmartCHANGE project

3. In the Netherlands, we will recruit child public health care facilities who are linked to schools. These facilities provide usual care to children 0-19 years old. Inclusion criteria for the adolescents are: 1) aged 11-14 years; 2) attending schools connected to the participating child public health care facilities. VUmc, through its Academic Collaborative Center Youth and Health, has a long-term structural collaboration (since 2009) with eight child public health care organisations (covering two provinces in the Netherlands and many cities, among which Amsterdam, Almere and Lelystad). This collaboration should guarantee adequate access to potential participants and progress of the recruitment. Engagement of child public health professionals in the participatory design will increase the relevance and acceptability of the tool which will facilitate recruitment for the main study.
4. In Finland, a convenience sample of 6 school nurses will be recruited at the area of Central Finland. School nurses' employer will get compensation for their extra working time needed for the execution of the study. Children will be recruited through respective schools.
5. Taiwan will mimic the approach described for Portugal.

5.2 Strategies for underperformance in recruitment

Strategies to tackle underperformance in recruitment are outlined across sites in the following paragraphs. It is worth mentioning that collaborative efforts for recruitment in case of challenges are planned throughout the recruitment period by using participants involved in co-design process to explore the need for appropriate incentives for relevant stakeholders.

1. Portugal: Each clinical site (i.e., hospital and family health care unit) will collaborate with the researchers to recruit a minimum number of participants. Since the number of children needed is not high, we do not anticipate under-recruitment. Moreover, the hospitals in Porto, particularly in CUF Hospital, have a high volume of young boys and girls eligible for participation. As a preventative measure, we will not only use the hospitals and family health care units, but also social media, university press offices, our website of the research centre, and the network of schools with whom we collaborate as part of the Internships units and modules in our university to recruit additional participants, if needed.

2. Slovenia: Schools attached to public health facilities typically have similar number of eligible participants which far exceeds the number of participants that need to be recruited. Since the anticipated number of participants is not large, underperformance is highly unlikely. All eligible participants will be approached, and recruitment will proceed on first come first served basis.

3. The Netherlands: In case the schools under the care of selected child public health care physicians do not succeed in recruiting sufficient children, we will invite additional physicians – in training - through our Academic Collaborative Center Youth and Health.

4. Finland: In schools, the number of pupils in grades 5 and 8 is high and underperformance in recruitment is highly unlikely. The participants will be recruited first come first served basis.

Overall, the recruitment will not be competitive. In case of overperformance in one study site, other sites will not change the target number of participants.

5.3 Sample size and power calculations

As this is a feasibility trial, it is not focused on efficacy or effectiveness, and as there are no similar previous studies to inform the power calculations, formal sample size calculation is not possible. A total of about 15 health care professionals in the experimental arm should allow for reliable estimates of feasibility and usability of the tool across different health care settings. In addition, we plan to enrol about 50 patients per arm in each site. To this end, more than 250 children and their parents / adolescents using the SmartCHANGE app for mobile phones in the experimental arm will enable valid conclusions about the usability of this application and the feasibility of its use in parallel with the web based SmartCHANGE app for healthcare professionals.

Still, as we plan to provide data for potential limited efficacy testing as a part of the feasibility study, we performed a-posteriori power calculations based on the feasible number of participants. Using GPower software, we estimated that by using ANOVA for repeated measures, (within-between interaction), 25 patients per study arm will provide power greater than 80% to detect a medium effect size (eta squared 0.25), with a two-sided significance level of 5% and assuming a correlation between pre and post measures of 0.7. It should be noted that 25 patients per arm are meant to permit both gender specific and setting specific analysis of both feasibility outcomes and the potential efficacy of the SmartCHANGE tool in the reduction of predicted risk of future NCDs. Hence, 50 patients per arm are envisaged in each study site, totalling 250 patients in experimental arm). Finally, to allow for 20% expected drop-out rate, we calculated that 20 patients per study arm will still provide power greater than 75% to detect a medium effect size with all other parameters unchanged. However, since this is a feasibility study, a focus will be on the direction and magnitude of between-group differences and not formal statistical significance estimate. The parameters about the size of the effect and its variability are meant to inform a formal sample size calculation for a future full-scaled RCT trial outside of the timeframe intended for this project.

6 Intervention

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 case of younger children) will download the SmartCHANGE mobile app and will be equipped by 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 in 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, 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 HCP-adolescent/family 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' office for the final assessment.

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7 Description of SmartCHANGE tools

7.1 Web application for HCP

Designed to assist HCPs in supporting families and adolescents, the web-app is intended to provide organized and accessible overviews of patient health history and current status. Furthermore, leveraging the AI services as developed in WP4 and WP5, it estimates risk of developing metabolic and cardiovascular diseases. Additionally, the web-app further guides healthcare professionals in selecting the most effective behavioural changes to promote healthier lifestyles.

In particular, the webapp provides an organized view of the **patient's overall health**, showing both current status and historical data. HCPs can access summary views or dive deeper into specific areas like physical measures, lab results, and lifestyle data.

During consultations, HCPs can document new encounters using a wizard-style form that guides them through steps like taking physical measurements, recording lab results, and filling out lifestyle questionnaires. The recorded data feeds into the AI risk prediction models.

The web app uses AI models to predict the likelihood of a child or adolescent developing future health risks. It assesses risk across various health parameters, such as lifestyle factors, clinical data, and family history. HCPs can access a dedicated "Risk Page" where AI-generated risk scores are displayed using a **color-coded gauge chart**. These scores reflect low (green), medium (yellow), or high (red) risk levels. A breakdown of the **key contributing factors** (e.g., diet, physical activity, sleep) is provided, showing how different behaviors impact the risk level. This helps HCPs understand the most important areas for intervention. The app includes **counterfactual analysis**, offering examples of how specific changes in behavior could reduce the overall risk. This allows HCPs to make informed decisions on which health behaviors to target for improvement.

From the webapp, HCPs can assign specific **behavior change goals** based on the patient's risk profile. These goals might include improvements in physical activity, diet, sleep, or other health-related behaviors. The **Goal Assignment Page** helps HCPs customize the intervention by selecting focus areas (e.g., physical activity) and setting measurable targets such as increasing steps per day or improving nutritional habits

The **Goal Monitoring Page** allows HCPs to track the patient's progress towards their assigned goals. For each behavior (e.g., steps per day), HCPs can see the current progress against the

target value. This page includes summaries of the main focus areas and recent **risk assessment results**, helping HCPs assess if interventions are working.

7.2 Mobile application for citizens

Figure 2 - Mobile application HappyPlant

Within the SmartCHANGE project a mobile application HappyPlant! has been designed to support children, families and adolescents with healthy behavior change based on the AI risk predictions. The application has two different variations, one to be used by adolescents and one to be used by families with young children.

In the application, users can adopt and take care of their digital plant. The plant gets happy and thrives when users take care of it via achieving daily and weekly health goals. These goals are designed to be achievable and fun. The focus of goals provided to the user can be adjusted by HCP, while the user has the control to select the goals they want to commit to that week.

Several strategies are implemented to stimulate healthy behavior change:

- First of all, *personalization* both in adopting and decorating a plant; and set of weekly goals provided, stimulates behavior change as it increases user commitment.
- Secondly, the application provides fun and achievable goals that change over time, while giving the user authority to select which ones to commit to.
- Thirdly, elements of gamification have been included and combined with educational components, such as a weekly health quiz or family health game.

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- Also, a balanced reward system has been included, providing variation of short term, long term and social rewards to keep the user engaged for a long period of time.

The adolescent version will include a social platform called 'the Park' where adolescents can share commitments and achievements with friends, 'like' each other's posts, and collaborate on goals. The social component is based on desires expressed by adolescents during the co-design, and will stimulate healthy behavior change.

The family app is designed for parents to use on their phones, with a focus on including the entire family. It offers goals for individual and multiple family members, if desired individual goals can be shared among family members as well. Additionally, among the list of weekly goals the app provides to the family, a fun ‘Family Game’ is included. The game creates precious moments between family members focused on the health themes movement, nutrition and mindfulness.

There are many more small details via which HappyPlant! stimulates healthy behavior change, for more information on this please consult D3.7.

8 Outcomes

All sites will collect: (1) feasibility outcomes; (2) outcomes relating to usability and user satisfaction; (3) outcomes relating to explainability of the SmartCHANGE tools and models; (4) clinical outcomes, i.e., estimates of the aggregated risk together with data on individual behavioural and biological risk factors for CVD as well as other relevant health outcomes. A priority set of outcomes will be focused on the feasibility, usability, and explainability of the SmartCHANGE tools. Secondary set of outcomes will enable limited efficacy testing through several clinical outcomes.

8.1 Feasibility outcomes

Table 1 outlines 7 areas of focus of feasibility assessment, related outcomes and assessment methods. Feasibility outcomes will be centred around 7 areas: 1) acceptability; 2) demand, 3) implementation, 4) practicality, 5) adaptation, 6) integration and 7) expansion and will be assessed after the end of the study. Table 1 outlines these seven areas of focus of feasibility assessment, related outcomes and assessment methods. Data will be collected via surveys, focus groups and semi-structured interviews with different users of the SmartCHANGE tools at the five sites (i.e., healthcare professionals, children, parents, adolescents). Survey data will be collected in anonymous manner from all adolescents or parents that have been assigned to experimental groups. In addition, all adolescents or parents will be invited to participate in focus groups discussions at each study site. Depending on their interest to participate, and resources available to the particular study site, we expect between 20 and 50 participants in focus groups. Focus groups will meet up to 6 times during a 6-month interval, depending on the quantity of feedback and their preference for dynamics of this process. Creative methods will be applied to facilitate adolescents and parents in expressing their opinions and experiences, for example through a journey mapping activity, during which participants draw or write e.g. their feelings, activities and experiences during the intervention period (Figure 3 depicts a journey mapping example). Semi-structured interviews will be conducted with all healthcare professionals involved in the experimental group. During these focus groups and interviews feedback from users will be sought to ensure personalization of health routines are sensitive to gender, diversity, cultural, and socio-economic differences. In line with data collection methods, the analyses will include both qualitative and quantitative methods.

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Table 2 - Seven areas of focus for the feasibility assessment with related outcomes and methods of assessment (adapted form Bowen et al., 2009[17])

Area of focus	Description	Outcomes	Methods of assessment
Acceptability	The extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention	• Satisfaction with the overall intervention • Perceived appropriateness • Fit within daily schedule or clinical routine	• Focus groups with children and parents; • Semi-structured interviews with healthcare professionals
Demand	How much was the demand for the SmartCHANGE tool at the citizens and healthcare professional level during the study. How much demand is likely to exist at the patient and healthcare professional level	• Uptake • Adherence • Actual use • Likelihood of continued use • Perceived demand • Perceived positive or negative effects on other aspects of life/work	• Process data from the recruitment process • Usage data from the apps; • Focus groups with children and parents; • Semi-structured interviews with healthcare professionals;
Implementation	The extent to which the intervention was implemented as planned.	• How was intervention implemented (e.g., amount of time used, amount of conversations with child) • Success or failure of execution of different elements of intervention • Barriers and facilitators	• Semi-structured interviews with healthcare professionals; • Usage data from the apps;
Practicality	Resources, time, and commitment requirements in relation to the perceived value of the intervention.	• Amount and type of resources needed to implement • Factors affecting implementation ease or difficulty • Efficiency and quality of implementation • Ability of participants to perform intervention activities	• Semi-structured interviews with HCPs; • Focus groups with children and parents;
Integration	The level of system change needed to integrate the intervention into an existing clinical routine, but also e-Health infrastructure.	• Ease of integration into the protocols and procedures within the specific healthcare setting • Perceived fit with existing infrastructure	• Semi-structured interviews with HCPs; • Semi-structured interviews with relevant experts from the Consortium;

		• Costs of full integration	
Adaptation	To what extent does SmartCHANGE intervention effects change between different settings and populations.	• Process and clinical outcomes comparison between five clinical settings	• Surveys; • Wearable data; • Physical measurements;
Expansion	Potential success of SmartCHANGE intervention with a different population or in a different setting.	• Perceived potential for expansion • Perceived barriers to expansion	• Focus groups with children and parents; • Semi-structured interviews with healthcare professionals

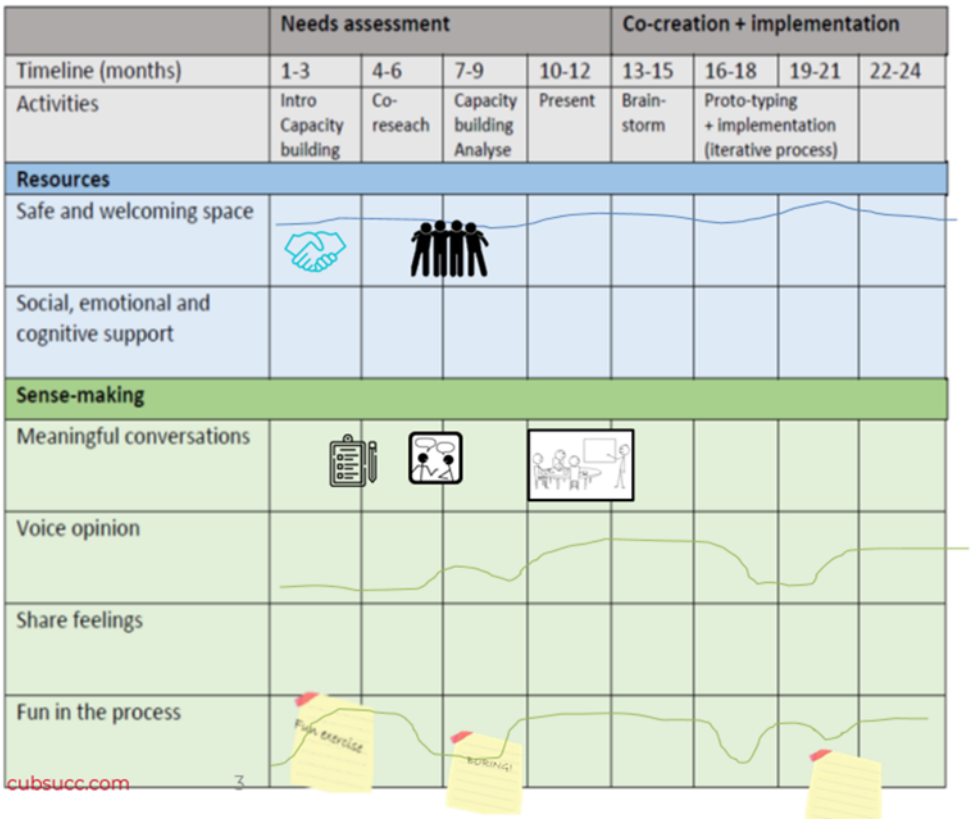

Figure 3 - Empowerment journey map (adapted from McCarty et al, 2016, and Chrifou et al. 2024) [18,19]

8.2 Usability outcomes and user experience

Usability outcomes will be assessed after the end of the study in the participants assigned to experimental group. The principal focus of the assessment will be on the two apps (web and

mobile), with possible secondary focus on the study protocol itself. One of the more interesting challenges is represented by the different user groups of the two apps (professionals versus families/children), whose usability objectives are likely to have significantly different natures, leading to possibly different methodologies to assess achievement of these different objectives. Usability testing generally includes a mix of quantitative (e.g., measuring the user's performance on a specific task) and qualitative (gathering user impressions and feedback on their experience) data collection. Depending on objectives and available tools, there may be different ratios of quantitative / qualitative methods applied to the web and mobile test environments. With regard to usability test environments, remote usability testing has become more available as web technology has matured. This increasingly popular variant (which allows users to interact with the app in their own environment) may turn out to be more feasible with the web app than the mobile app – again, depending on the objectives for each user community. We will also examine moderated (where a user experience expert guides the session) versus unmoderated (likely to be more feasible in the SmartCHANGE context) usability testing scenarios as the study environments become clearer.

With a view toward the assessments, usability metrics will be defined together with involved partners that reflect the objectives for each of the different user communities. It is expected that these metrics will be accompanied by questionnaires to accompany the quantitative data with the more qualitative feedback from the users.

8.3 Explainability outcomes

The main goals behind testing explainability outcomes can be for multiple objectives looking at the perspective of healthcare professionals. To this end, we describe what we consider could be tested. The following objectives could be tested in Explainability Studies (adapted from Mohseni et al., 2021[20], Tintarev and Masthoff, 2015[21], and Smuha, 2019[22]).

1. Transparency: The primary goal of an explainable system/model/algorithm is to enable its users to understand how it works. By getting an insight on the working of the algorithm, the users (HCPs in our case) should be able to better map the inputs to the outputs.

2. Scrutability: Biased decisions leading to discriminative outcomes is an unintended yet dire consequence of machine learning. Given that the algorithms learn only a mathematical simplification of the data they are supplied with (which could have its own biases), they often fail to capture nuances, easily visible to the human eye. Explanations can hence serve as a medium to identify and mitigate such biased decisions.

3. Trust: By enabling transparency and scrutability, the machine learning algorithm is no longer a black-box. Thus, the user who can understand the working of the algorithm and who can reason about its results would have increased confidence in the system.

4. Effectiveness: An understanding of the algorithm and its decision might assist the users in making better decisions. For example, instead of just saying that a patient is at risk for cardiovascular disease and the patient needs to lead a healthier lifestyle, stating that High Systolic blood pressure is the feature that has the highest contribution towards the decision might offer a good starting point to a healthy lifestyle.

5. Satisfaction: Explaining the system functioning with an interactive component (visualization tool) is expected to increase user satisfaction in the system. Here again, instead of having a black-box output only the decision, the ability to examine the decision for understanding and scrutiny should increase satisfaction.

There are other parameters such as Efficiency, Persuasiveness, and Privacy Awareness that can be used to evaluate explainability systems. However, we believe that these parameters are not aligned with the objective of our study in the context of SmartCHANGE project.

Given that healthcare professionals (HCPs) are the intended recipients of the explanations, they will be the participants of the tests for Feasibility. To test the same, semi-structured interviews along with a survey and interactive tasks should be conducted. Since there are 25-35 HCPs involved in total, at least 10 participants are required for explainability assessment. HCPs will be sent an invite to participate in the study. Participation will be voluntary and based on preferences of participating healthcare professionals. Different cases (based on risk for a certain disease) will be generated and presented to the participants.

A breakdown of the parameters and their description is given in Table 2.

Table 3 - Five parameters, their desired outcomes and methods of assessment for evaluating explainability outcomes

Parameter	Description	Outcomes	Method of Assessment
Transparency	How well does the HCP understand the system functioning	• Understanding of the system functioning • Ability to map the inputs to the output	• Semi-structured Interview • Survey

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Scrutabililty	Can the HCP identify if the system is providing misleading decisions including biased decisions?	• Examine the system thoroughly and identify discrepancies, if any	• Semi-structured Interview • Survey
Trust	Has the HCPs confidence in the system increased?	• Increased confidence in the system with explanations compared to without explanations	• Semi-structured interviews • Survey
Effectiveness	Will the HCP recommend lifestyle changes according to the explanations?	• The HCP recommends feasible lifestyle changes according to the explanations	• Semi-structured interviews • Survey
Satisfaction	Does the HCP enjoy using the system?	• The HCP enjoys using the system • The HCP recommends the system outside of the study	• Semi-structured interviews • Survey

8.4 Clinical outcomes

Main clinical outcome will include the change in aggregated risk calculated by SmartCHANGE tool. Intermediate clinical outcomes will include changes in individual lifestyle behaviours (e.g., physical activity, sedentary time, sleep, diet) across all settings, changes in biological risk factors (BMI, blood pressure, resting heart rate, heart rate variability…) depending on the setting, and other relevant outcomes included in the models for risk prediction (e.g., physical fitness) when feasible. Biological risk factors will be measured by the HCP during regular visits at 4 and 9 months (BMI, blood pressure) or harvested from the wearable device (resting heart rate, heart rate variability) at the same time points. At the same time, lifestyle behaviours will be measured by the SmartCHANGE mobile app, either self-reported by logs (diet, screen time), or through a wearable activity monitor (physical activity, sleep). All clinical outcomes

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will be assessed at baseline, at midterm (after 3-4 months) and after the end of the study (after 7-9 months).

9 Data management plan

As it has been already defined in the context of **D1.2 – Data Management Plan**, the Data Management Plan (DMP) seeks to identify the best practices and specific standards for the generated data and assess their suitability for sharing and reuse in accordance with official guidelines. Its overall goal is to support the data management lifecycle for all data that will be collected, processed, or generated by the project to maximize its access. Especially for the five (5) pilot sites, the SmartCHANGE's DMP is already compliant with the European Commission's (EC) DMP template, as it was refined for Horizon Europe, and it specifies how the generated data are easily discovered and accessed, ensuring open access and interoperability. The DMP related to the different countries that are participating in the proof-of-concept studies is based on key principles such as the FAIR management of research data and is following the best practices for high-quality data generation. All this information is available in the related deliverable (**D1.2 – Data Management Plan**), apart from the information related to the TMU who joined later to the SmartCHANGE consortium.

Based on the already provided DMP, there are five (5) different types of collected and generated data, namely the: (i) Data collected/generated through internal administration procedures, (ii) Data collected/generated for external communication procedures, (iii) Data collected/generated for technical purposes, (iv) Data collected/generated for feasibility study purposes, and (v) Data collected/generated for SmartCHANGE evaluation. What is of key importance in the context of the current deliverable is to confirm and identify the Data collected/generated for proof-of-concept purposes, and specifically answer to the questions related to the following topics:

- Data description
- Data origin
- Data reuse
- Methodologies for data collection/generation
- Data format
- Data storage
- Data size
- Metadata and standards used
- Data usefulness
- Data access, sharing and licensing
- Data personal/non-personal
- Data sensitivity

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- Data Protection Officer (DPO)
- Data protection policies

In the following tables, this information for the participating countries is being provided, including updated content with regards to the one that was provided at the 6th month of the project where D1.2 was submitted, also containing information for the data of the TMU partner in Taiwan.

Table 4 - UPORTO: Feasibility study related data

Demographics data	***Description***
Data description	Individual data from participants about their demographics
Data origin	The data will originate from the SmartCHANGE mobile app, as well as research logs
Data reuse	Data will be reused after anonymisation
Methodologies for data collection/generation	Part of it will be collected by the mobile app, whereas another part will be collected/generated by questionnaires administered by the research staff
Data format	This is not known yet
Data storage	Data will be stored in UPorto server in a VM
Data size	This is not known yet
Metadata and standards used	This is not known yet
Data usefulness	The data will be useful to all partners involved in any assessment related to the feasibility study. This data will be also useful for SmartCHANGE external stakeholders (e.g., scientific community, policymakers, health

	professionals working with children) and technical project partners
Data access, sharing and licensing	Data will be available at the UPorto server and at the project repository only to those members of the consortium who are directly involved in feasibility study
Additional information	
Is the data personal?	Yes, but it will be anonymized
Is the data sensitive?	Yes, although not trackable
Is there any Data Protection Officer (DPO) responsible for this data?	Susana Pereira - dados.pessoais@up.pt
Is there any data protection policy assigned to this data?	This is not known yet

Table 5 - VUMC (AMC): Feasibility study related data

Questionnaires	***Description***
Data description	Data collected from questionnaires based on questions from *Jij en je Gezondheid* focusing on diet, exercise, lifestyle and context (e.g., socio-economic background).
Data origin	Data will be collected from participants in the pilot and the proof-of-concept study
Data reuse	Data is for the purposes of this study only
Methodologies for data collection/generation	The datasets will be collected through digital questionnaires

Data format	The data will be provided in: .spss
Data storage	The original datasets will be stored on the Amsterdam UMC (location VUmc) servers - The location where the data will be stored to inform the app is not clear yet
Data size	The data will be in an order of MBytes
Metadata and standards used	The metadata includes a codebook of the datasets, without any standards being used
Data usefulness	This data will be essential for the functioning of the app, in that it helps to provide the initial risk prediction
Data access, sharing and licensing	These datasets will not be shared with partners
Additional information	
Is the data personal?	Yes, therefore data will be pseudonymized
Is the data sensitive?	Yes, therefore data will be pseudonymized and not shared among other partners.
Is there any Data Protection Officer (DPO) responsible for this data?	Yes, data protection officer of Amsterdam UMC (location VUmc); contact via researchers (Claudia Dictus, Mariëtte Hoogsteder, Teatske Altenburg)
Is there any data protection policy assigned to this data?	GDPR; Data Protection Impact Assessment (DPIA) will be conducted within our institute.

Evaluation data	***Description***

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Data description	Data gathered to evaluate user experiences during the proof-of-concept study (i.e., questionnaires, interviews, focus groups)
Data origin	Data is collected from participants in the pilot and proof of concept studies
Data reuse	Data is not intended for reuse
Methodologies for data collection/generation	Data will be collected/generated through interviews, questionnaires and focus groups, including some physical products (i.e. journey maps)
Data format	This is not known yet
Data storage	Data will be stored within the secure servers of the VUMC
Data size	This is not known yet
Metadata and standards used	Specific Codebooks will be used, along with interview scripts and questionnaire questions that will be provided
Data usefulness	This data will be useful for the consortium to evaluate and improve on the intervention
Data access, sharing and licensing	These datasets will not be shared with partners
Additional information	
Is the data personal?	Yes, therefore data will be pseudonymized
Is the data sensitive?	No

Is there any Data Protection Officer (DPO) responsible for this data?	Yes, data protection officer of Amsterdam UMC (location VUmc); contact via researchers (Claudia Dictus, Mariëtte Hoogsteder, Teatske Altenburg)
Is there any data protection policy assigned to this data?	GDPR; Data Protection Impact Assessment (DPIA) is part of the assessment by the Medical Ethical Review board, which will be conducted within our institute.

Table 6 - JAMK: Feasibility study related data

	Description
Data description	It includes a) data collected by questionnaires from adolescent participants on their demographics (age, gender, socioeconomic status, parental education) and lifestyle (diet, exercise, sleep), b) data on fitness tests performed during PE classes at school (Move! Measurements) c) data on health measurements during the visit to school nurse, d) data collected by interviews, and e) data from mobile and web applications
Data origin	Data is collected from participants in the pilot study and in the proof-of-concept study (i.e., feasibility study). In Finland participants are children & adolescents and health care professionals (school nurses). Data on Move! Measurements will be collected from PE teachers
Data reuse	Data is for the purposes of this study only
Methodologies for data collection/generation	The datasets will be collected through digital questionnaires, health examinations, interviews and applications
Data format	The data will be provided in: .spss, .xlsx, .csv, .txt, .dat
Data storage	The original datasets will be stored on the JAMK servers (i.e., for the data with identifiers: a, b, c, and d). The location where the data from the app will be stored is not defined yet (i.e., this is the case for the data with identifier e)

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Data size	The size of the data will be some MBytes
Metadata and standards used	Variable descriptions will be included as metadata
Data usefulness	The data will be useful for project consortium in order to evaluate the feasibility of the apps and improve them, and to inform external stakeholders
Data access, sharing and licensing	At JAMK data collected during the study (i.e., for the data with identifiers: a, b, c, and d) will be stored on local servers protected by firewalls and monitored-access control. Collected personal data will be stored at JAMK's servers to shared folders at the drive that is suitable for storing confidential and sensitive data. Access to shared folders will be managed by PI. The location of data from the app is not yet clear (i.e., this is the case for the data with identifier e).
Additional information	
Is the data personal?	Yes, but it will be pseudo-anonymized
Is the data sensitive?	Yes
Is there any Data Protection Officer (DPO) responsible for this data?	Data Protection Officer at JAMK University of Applied Sciences is Annukka Akselin - Contact can be performed via researchers (Tuija Tammelin and Piritta Asunta) or directly for data protection issues, to the following email: tietosuoja@jamk.fi
Is there any data protection policy assigned to this data?	The researchers and research assistants will comply with the requirements of the GDPR, Finnish National Board of Research Integrity (TENK) and the instructions of JAMK. Statement from JAMK's ethics committee will be requested

Table 5 - ULJ: Feasibility study related data

Participant's characteristics	*Description*
Data description	Individual data from participants about their demographics
Data origin	The data will originate from the SmartCHANGE mobile app as well as related research logs
Data reuse	Data will be reused after anonymisation
Methodologies for data collection/generation	Part of it will be collected by the mobile app, whereas another part will be collected/generated by questionnaires administered by the research staff
Data format	This is not known yet
Data storage	Data will be stored partly in the cloud offered by ULJ, whereas other parts will be stored locally
Data size	This is not known yet
Metadata and standards used	This is not known yet
Data usefulness	The data will be useful to all partners involved in any assessment related to the feasibility study
Data access, sharing and licensing	Data will be available at the local computer in ULJ and at the project repository only to those members of the consortium who are directly involved in feasibility study
Additional information	
Is the data personal?	Yes
Is the data sensitive?	Yes

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Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si
Is there any data protection policy assigned to this data?	This is not known yet

Lifestyle behaviours	***Description***
Data description	Individual data from participants about their physical activity, sleep, diet and mindfulness
Data origin	The data will originate from the SmartCHANGE mobile app
Data reuse	Data will be able to be reused after anonymisation
Methodologies for data collection/generation	The data will be collected through the (i) Garmin wearable activity monitor for physical activity and sleep, (ii) Phone for screen use, and (iii) Questionnaires for diet and mindfulness
Data format	This is not known yet
Data storage	Data will be stored in the cloud repository provided by SLOfit
Data size	The size of the data will be probably large if raw data will be preserved (>250 days of sensor readings)
Metadata and standards used	This is not known yet
Data usefulness	The data will be useful to SmartCHANGE app for providing estimates of risk and in after the study ends to the partners involved in limited efficacy testing

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Data access, sharing and licensing	Data will be available only at the project repository to those members of the consortium who are directly involved in limited efficacy testing
Additional information	
Is the data personal?	Yes
Is the data sensitive?	Yes
Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si
Is there any data protection policy assigned to this data?	This is not known yet

Fitness data	***Description***
Data description	Yearly data related to the physical fitness of participants
Data origin	The data originate from the ŠVK information system
Data reuse	The data can be reused through the transfer to web-based application required via API
Methodologies for data collection/generation	Data are collected by a standard protocol in line with written instructions (supervised) by PF teachers. Description of the fitness tests: https://en.slofit.org/measurements/test-battery Data will have to be pulled by the web-based app for HCP at two time points
Data format	This is not known yet

Data storage	The data will be stored on the cloud provided by SLOfit. Currently, it is stored in MS SQL database (used by My SLOfit web app)
Data size	The size of the data is quite small
Metadata and standards used	N/A
Data usefulness	The data will be useful to SmartCHANGE app for providing estimates of risk and in after the study ends to the partners involved in limited efficacy testing
Data access, sharing and licensing	Data will be available only at the project repository to those members of the consortium who are directly involved in in limited efficacy testing
Additional information	
Is the data personal?	Yes
Is the data sensitive?	Yes
Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si
Is there any data protection policy assigned to this data?	Yes, described in DPIA (Data Protection Impact Assessment; in Slovene) and https://www.slofit.org/o-slofit/varstvo-osebnih-podatkov (in Slovene)

Biological risk data	***Description***
Data description	Data related to the body size, blood pressure and blood tests

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Data origin	Data will be collected by the HCP involved in the feasibility study
Data reuse	Before original data can be used in the project, it must be anonymised
Methodologies for data collection/generation	Data are collected by a standard protocol used in daily clinical routine
Data format	This is not known yet
Data storage	Data will be stored at local servers
Data size	The size of the data will be probably very small (100 individuals, 0-10 data points per person)
Metadata and standards used	This is not known yet
Data usefulness	The data will be useful to SmartCHANGE app for providing estimates of risk and in after the study ends to the partners involved in limited efficacy testing
Data access, sharing and licensing	Data will be available only at the project repository to those members of the consortium who are directly involved in efficacy testing
Additional information	
Is the data personal?	Yes
Is the data sensitive?	Yes
Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si

Is there any data protection policy assigned to this data?	N/A

App usage data	***Description***
Data description	Data about the usage of SmartCHANGE mobile and web applications
Data origin	The data will originate from the SmartCHANGE applications
Data reuse	Before individual data can be used by other partners, personal identifiers should be removed
Methodologies for data collection/generation	This is not known yet
Data format	This is not known yet
Data storage	This is not known yet
Data size	This is not known yet
Metadata and standards used	N/A
Data usefulness	The data will be useful for feasibility and usability assessment
Data access, sharing and licensing	Data will be available only at the project repository to those members of the consortium who are directly involved in feasibility and usability assessment
Additional information	
Is the data personal?	Yes

Is the data sensitive?	No
Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si
Is there any data protection policy assigned to this data?	This is not known yet

Focus group data	***Description***
Data description	Feedback from participants of focus groups
Data origin	This data will originate from logs created during focus group discussions with families and HCPs
Data reuse	The data will be anonymised and will be able to be reused
Methodologies for data collection/generation	Data are collected within focus group discussions
Data format	The data will be provided in: .pdf
Data storage	The data will be stored in the project's password-protected repository
Data size	This is not known yet
Metadata and standards used	This is not known yet
Data usefulness	The data will be useful for partners involved in feasibility, explainability and usability assessment
Data access, sharing and licensing	Data will be available only at the project repository to those members of the consortium who are directly

	involved in feasibility, explainability and usability assessment
Additional information	
Is the data personal?	No – data will be anonymized
Is the data sensitive?	No, since data will be anonymized
Is there any Data Protection Officer (DPO) responsible for this data?	Nina Komočar Urbanija - dpo@uni-lj.si
Is there any data protection policy assigned to this data?	Yes, described in DPIA (Data Protection Impact Assessment; in Slovene) and https://www.slofit.org/o-slofit/varstvo-osebnih-podatkov (in Slovene)

Table 6 - TMU Feasibility study related data

Demographics data	***Description***
Data description	Data will be collected by individual participants (demographics, physical activity, sleep behaviour and lifestyle through questionnaires)
Data origin	The data will originate from the SmartCHANGE app and Research logs
Data reuse	Data will be able to be reused only after anonymization
Methodologies for data collection/generation	Data will be collected through the mobile application and related questionnaires
Data format	The format of the data will be: .csv
Data storage	Data will be stored in the TMU lab server

Data size	The size of the data will be: 2- 5 GBytes (approximately)
Metadata and standards used	N/A
Data usefulness	The data will be useful to all stakeholders responsible for the feasibility study
Data access, sharing and licensing	Data will be available in local server of TMU, and the project repository only shared with the consortium members who are directly involved in the feasibility study
Is the data personal?	Yes
Is the data sensitive?	Yes
Is there any Data Protection Officer (DPO) responsible for this data?	Alex Nguyen - alex0303@tmu.edu.tw
Is there any data protection policy assigned to this data?	No

It should be noted that after the feasibility study, all the pilot sites have mentioned that they would like: (i) part of the data to be anonymised or pseudo anonymised and made openly available on a public data repository (i.e., the case for ULJ, UPORTO, TMU, JAMK), (ii) kept stored at the local servers and the project repository (the case for ULJ, UPORTO, TMU, JAMK), or (iii) to store the data up to some years (i.e., 10 years) after the study, after which point it should be destroyed (i.e., the case for VUMC).

Beside storing data at individual sites, we plan to centralise the data for joint analysis. It should be highlighted that data will be anonymised before data transfer according to the harmonised protocol (as detailed in Section 4.2.3 of *D1.2 - Data Management Plan*). Also, explicit consent of participants for transfer of the anonymised data will be included in the informed consent forms in all study sites.

10 Comparison

The intervention will be compared to the usual care, specific to different settings across pilot sites. In addition to usual care 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. The use of these devices has been shown to promote healthy lifestyle in school-aged children, although the effects might not be large[23].

Some specificities in usual care across sites are described in the following section.

1. In Portugal, health consultations for children and adolescents are part of the national health system, focusing on preventive care, early diagnosis, and holistic health monitoring. These consultations follow guidelines established by the Portuguese Ministry of Health, emphasising periodic health evaluations at different ages and promoting physical, mental, and social well-being. The approach is designed to ensure that each child and adolescent receives appropriate care tailored to their developmental stage, identifying potential health risks and addressing emerging issues.

During infancy and early childhood (4-9 years), these yearly consultations focus on physical development milestones, nutritional guidance, and vaccination according to the National Vaccination Plan. Doctors and nurses assess motor and cognitive development, hearing, and vision and guide parents on safe sleeping practices, nutrition, and growth expectations. Preventive measures against common childhood illnesses and conditions are also part of these consultations, aiming to establish a healthy foundation for the child's future.

As children grow into adolescence, consultations (every two years) continue to address physical health but increasingly focus on psychological and social well-being. Adolescents receive guidance on maintaining a balanced diet, physical activity, mental health, and coping mechanisms for stress. Consultations also address lifestyle risk factors, including smoking, alcohol, drug use, and sexual health education. Mental health assessments become more prominent, particularly around stress, anxiety, and self-esteem issues, as adolescent years can be turbulent. The Ministry of Health provides structured guidelines for healthcare professionals to use, encouraging open, confidential conversations between adolescents and healthcare providers.

Ultimately, the system is structured to provide age-appropriate, holistic health care that grows with the child. In addition to general practitioners, school-based health teams sometimes assist, supporting adolescent health in educational settings.

2. In Slovenia, usual care consists of regular medical examinations of school doctors – paediatricians, identification of children deemed at health risk and interdisciplinary family intervention for identified child, his siblings and parents, defined with the protocol which describes the role of all HCPs involved in multidisciplinary team. Identification of a health risk of children in usual care is based on percentiles of BMI for specific age and sex group, combined with waist circumference and height ratio, cut-off values of blood pressure and information on family environment. Furthermore, all children, regardless of their health risk identified: a) participate in physical education which emphasize physical and health literacy; b) can access to their fitness scores, associated assessment of health risk and advises for behaviour changes in MySLOfit application; c) participate in special lessons about healthy lifestyle conducted by nurses and organised within school setting, Thus, control children will have all mentioned elements of usual care available, however they will not be provided with an SmartCHANGE app to support their lifestyle behaviors.

3. In the Netherlands preventative care differs per region. In the greater metropolitan area of Amsterdam, along with a few other provinces, this includes a screening questionnaire (jij en je gezondheid) and physical health test that takes place in the second year of secondary school when adolescents are between the ages of 11 and 14. Based on this questionnaire, which covers mental and physical health, adolescents are categorized using a stop-light system (green, yellow, red), where only those that are considered to be at a higher risk are brought into contact with the youth healthcare facilities affiliated with each school. This is based almost entirely on self-report measures. Both the control group and the experimental group will take part in this program as per usual, but in the case of the experimental group this will be followed by the use of the SmartCHANGE app.

4. In Finland the comprehensive health check-up for all 5th and 8th graders in Finland assesses the overall well-being of adolescents. At least one parent participates in the check-up, especially for assessing family well-being and discussing important topics like career choices and driving health. Family well-being evaluations includes living conditions, health habits, and interactions within the family. Nurses and doctors provide tailored health advice to the adolescent and family based on individual needs. Additionally, the adolescent has a confidential one-on-one meeting with a school health professional to discuss personal concerns. Discussion topics with the adolescent include substance use (alcohol, tobacco, drugs), sexual health, physical activity, screen time, sleep, and friendships. Clinical examinations include measurements of height, weight, hearing, vision, blood pressure, and heart auscultation, among others. Necessary vaccinations are administered, and general health guidance is provided. The check-up also includes an assessment of psychological and psychosocial well-being, focusing on issues like depression, anxiety, and eating disorders, as well as the adolescent's learning and well-being at school. Move! is a national physical functional capacity monitoring and feedback system for Finnish 8th grade pupils. It assesses endurance, strength, speed, mobility, balance, and basic motor skills through various tests.

The results from Move! measurements are integrated with the comprehensive health check-up, where they will be discussed if the parent has given permission to transfer them to health care. The control group will have the above-mentioned comprehensive health check-up but will not be provided SmartCHANGE app to support their lifestyle behaviours.

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11 Blinding

Due to the nature of the intervention, blinding of the participants and HCP to group allocation will not be possible.

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12 Intervention fidelity promotion

To support the implementation of the intervention from the HCP side, and to maintain their engagement throughout the whole intervention, we have envisaged constant interaction with the HCP. First, before the start of the main study, we will organise workshops at each study sites that will empower HCP to use the SmartCHANGE web application and get them acquainted with the contents of the mobile application for families or adolescents (depending on the study site participants). In addition, during the main study, researchers will offer monthly meetings with HCPs involved at a specific study site to receive feedback on the course of the intervention, as well as share and address encountered issues and challenges. Lastly, we will organise one remote meeting of HCPs across all sites to provide them with the opportunity to share their experiences with international colleagues. This meeting will be set after mid-term assessments to allow time for lessons learned to be implemented during the second part of the intervention.

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13 Ethical considerations

This study involves human participants, and all study procedures will be in accordance to the Declaration of Helsinki. All participants will be informed about the aim and procedures of the study before enrolment and written informed consent will be sought from the parents, while oral assent will be required from children and adolescents. As study sites deviate in procedures due to the inherent differences in daily clinical routine and healthcare settings, each study site will seek approval from their Ethical Committees, as required by national legislations. Appropriate documents are being prepared in coordination with all study sites and submission is planned in November by all study sites.

Benefits for participants include increased awareness of healthy lifestyle behaviours and access to support for behavior change and adherence to healthy lifestyle. Risks may involve data privacy concerns, although these risk do not superceed risks encounted in daily lives of today's youth driven by their high engagement in digital technologies. It is worth saying that the m-Health tool that will be used in the study has been co-designed with adolescents in order to guarantee maximal safety and allignment with needs and preferences of the intended users during the study.

Public engagement was taken into account through co-design session conducted within WP3. Study procedures were discussed during September and October 2024 with adolescents in Finland and the Netherlands, and with HCPs in Finland, the Netherlands and Slovenia. Feedback from stakeholders was collected and used to fine-tune the procedures of the study.

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14 Timing of study procedures

Detailed timeline is given in the table below:

Table 8 - Study procedure timeline

Study procedure	Timeline
Ethical approvals	October 2024-January 2025
Recruitment	December 2024-September 2025
Pilot study	January 2025-March 2025
Main study	October2025 – June 2026
Analysis and reporting	July 2026-April 2027

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