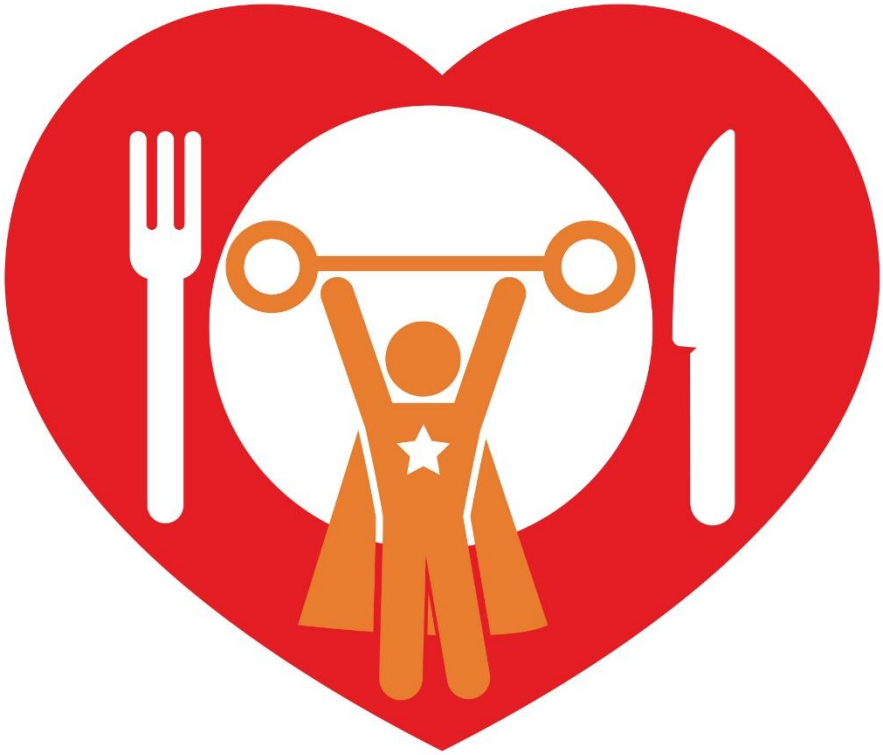

SUPERKIDS PROTOCOL

SuperKids - Empowering Healthy Lifestyle Behaviour Through Personalized Intervention Portfolios to Prevent and Control Obesity During Vulnerable Stages of Life: The HealthyW8 Project.

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1. Research team

1.1 Principal investigator

Gitte Ravn-Haren

Tel.: +45 93 51 89 89

E-mail: girh@food.dtu.dk

1.2 Research team

Tel.: +45 35 88 77 11

E-mail: hw8@food.dtu.dk

Adress:

Technical University of Denmark (DTU) Fødevareinstituttet
Henrik Dams Allé
Bygning 202
2800 Kgs Lyngby

1.3 Clinical Responsible

Jacob Borch, MD

Tlf: +45 35 32 61 39

E-mail: jacob.borch@sund.ku.dk

The study is being conducted by the Technical University of Denmark (DTU) as part of the European HealthyW8 consortium. The project is carried out through a cross-sectoral collaboration between DTU (project lead), Gladsaxe Municipality (Fællesskabet Værebro, Social Balance and public health nursing), the University of Copenhagen (KU), as well as local associations, parents/guardians, and other stakeholders. The initiative is based, among other things, on Gladsaxe Municipality's political strategy *Social Balance*, which emphasizes that all citizens should have equal opportunities to live a healthy and active life, regardless of where in the municipality they grow up.

1.3 Participant definition

The study population consists of children aged 5-12 years with support from their parents/guardians. The child is the participant in the study, and all primary outcomes relate to the child.
Parents/guardians support participants by contributing to intervention components (e.g., digital tools, activities, questionnaires) and assisting the child throughout the study. If additional family members (e.g., siblings) participate in specific activities, this will be on a voluntary basis, and they will not be considered study participants unless separate consent is obtained.

Parents/guardians participating in questionnaires, interviews, use of digital tools, or other study-related activities are considered research participants with regard to these procedures. Written informed consent will therefore be obtained from parents/guardians for their own participation in the study (appendix 3c), in addition to the consent given on behalf of their child (appendix 3a and 3b).

2. Background

30% of EU citizens in vulnerable positions are at an increased risk of transitioning from normal weight to overweight or obesity (HealthyW8, 2023). Among the groups at risk of developing overweight are children. A recent report published by the World Health Organization (WHO) shows that every third child in Europe is overweight (WHO, 2022). Social inequality is evident, among other things, in the higher prevalence of obesity, the increased risk of developing lifestyle-related diseases, and reduced quality of life. Although Denmark is a welfare society, there is still social inequality in health, with vulnerable groups being particularly affected (Vedsted et al., 2023).
It is well known that being physically active and eating in accordance with the Danish dietary guidelines have a positive impact on the prevention of lifestyle diseases and increase quality of life (Marquez et al., 2020; Oster & Chaves, 2023). Studies have shown that children of parents with low socioeconomic status are less active than children of parents with higher socioeconomic status (Tandon et al., 2021). Furthermore, there may be sociocultural barriers, as families unfamiliar with organized associations are less likely to have children participating in community sports or clubs (Kvist, 2023). There are many reasons why these children are less active. Some are financial, such as not being able to afford participation or transportation to training, while others are social, for example, not feeling like part of the "team" (Tandon et al., 2021). Additional factors include a lack of knowledge about local

opportunities and clubs, not knowing how to register for activities, limited understanding of the unwritten social rules among parents, and lower prioritization of children's leisure activities in families, perhaps in favor of homework or family obligations (Kvist, 2023).

Healthy eating habits formed during childhood often continue into adulthood (Movassagh et al., 2017), helping to protect against chronic conditions such as overweight and obesity (Hruby et al., 2016), type 2 diabetes (Alhazmi et al., 2014), and cardiovascular disease (Mikkilä et al., 2004). However, children from low socio-economic backgrounds are more likely to develop unhealthy eating patterns due to factors such as limited access to nutritious foods, greater exposure to unhealthy food environments, time and financial constraints, lower nutrition literacy, and higher stress levels (Mackenbach et al., 2019).
It is important to intervene early in children's lives to teach them healthy habits related to diet and exercise that can influence their health as adults. However, it should be noted that being overweight early in life does not necessarily lead to health problems later (Bjerregaard et al., 2018). In one study, researchers found that if a child was overweight at age 7 but not at age 13 or in early adulthood, they did not have an increased risk of developing type 2 diabetes. Conversely, those who were overweight both at ages 7 and 13 had a higher likelihood of staying overweight and developing type 2 diabetes (Bjerregaard et al., 2018). Therefore, the target group for this particular project is highly relevant, as children aged 5-12 can positively influence their future health through interventions at this stage.
HealthyW8 is an international research project that investigates how digital technologies and local health activities can promote healthy lifestyles and prevent overweight and related diseases among children, adolescents, and older adults. SuperKids is DTU's contribution to HealthyW8 and focuses on children aged 5-12. The aim is to test a digital solution that, through healthy tasks, dietary recommendations and recipes, can reduce the risk of overweight and associated diseases using an interdisciplinary and technological approach. In addition, a local initiative will be developed in the disadvantaged residential area of Værebro Park in Gladsaxe Municipality. This area is characterized by poorer self-rated health and lower participation in recreational and community activities compared to the rest of the municipality. The local initiative aims to reduce social inequality in health by promoting healthy habits, well-being, and participation in communities through physical activity and by building bridges to organize community life.

3. Aim

The overall goal of the HealthyW8 project is:

to assess the usefulness and effects of a digital-based healthy lifestyle recommender system (HLRS) on the prevention of obesity in the following populations: children (5-12 y), young adults (18-25 y) and elderly people (>65 y).

The goal of the SuperKids project is:

to investigate whether the digital-based HLRS, reflecting a multi-portfolio intervention developed within this project, will be able to reduce the risk of obesity and associated co-morbidities in children 5-12 years old.

3.1 Overall Objective

To evaluate the effectiveness of the HLRS a personalized, primarily digital, multi-component lifestyle intervention on reducing the risk of developing obesity among Danish children aged 5-12 years.

3.3 Hypothesis

It is hypothesized that participation in the one-year HLRS-based intervention will lead to a significant improvement in health behaviours related to obesity prevention, specifically healthier dietary patterns and increased physical activity levels, resulting in a lower risk of obesity among Danish children aged 5-12 years, compared to a control group.

3.4 Primary Outcome

- BMI Z-score

3.5 Secondary Outcomes

Body composition:

- Fat mass (%)
- Fat-free mass (kg)
- Body fat/fat-free mass ratio
- Visceral fat
- Waist, hip and thigh circumference

Anthropometrics:

- Weight (kg)
- Height (cm)
- BMI

Bone health (if measured):

- Bone mineral density (BMD)
- Bone mineral content (BMC)
- T-score

Cardiometabolic parameters:

- Blood pressure
- Metabolic biomarkers from biological samples (urine, saliva, faeces, capillary blood)

Physical fitness:

- Handgrip strength
- Step-up test

Health behaviours:

- Physical activity (accelerometer data)
- Food intake (FFQ)

3.6 Trial Registration

The SuperKids study is part of the HealthyW8 project under the identifier "HEALTHYW8-CHILDRENTRIAL-DK-2" and is on www.clinicaltrials.gov registered under NCT07011368.

3.7 Markers of compliance

- Attendance at organized sessions (physical activity and nutrition classes) in Værebro Park.
- Data on both dietary habits and physical activity collected via the GameBus API.

4. Methods

4.1 Study design

This study is a non-randomized, community-based, controlled intervention trial involving children aged 5-12 years supported by their parents/caregivers.

The study follows a parallel-group design with an intervention group and a control group. Participants in the intervention group will be exposed to the HLRS and related local health-promoting activities, while the control group will receive standard health information based on the official Danish dietary guidelines (Fødevarestyrelsen), information on Healthy Beverages (DTU), and Recommendations for Physical Activity for Children and Adolescents (Sundhedsstyrelsen).

We will recruit children in vulnerable situations, particularly from disadvantaged neighborhoods in Gladsaxe Municipality.

- Intervention group: children and their parent(s) living in Værebro Park, where community-based health activities will also take place.
- Control group: recruited from a demographically comparable area within Gladsaxe Municipality (e.g. Høje Gladsaxe and Mørkhøj).

This design allows comparison of outcomes under similar socio-demographic conditions and avoids potential contamination between groups.

In accordance with the EU HealthyW8 protocol, the wearables, questionnaires, and tests will be identical for both groups. All participants will therefore undergo the same measurement procedures, data collection, and assessment schedule, irrespective of group allocation.

4.1.1 Clarification of participant involvement

In both study groups, the child is the study participant undergoing all clinical measurements and assessments.

Parents/guardians are required to:

- support the child in the use of digital tools
- use digital tools to impact children's health behaviour
- participate in selected questionnaires about the child
- support children in relevant activities when applicable
- No biological samples are collected from parents/guardians as part of this study.

Intervention group: child supported by parents/guardians actively participate in the digital intervention, local community-based activities and data collection procedures.

Control group: child and parents/guardians receive standard health information and the child participate in data collection procedures but won't get access to intervention components.

4.2 Intervention description

The SuperKids intervention is a multi-component, technology-based program designed to promote healthy behaviours related to diet, physical activity and well-being. The program integrates mobile applications and wearable devices into participants' daily routines and is complemented by locally implemented physical activity and nutrition-related activities.

The intervention consists of two interconnected components:

1. The digital HLRS-based program
2. Local community-based health-promoting activities

4.2.1 The digital HLRS-based program

The digital component combines behavioural monitoring, gamification, and personalized recommendations through several interoperable tools and includes the following elements: Gamebus web-based platform, Nutrida meal-recommender app, HealthyW8 watch app and the Calendar web-based platform.

The HLRS includes physical activity- and nutrition-related tasks in the Gamebus web application, designed to integrate game-like elements to promote healthy behaviours. HealthyW8 watch app connects the child's Garmin watch with Gamebus.

The Nutrida app is also connected to the Gamebus platform supplementing nutrition-related components of Gamebus and offering personalized meal recommendations based on the preferences of the users.

An overview of the included digital tools and their main features is presented in table 1.

Table 1. Included SuperKids features.

The Gamebus Web Application	This app aims to promote physical activity (e.g., walking and step counting) and other health behaviours (e.g., preparing healthy meals, participating in activities) through gamification and motivational nudges. Developed by the Technical University of Eindhoven, Gamebus serves as a prototype health data management platform, enhancing user engagement through mobile health (mHealth) platforms. It includes a REST API based on Java Spring, an open-source web app frontend (using Ionic), and a restricted interface for smartwatches. Additional information can be found here: https://blog.gamebus.eu/
The Nutrida Application incl. recipes	This app offers personalized weekly meal plans, tailored to the participant's preferences, budget, allergies, and caloric requirements. The meal recommendation system is based on the Active Assisted Living (AAL) project, LIFANA, and has been further developed by the Nutrida app, created by NIUM (Esch-sur Alzette, Luxembourg), in collaboration with the Luxembourg Institute of Science and Technology (LIST) and the European Federation of the Association of Dieticians (EFAD), which integrate regional recipes into the app.
Wearable Device	Participants will use the Garmin Vivosmart 5 fitness tracker. This device monitors 24-hour movement, step count, sleep, pulse, and heart rate, allowing for stress level tracking (via heart rate) and related inferences. The device complies with GDPR regulations, ensuring data privacy.
HealthyW8 watch app	This open-source suite is used for experience sampling studies with Garmin wearables. Data collected through the synchronization is stored in Gamebus, which ensures compliance with GDPR and utilizes FHIR (Fast Healthcare Interoperability Resources) for FAIR (Findable, Accessible, Interoperable, and Reusable) data management. This module enables the integration of feedback from the Garmin wearable into Gamebus. This app will be available for participants after the trial is finished.
SENS Motion Accelerometers	Participants will be required to wear a SENS Motion accelerometer continuously for 9 consecutive days to objectively assess their physical activity levels and sedentary behaviour. This device will provide detailed data on movement patterns, energy expenditure, and sleep-wake cycles, allowing for a comprehensive analysis of participants' activity and rest periods. To ensure data accuracy, participants will be instructed on proper device placement and usage.
Calendar Web Application (optional)	Developed by EU HealthyW8 partner VirTech (Bulgaria), this application enables the study leader to schedule local events and inform participants about their potential involvement. The event data is securely stored on servers at LIST, Luxembourg.

4.2.2 Local community-based activities

Physical activities

The second component consists of regular physical activity sessions, with a fixed weekly session every Wednesday from 16:00 to 17:30 in local community facilities, such as the gym in Værebro Park, which includes badminton courts and open indoor spaces. In addition, up to 4 sessions per week may be organized depending on available facilities and participants' interest (e.g. outdoor activities or sessions in other local venues). Activities are led by sports science students from the University of Copenhagen, volunteers with a coaching background, supported by researchers from DTU.

The sessions aim to make physical activity fun and accessible for all children while introducing them to a variety of movement forms. Different instructors will lead activities throughout the intervention to provide variety, while some instructors will repeat sessions to ensure familiarity and continuity.

Activities may include ball games, running, dancing, outdoor play, and swimming etc. In addition, participating children and parents/guardians will be invited to information meetings focusing on nutrition and active family routines.

During the intervention, the project team will establish collaborations with local sports clubs and associations to create lasting connections. Part of this effort involves introducing children to nearby clubs. During selected activity sessions, representatives from local clubs will be invited to meet participating children and parents/guardians, present their programs, and provide opportunities for children to continue participating in club activities after the intervention ends.

The aim is to create sustainable pathways for ongoing physical activity in the local community, promoting children's health, well-being, and enjoyment of movement.

Nutrition-related activities

The intervention also offers practical nutrition activities for children and parents to reinforce knowledge and motivation from the app.

Children can engage in playful, hands-on activities such as tasting sessions, identifying healthy ingredients, or simple food preparation exercises. These activities promote curiosity, positive experiences with healthy foods, and practical understanding of nutrition. Parents participate alongside their children.

Skovbrynet School located in Værebro Park has made its school kitchen and theatre hall available for the project. These facilities may also be used for other study-related activities.

4.3 Recruitment, pre-screening and information meeting

4.3.1 Recruitment procedure

Recruitment will be carried out through multiple channels, including Aula, social media (Facebook, Instagram, WhatsApp), flyers, and local community meetings as well as through collaboration with a public health nurse associated with the project.

At local community meetings, brief information about the study will be provided collectively to attendees in a brief and general manner. There will be no individual or unsolicited approach to attendees. Instead, they will be informed that the project exists, and that they are welcome to contact the research team if they are interested in learning more. Flyers with contact details may be distributed for this purpose.

It will be clearly stated that this does not constitute the formal information meeting about the study. Any further information will only be provided upon initiative from interested families. Participation will therefore occur solely on the basis of voluntary interest.

All recruitment materials (Appendix 7) will include a QR code linking to a short online screening questionnaire (Appendix 13) hosted on SurveyXact. When scanning the code, parents/guardians will be guided to answer a few questions that help determine whether their child meet the inclusion criteria. The questionnaire includes items on the child's age, weight and height (for BMI calculation), physical activity, vegetable intake and consumption of sugar-sweetened beverages.

Participants will also be asked to indicate whether they prefer communication and written material in Danish or English. The research team receives the responses directly through SurveyXact and uses this information to assess eligibility and invite parents/guardians and their children to the appropriate information meeting in their preferred language. Before submitting the questionnaire, parents/guardians are informed that by completing the screening questionnaire they provide consent for the research team to store and process the collected information for screening purposes and to contact them based on their responses.

A public health nurse (DK: sundhedsplejerske) affiliated with the project will inform parents/guardians and their children about the SuperKids study during routine consultations (e.g. school health visits). The nurse will only provide information about the study and ask whether they are interested in receiving further information. If parents/guardians and their children express interest, they will receive the QR code for the pre-screening form or will be referred to the research team, who will provide further information and, if relevant, invite them to an information meeting. The public health nurse will not actively recruit participants or obtain informed consent.

The nurse works with children aged 5-12 years at two schools in Gladsaxe Municipality: Skovbrynet School (Værebro Park) and Enghavegård School (Mørkhøj). No information from patient records or other health records will be accessed or used for recruitment purposes. For the control group, recruitment will take place in a socio-demographically

comparable neighborhood in Gladsaxe Municipality (e.g. Høje Gladsaxe and Mørkhøj), using identical materials, language, and communication channels.

This figure visualizes the recruitment process:

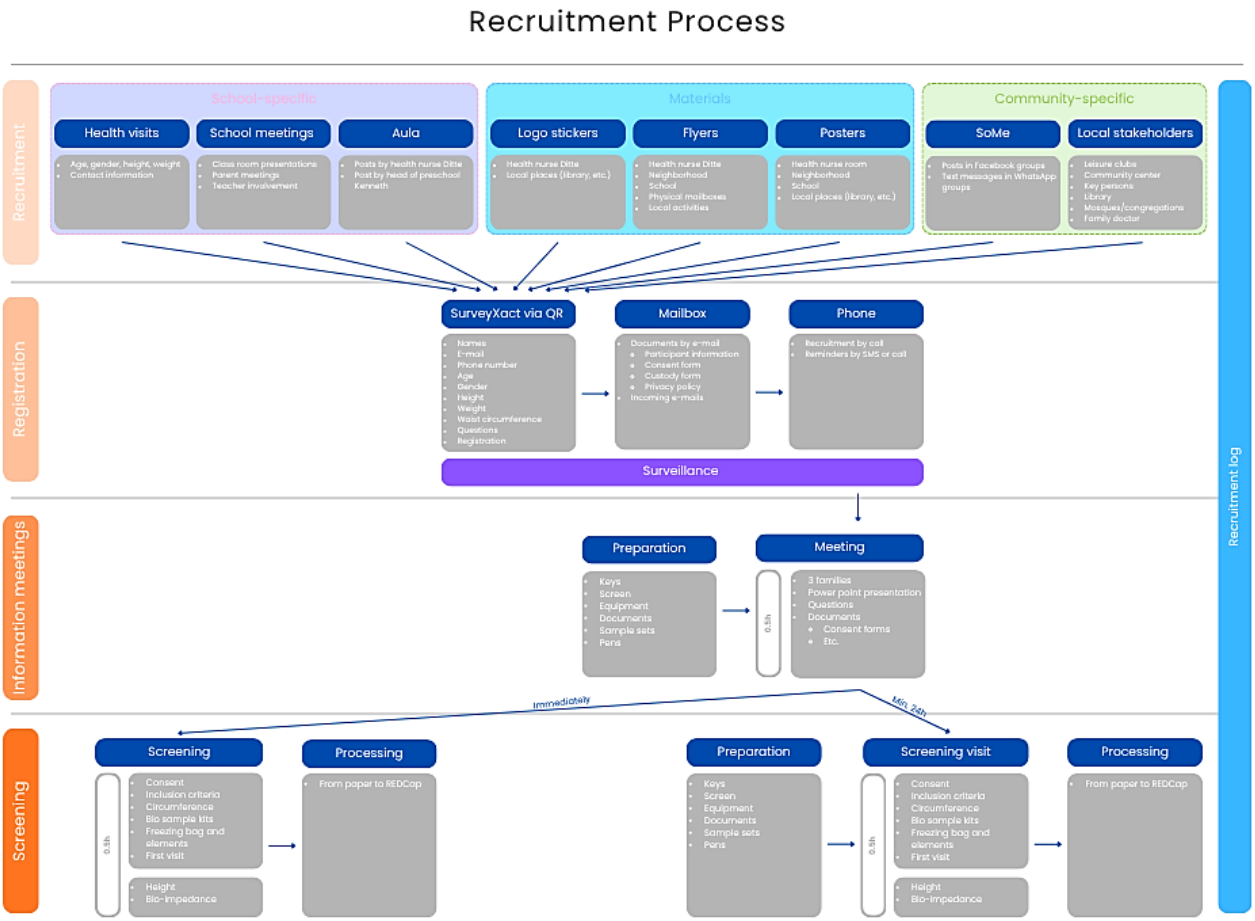

Figure 1. Recruitment process.

Participants are referred to research staff either through recruitment at community meetings, through school settings or through social media and flyer/posters. Registration for information meetings is confirmed via SurveyXact or research staff directly.

4.3.2 Recruitment via social media

Recruitment via social media will take place on relevant platforms (e.g. Facebook, Instagram, Aula, WhatsApp). It will not be possible to tag individuals or otherwise identify potential participants through recruitment materials. If the technical setup of the platform allows commenting or tagging, all activity will be actively monitored by the research team. Any content that may compromise participant privacy or reveal sensitive information will be removed without delay. All recruitment materials will be identical across platforms and approved by the Danish Research Ethics Committee prior to use.

4.3.3 Pre-screening questionnaire

Parents/guardians and children who are interested in the study are invited to access a short online screening questionnaire via a QR code. The questionnaire is completed electronically using SurveyXact (Appendix 13) and includes questions about the child's age, height and weight (for calculation of BMI), intake of sugar-sweetened beverages, vegetable intake, and physical activity habits.
Before completing the questionnaire, parents/guardians are informed about the purpose of the screening and are asked to provide consent for the research team to store and process the information provided for pre-screening purposes. SurveyXact is used to automatically assess, based on the information provided, whether the child appears to meet the study's inclusion criteria.
If the inclusion criteria are not met, the questionnaire is automatically closed after completion, and no further contact is made.

4.3.4 Information and informed consent

If the child appears to meet the inclusion criteria, parents/guardians will receive an email with further information about the study, including an invitation to an information meeting and written study materials.

- Participant Information Sheet (Appendix 1)
- Information from the Danish Research Ethics Committees regarding participant rights (Appendix 2)
- Copy of the Informed Consent Form (Appendix 3a, 3,b and 3c)

Parents/guardians will receive separate participant information and will provide separate written informed consent for their own participation in study-related activities, including questionnaires, interviews, and use of digital tools where applicable.

All oral information and written materials will be provided in Danish or English. Participants will be invited to attend an information meeting held in a suitable facility in the Værebro Park area (intervention group) and Mørkhøj/Høje Gladsaxe area (control group). Information meetings will normally be conducted in Danish, with up to 15 families per session to ensure that all attendees can ask questions and fully understand the information. If requested by a potential participant, the meeting may alternatively be conducted in English. Participants may bring a companion who is fluent in Danish or English. The information meeting will be conducted by qualified research staff from DTU, trained in the study protocol and delegated by the principal investigator. The public health nurse may also participate.

During the meeting, information will be provided on:

- Background and objectives
- Study design, timeline, and procedures
- Risks, side effects, and inconveniences
- Voluntary participation and right to withdraw

- Data confidentiality
- Access to data by regulatory authorities
- Use of already collected data upon withdrawal

Participants will have the opportunity to ask questions both in plenary and in private one-to-one discussions. All participants will be offered at least 24 hours of reflection time before signing informed consent. Participants who consider themselves sufficiently informed may choose to provide written informed consent on the same day as the information meeting. This decision must be made voluntarily and without pressure, and after it has been clearly communicated that they have the right to take the full reflection period.

4.4 Screening

Screening will only take place after written informed consent has been obtained. Once consent has been signed, participants will receive a copy of the signed document. For participants who voluntarily provide informed consent on the same day as the information meeting, screening may be carried out immediately afterwards in a separate room ensuring privacy and confidentiality. Participants who choose to use the 24-hour reflection period will be scheduled for a separate screening visit.

A separate room will be available where children with their parents/guardians can be invited for individual screening.

At the screening visit, the research staff will:

- Confirm that all inclusion and exclusion criteria are met
- Collect background information about the child (e.g., age, residence, health status, consumption of sugar-sweetened beverages, vegetable intake, physical activity habits, and BMI percentile)
- Measure weight, height, waist, hip and thigh circumference, and conduct a bioimpedance measurement
- Distribute and provide instructions for the use of sample collection kits (urine, saliva and stool)

The public health nurse may assist the research staff during screening, particularly in performing height and weight measurements and ensuring that children feel comfortable during the procedures. The public health nurse will also assist the distribution of biological sample kits (saliva, urine and stool) to participating children and their parents/guardians.

Screening procedures will be identical for the control group, ensuring that both intervention and control participants undergo the same assessments, data collection, and follow-up schedule.

An expected dropout rate of approximately 25% is anticipated, and screening continues until a total of 125 participants are included.

4.5 Study timeline and assessments

The study includes five main assessment time points: baseline, 3 months, 6 months, 9 months, and 12 months.

The baseline, 6-month, and 12-month assessments consist of two visits (R1 and R2), resulting in a total of 8 physical study visits per participant.

Overview of visits

- Baseline: 2 visits (R1 + R2)
- 3 months: 1 visit
- 6 months: 2 visits (R1 + R2)
- 9 months: 1 visit
- 12 months: 2 visits (R1 + R2)

Total: 8 study visits

Baseline Assessment (2 Sessions: R1 and R2)

R1 (1.5 hours)

- Measurement of capillary blood glucose/lipids (finger prick)
- Blood pressure measurement (child-sized cuff).
- Physical function tests: handgrip strength and step-up test.
- Collection of urine, saliva, and stool samples.
- Issuance of a SENS Motion to be worn for 9 consecutive days.
- Completion of online questionnaires in REDCap with assistance from research staff.
- Completion of the Food Frequency Questionnaire (FFQ) together with research staff.
- Scheduling of the R2 visit (~ 9 days later).

R2 (1.5 hours)

- Return of the SENS Motion device.
- Completion of the remaining questionnaires in REDCap together with research staff.
- Activation of access to digital tools (Gamebus, Nutrida, Garmin).
- Instructions in using and downloading the digital tools (Gamebus, Nutrida, Garmin).
- Distribution and synchronization of the Garmin wearable with the participant's app.

3-Month Follow-Up (Single Visit) (30 minutes)

- Anthropometric measurements (weight, height, waist, hip, thigh circumferences and bioimpedance measure).
- Brief motivational conversation about app use and engagement.

6-Month Assessment (2 Sessions: R1, R2)

R1 (2 hours)

- Anthropometric measurements (weight, height, waist, hip, thigh circumferences and bioimpedance measure).
- Blood pressure measurement (child-sized cuff).
- Physical function tests: handgrip strength and step-up test.
- Issuance of a SENS Motion accelerometer for 9 consecutive days.
- Completion of the Food Frequency Questionnaire (FFQ) together with the research team.
- Completion of online questionnaires in REDCap with assistance from research staff.
- Distribution of biological sample kits (saliva, urine and stool).
- Scheduling of the R2 visit (~ 9 days later).

R2 (45 minutes)

- Capillary blood glucose/lipids (finger prick) test.
- Collection of urine, saliva, and stool samples.
- Return of SENS Motion device.
- Completion of the remaining questionnaires in REDCap together with research staff.

9-Month Follow-Up (Single Visit) (30 minutes)

- Anthropometric measurements (weight, height, waist, hip, thigh circumferences and bioimpedance measure).
- Short check-in regarding digital tool adherence and local activity participation.

12-Month Final Assessment (2 Sessions: R1, R2)

R1 (2 hours)

- Anthropometric measurements (weight, height, waist, hip, thigh circumferences and bioimpedance measure).
- Blood pressure measurement (child-sized cuff).
- Physical function tests: handgrip strength and step-up test.
- 9-day SENS Motion accelerometer provided.
- FFQ completed with researcher.
- Completion of online questionnaires in REDCap with assistance from research staff.
- Biological sample kits distributed.
- R2 appointment scheduled (~ 9 days later).

R2 (45 minutes)

- Capillary blood glucose/lipids (finger prick) test.
- Collection of urine, saliva, and stool samples.
- Return of SENS Motion devices.
- Completion of the remaining questionnaires in REDCap together with research staff.

After the 12-month assessment, participants retain access to digital tools (Gamebus, Nutrida, Garmin) for the remainder of the intervention period. Researchers may contact participants to clarify or complete missing data or samples. Digital platforms (REDCap, Nutrida, Gamebus, Garmin) will support data collection, personalized feedback, and participant engagement.

Timeline: The timeline and contents for the different visits will be as follows:

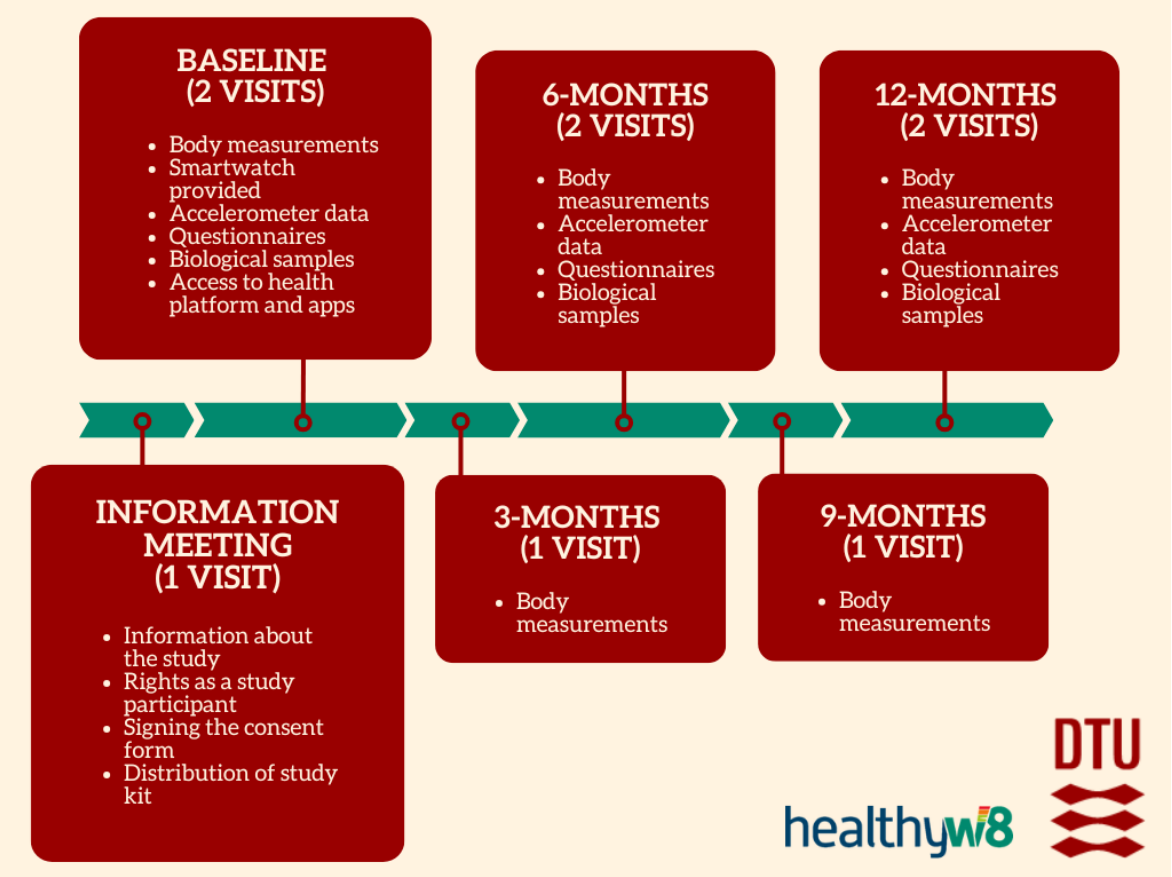

Figure 2. Timeline for visits.

Table 2. Body measurements chronogram

Body measurements and tests	Baseline	3m	6m	9m	12m
Anthropometry (weight, height, waist, hip & thigh circumference)	X	X	X	X	X
Bioimpedance (& DEXA if available)	X	X	X	X	X
Blood pressure	X		X		X
Hand-grip strength	X		X		X
Step-up test	X		X		X

Table 3. Biological samples chronogram.

Biological samples	Baseline	3m	6m	9m	12m	Collection details

Blood (finger prick)	X		X		X	Fasting capillary blood (finger prick) collected using Smart Bundle Pack (eGLUTM) to analyze glucose, lipid profile (total cholesterol, HDL, triglycerides), and derived values (LDL, cholesterol/HDL ratio) using a CardioCheck Plus Analyser (PTS Diagnostics).
Urine	X		X		X	First morning void, fasting state, collected in 120 mL sterile container.
Saliva	X		X		X	Two fasting samples collected in the morning (C1 and C2, separated by 30 min).
Faeces	X		X		X	Collected using DNA/RNA Shield Fecal Collection Tubes (Zymo Research).

4.6 Inclusion and exclusion criteria

Table 4. Inclusion and exclusion criteria

	CHILDREN (n=94)
INCLUSION CRITERIA	**AGE:** Children 5 to 12 years old **with supports from their parents/guardians** **Residence:** in the region **Overweight:** (BMI between p85 and p97; equivalent to 25-30 kg/m2) Free software for WHO percentile calculation (***WHO AnthroPlus***) available at *https://who-anthroplus. freedownloadscenter.com /windows/* (An easy way to measure the percentile during the visit. It needs to be downloaded and installed from WHO's website) **Mitigation plan (maximum 45 participants):** **Age:** same (5 to 12 years) **Weight:** BMI percentile p15 to p97 (https://www.aepap.org/sites/default/files/curvas_oms.pdf) + waist-to-height ratio (WHtR) ≥ 0.5. (Muñoz-Hernando J, et al. Usefulness of the waist-to-height ratio for predicting cardiometabolic risk in children and its suggested boundary values. Clin Nutr. 2022;41(2):508-516. doi:10.1016/j.clnu.2021.12.008 https://www.sciencedirect.com/science/article/pii/S0261561421005574?via%3Dihub) For children who do not meet the overweight criterion, at least two of the following lifestyle-related risk factors must be present: • Do not consume vegetables daily. • Consume three or more servings of sugar-sweetened beverages per week. • Are physically active fewer than two times per week. These criteria are assessed during pre-screening and are used as part of the eligibility assessment.
EXCLUSION CRITERIA	1. Diagnosis of obesity. 2. Not having a smartphone or lacking knowledge of digital technology (not applicable for children but for parents). 3. Presence of chronic disease (Appendix 11) or taking medication that causes metabolic

	changes. 4. Parents with DMII or other metabolic pathologies 5. Severe psychological disorders (Appendix 11). 6. Following strict diets (either by their own decision or on the recommendation of their doctor). 7. See Appendix 11 for additional exclusion criteria specified for children.

4.7 Rationale for design

A parallel-group, community-based design was selected to ensure feasibility and ecological validity in a real-world setting.
This approach was chosen primarily for practical reasons: it allows children to participate together with peers from their local area, ensures that activities take place nearby, and is more cost-effective. This pragmatic setup also enables the study to reflect realistic implementation conditions in vulnerable communities.

4.8 Data collection and statistical methods

4.8.1 Data collection

All information will be treated confidentially, and personally identifiable data will be stored in accordance with applicable legislation, including the Data Protection Act and GDPR. Participant identities will be coded throughout the study. All biological samples will be pseudonymized prior to shipment and analysis. A unique participant code will be used to link samples to participants. Only authorized research personnel will have access to the code key. Biological material will not be considered fully anonymized, as re-identification via the code key is possible during the study period in accordance with data protection regulations.

The coding system follows a standardized structure:

- Partner code: 06 (DTU)
- Age/Target group code: 01 = Children (5–12 years)
- Participant code: Sequential numbering from 001 to 125
- Visit numbering:
    - 0 = Baseline (Month 0)
    - 1 = Month 3
    - 2 = Month 6
    - 3 = Month 9
    - 4 = Month 12 (Final assessment)

Example: Participant code 06010010 represents DTU (06), children (01), participant 001, baseline visit (0).

Participants will be informed about who has access to their personally identifiable data, and that data collected prior to any potential withdrawal from the study may still be used by the researchers in the overall data analysis. The study is registered in DTU's mandatory records of data processing activities. These records are available to the Danish Data Protection Agency upon request.

4.8.2 Journal data

No information from patient journals will be accessed or used for recruitment purposes.

4.8.3 Statistical methods

Statistical analysis will be conducted both at the national level (Denmark) and as part of the overall HW8 analysis coordinated by CREDA (Appendix 12, WP5, p. 18-19). The Danish research team will be responsible for analysis of data from participants in the Danish intervention, while CREDA oversees the harmonized statistical framework across all participating partners in the EU project.

For the primary and secondary outcomes, comparison between intervention and control groups will be performed using linear mixed-effect models and regression analysis, adjusting for baseline outcome levels age, sex and other relevant covariates. These models allow the inclusion of repeated measures and clustering across and participants.

As outlined in WP5, additional statistical evaluations will include:

- Correlations, repeated measures ANOVA, and regression analysis
- Primarily Structural Equation Modelling (SEM), which combines factor analysis and multiple regression to estimate multiple and interrelated dependencies within a single analytical framework;
- Multinomial Logit Models, to explore categorical outcome patterns;
- Latent Class Models and cluster analyses, to stratify participants and examine heterogeneity across subgroups based on main outcomes and characteristics;
- Difference-in-Differences (DiD) models, to evaluate intervention effects by comparing changes over time between the intervention and control groups.

Sensitivity analyses will be conducted to assess the robustness of results. Missing data will be handled using mixed-model procedures or multiple imputation, as appropriate. Subgroup analyses (e.g., by age or gender) may be carried out if statistically justified.

All statistical analyses will be conducted using R or similar software. The significance level is set at $p < 0.05$.

The national analysis plan will be developed in collaboration with CREDA and the SuperKids research group to ensure alignment with the overall EU analysis strategy (WP5).

4.9 Transfer of personal data and biological material to other countries

As part of the HealthyW8 project, biological samples and/or associated data may be transferred to collaborating research institutions in other countries for analysis.

4.9.1 Countries and purpose

Biological material will be transferred to HealthyW8 research partners within the EU for the purpose of specific laboratory analyses.

- Urine samples: Luxembourg Institute of Health (LIH), Luxembourg, and Institut d'Investigació Sanitària Illes Balears (IdISBa), Spain
- Saliva samples: University of Évora (UÉV), Portugal
- Faecal samples: Luxembourg Institute of Health (LIH), Luxembourg

All transfers of biological material will be carried out in accordance with applicable data protection legislation, including the EU General Data Protection Regulation (GDPR).

Data will be shared within the HealthyW8 consortium for the purpose of coordinated data analysis. The participating countries include:

- Denmark
- Spain
- Netherlands
- Luxembourg
- Germany
- Italy
- Bulgaria
- Portugal

4.9.2 Data protection compliance

All transfers of personal data and biological material will comply with the General Data Protection Regulation (GDPR).

For transfers within the EU/EEA, GDPR applies directly.

No data is transferred to countries outside the EU/EEA (third countries).

4.9.3 Legal framework in recipient countries

Data is only processed inside the EU/EEA (no third countries), thus protected by GDPR.

4.9.5 Data processing agreements

Data responsibility is shared among the partners of the HealthyW8 consortium in accordance with the signed Data Sharing Agreement. This agreement incorporates a Data Processing Agreement, ensuring compliance with the General Data Protection Regulation (GDPR) and applicable Data Protection Act requirements. Additional data processing agreements

concerning biological samples and long-term storage in research biobanks will be established within the HealthyW8 consortium, likewise, ensuring compliance with General Data Protection Regulation (GDPR) and Data Protection Act requirements in receiving institutions.

Further data processing agreements with Gladsaxe Kommune and SENS motion will be established ensuring compliance with GDPR requirements.

4.9.6 Handling of biological material abroad

Only the analyses that are part of the study (and described in this protocol) will be conducted during the project period, with non-specific future analyses requiring new approval from an ethics committee.

All handling of biological material will comply with applicable ethical and legal standards.

Further information of handling of biological material abroad is described in section “12. Research biobank”.

5. Power calculation and sample size

The primary outcome is the change in BMI z-score after 12 months of intervention. Based on literature and previous considerations within the pilot project, the standard deviation (SD) of change in BMI z-score in paediatric weight management interventions is typically reported around 0.40-0.50, and clinically relevant effects are generally considered to be the range of 0.15-0.25 BMI z-score units (Kelly et al. 2014; Patterson et al. 2024; Raducha et al. 2022).

With an α of 0.05 and a power of 80%, the corresponding sample size requirements are as follows: For an expected mean difference of 0.25 BMI z-score and SD = 0.40, approximately 41 completers per group are required. Accounting for an expected 25% dropout, this corresponds to ~55 recruited participants per group (i.e. ~110 participants in total).

In practice, a requirement of 125 children in total is planned to accommodate expected dropouts and to compensate for partner institutions that have withdrawn, ensuring that the overall power of the study is maintained (see appendix 8). With this recruitment target (approximately 62 recruited per group, yielding about 47 completers per group assuming 25% dropout), the study will have 80% power to detect a between-group difference of approximately 0.23 BMI z-score units of SD = 0.40 (or about 0.29 BMI SD = 0.50).

The chosen total sample size of 125 participants therefore represents a pragmatic balance between recruitment feasibility and adequate statistical power, while remaining consistent with the assumption used in the overall EU project protocol.

6. Withdrawal and interruption of the study

Participants may withdraw from the study at any time without providing a reason, and this will not have any consequences for them.

A participant may also be excluded from the study at their own request, or if they are unable or unwilling to comply with the study procedures described in the protocol. In such cases, the participant will be informed of the reason for and decision regarding their exclusion. All reasons for withdrawal or exclusion will be documented.

If new and important information about the intervention or study procedures becomes available during the study, participants will be informed. If such information is relevant to participant safety, they will be asked to provide renewed consent if they wish to continue in the study.

If a participant withdraws consent during the study, the research staff will ask whether they are willing to take part in a final study visit and, if possible, to provide the reason for their withdrawal. It will be made clear that this is entirely voluntary.

The study may be terminated in whole or in part if unforeseen safety issues arise, if participation is deemed to pose an unacceptable risk to the participants, or if new knowledge emerges that makes continuation of the study unethical. Furthermore, the study may be discontinued for organizational or financial reasons following a decision by the principal investigator.

7. Study groups

7.1 Intervention group

The intervention group will consist of children aged 5-12 years living in Værebro Park and nearby areas, where access to the activities is convenient.

- Primary intervention: digital, via the HLRS, providing personalized recommendations for diet, physical activity, and broader health behaviours.
- Supplementary physical intervention: weekly in-person activities at Værebro Park, organized as workshops led by sports science students.
- Schedule and logistics: activities will take place every Wednesday from 16:00 to 17:30 in facilities provided at Værebro Park.
- Additional components: cooking classes with practical recipe-based exercises, facilitated by project staff.

This multi-component approach is designed to engage children with supports from their parents/guardians, promote healthy behaviours, and support sustained health behaviour changes through both digital and in-person interventions.

7.2 Control group

The control group will consist of children aged 5-12 years living in demographically similar socially vulnerable areas (e.g., Høje Gladsaxe and Mørkhøj).

- Participants will receive general information on diet and physical activity based on official Danish health guidelines and recommendations (see appendix 9).

- No structured digital or physical interventions will be provided beyond standard health information.
- Participants in the control group will use the same wearable device (Garmin), digital tool (HealthyW8 watch app), questionnaires, and assessment procedures as the intervention group, exclusively for data collection purposes and without access to behavioural components.

This setup allows comparison between children exposed to a multi-component intervention and those receiving standard health information under similar socio-demographic conditions.

8. Measurements

All measurements will be performed according to the Standard Operating Procedures (SOPs), including the use of the instruments specified in the relevant SOP's.

8.1 Height

Height will be measured using a wall-mounted stadiometer. Participants will remove their shoes and stand upright with the back of the head, shoulders, and buttocks touching the stadiometer. They will be instructed to look straight ahead, keep their arms relaxed at their sides, and inhale deeply. The measurement will be taken before exhalation and recorded to the nearest 0.5 cm.

8.2 Weight

Weight will be measured after participant has emptied their bladder, using a Tanita MC780 MA (Portable) bioimpedance scale or a calibrated digital scale.
Participants stand centred on the scale platform, distributing their weight evenly on both feet. Once the reading stabilizes, weight will be recorded in kilograms to the nearest 0.1 kg.

8.3 Waist, hip, and thigh circumference

Circumference measurements will be performed after the participant has emptied their bladder, using a flexible, non-elastic measuring tape.

- Waist circumference: measured midway between the lower rib and the iliac crest (top of the hip bone), at the end of a normal exhalation.
- Hip circumference: measured around the widest part of the hips and buttocks.
- Thigh circumference: measured at the midpoint between the inguinal crease (groin) and the upper border of the patella (kneecap).

Each circumference will be measured twice to the nearest 0.5 cm, and the average of the two readings will be recorded. Measurements will be taken directly on the skin while the participant stands relaxed, with arms at their sides and muscles not flexed.

8.4 Body composition

Body composition will be assessed at baseline and at the 3-, 6-, 9- and 12-month visit using bioelectrical impedance analysis (BIA), which provides estimates of fat mass, lean mass, and total body water.
In a subset of participants, a DXA-scan will be used to measure:

- Bone mineral density (BMD) and T-score
- Fat mass and fat-free mass
- Visceral adipose tissue

DXA scans will be conducted in the morning after an overnight fast. Participants will lie supine on an open DXA table while a scanning arm passes slowly over the body.
All metal items must be removed before the scan, and participants should wear light, metal-free clothing.
DXA involves the use of low-dose ionizing radiation. Participants may undergo up to two DXA scans during the study (baseline and 12-month follow-up). The total radiation dose from these scans is approximately 0.002 mGy and is associated with a very small estimated increase in lifetime cancer risk of approximately 0.01%

For comparison, the average annual background radiation exposure in Denmark is approximately 3 mGy per year (corresponding to approximately 0.008 mGy per day). The radiation dose from a DXA scan is therefore considered minimal and comparable to a small fraction of natural background radiation.

8.5 Blood pressure and resting heart rate

Systolic and diastolic blood pressure and resting heart rate will be measured using a validated automatic arm blood pressure monitor, after 5-10 minutes of seated rest.
Three measurements will be taken (a fourth if the last two readings differ by more than 5 mmHg).
The mean of the final two readings will be recorded to the nearest 1 mmHg.
All measurements will be taken on the same arm throughout the study.

8.6 Physical fitness tests

- **Handgrip Strength Test**
  This test assesses upper-body muscular strength using a hand dynamometer.
  Participants will be seated with the elbow flexed at 90°, and the maximum isometric grip force (in kilograms) will be recorded. Two attempts will be made per hand, and the highest value will be used for analysis.
  Handgrip strength is considered a reliable indicator of general muscle function and overall health.

- **Step-Up Test**
  This test evaluates lower-body strength and endurance. Participants will repeatedly

step up and down on a standardized platform for a defined time period or number of repetitions.
The number of completed step cycles will be recorded to assess lower-limb strength and functional fitness.

8.7 Biological samples

The study involves the collection of biological samples including urine, saliva, faeces, and capillary blood (finger prick). The purpose of collecting these samples is to analyse metabolic and biological markers related to obesity risk, dietary intake, physical activity, and overall health status. Analyses will include biomarkers related to metabolic health (glucose, lipid profile), microbiome composition (faecal samples), and selected molecular or cellular markers reflecting physiological responses to the intervention. The analyses performed in this study are not intended for clinical diagnosis or treatment purposes. No genetic testing for disease prediction or diagnosis will be performed.

8.7.1 Type and quantity of biological material

The following biological samples will be collected from each participant:

Urine samples:

- Up to 120 mL urine samples collected at baseline, 6 months, and 12 months corresponding to a total of up to 360 mL
- After each collection, urine samples will be portioned out to 13 cryovials with 0,45 mL urine in each cryovial.
    - 4 cryovials to Luxemburg Institute of Health (LIH), Luxembourg
    - 4 cryovials to Health Institute of the Balearic Islands (IdISBa), Spain
    - 5 cryovials to DTU, Denmark

Saliva samples:

- 2 samples (at 0 minutes and after 30 minutes) collected at baseline, 6 months, and 12 months
- Each sample consists of the amount of saliva that is collected over a period of 4 minutes into a tube (~50 mL falcon tubes)

Faecal samples:

- 1 sample collected at baseline, 6 months, and 12 months using standardized faecal collection tubes for 1g or 1ml stool sample

Capillary blood samples (finger prick):

- A few drops of blood (~ 0,1 mL) collected at baseline, 6 months, and 12 months

The total volume of biological material collected is considered minimal and is within acceptable limits for paediatric research.

8.7.2 Analyses and scientific purpose

The collected biological samples will be used to investigate biological and behavioural factors associated with the development and prevention of overweight and obesity.

A detailed overview of all planned analyses, including specific biomarkers, sample types, and responsible institutions, is provided in Table 6.

In summary, analyses will include:

- Metabolic and clinical biomarkers (e.g. glucose and lipid profile)
- Biomarkers related to dietary intake (e.g. urine-based markers such as sodium, potassium, and creatinine)
- Indicators of oxidative stress and cellular processes (e.g. F2-isoprostanes and DNA/RNA oxidation products)
- Microbiome composition and activity in faecal samples (e.g. 16S rRNA, short-chain fatty acids)
- Salivary biomarkers related to physiological responses (e.g. cortisol and proteomic markers)

The analyses will be conducted across collaborating institutions in Europe, including the Technical University of Denmark (DTU), Luxembourg Institute of Health (LIH), Luxembourg, Institut d'Investigació Sanitària Illes Balears (IdISBa), Spain and Universidade de Évora (UEV), Portugal.

Table 5. Receiving Centers

Receiving Center	Contact	Shipping Address	E-mail and contact telephone number
LIH	Torsten Bohn	Luxembourg Institute of Health Department of Precision Health 1A-B, rue Thomas Edison, L-1445 Strassen Luxembourg	torsten.bohn@lih.lu +352 26970394 +352 621216637 +352 621763805
IDISBA	Margalida Monserrat	Guillem Colom Bldg, Campus University of the Balearic Islands,	margalida.monserrat@uib.es +34 971 17 2981

		07122 Palma de Mallorca, Spain	+34 971 17 3142
UEV	Elsa Lamy	Institute for Agriculture, Environment and Development - MED Oral Biology and Salivary Proteomics Lab Universidade de Evora Polo da Mitra 7000-083 Évora	ecsl@uevora.pt +351 94 662 825

This is a hypothesis-generating study, aiming to explore interactions between behavioural, biological, and environmental determinants of obesity risk.

The study forms part of a larger European research initiative and contributes to identifying determinants that may support future personalized intervention strategies.

The analyses performed in this study are not intended for clinical diagnosis or treatment purposes.

Table 6. Biological samples and biomarkers.

Biomarker	**Biological sample**	**Collection tube or container**	**Institution in charge of the analysis**	**Volume (if applicable)**
Albumin (mg/L)	Urine	Urine tube	DTU	
Uric acid (mg/dL)	Urine	Urine tube	DTU	
Creatinine (mg/dL)	Urine	Urine tube	DTU	
Sodium (mmol/L)	Urine	Urine tube	IdISBa	
Potassium (mmol/L)	Urine	Urine tube	IdISBa	
Calcium (mg/dL)	Urine	Urine tube	IdISBa	
Magnesium (mg/dL)	Urine	Urine tube	IdISBa	
Total proteins (g/L)	Urine	Urine tube	DTU	
Oxidative stress				
F2- isoprostanes	Urine	cryovial	LIH	50 µL
DNA/RNA breakdown products (8-oxodG/8-oxoG)	Urine	cryovial	LIH	150 µL
Microbiota				
16SrRNA	Stool	DNA/RNA shield fecal collection tube	LIH	
Fecal calprotectin	Stool	DNA/RNA shield fecal collection tube	LIH	
Trimethylamine N-oxide (TMAO)	Stool	DNA/RNA shield fecal collection tube	LIH	

Short-chain fatty acids	Stool	DNA/RNA shield fecal collection tube	LIH	
Stress hormone and Omics				
Cortisol, proteomics	Saliva	cryovial	Évora (UEV)	

8.7.3 Handling of biological material and data protection

All biological samples will be labelled with a unique participant code and handled in a pseudonymized manner. A code key linking participant identity to sample ID will be securely stored and accessible only to authorized research personnel. Samples will not be fully anonymized during the study, as re-identification is necessary for study-related follow-up and data management.

8.8 Questionnaires

Participants and their parents will complete standardized questionnaires entered and managed in REDCap, a secure electronic data capture platform. In case of technical issues, participants will be provided with printed versions of the questionnaires. Their responses will be entered into the REDCap system as soon as the technical issues are resolved, after which the printed copies will be immediately deleted.
All questionnaires will be completed with assistance from research staff, either by reviewing each section to ensure accuracy and completeness or to simply assist if the participant has questions regarding the questions.

The questionnaires included in the study are shown in table 7.

Table 7. Children Questionnaires.

		Baseline	3m	6m	9m	12m
Access to questionnaires with a unique Redcap Code **per visit**	Diet (FFQ) *(to be done with direct researcher assistance)*	X		X		X
	IPAQ-C	X		X		X
	Socio-demographic profile (children & parent survey)	X		X		X
	Kidscreen (children & parent surveys)	X		X		X
	Work/studies flexibility & satisfaction (parent survey)	X		X		X
	Family lifestyle (children & parent surveys)	X		X		X
	Personality traits: BFI-10 (parent's survey)	X				

	User Experience Questionnaires (children & parent surveys)	X

8.9 Interviews

As part of the project, qualitative interviews and observations will be conducted with a smaller number of parents/guardians and their children participating in the study. The purpose is to gain a deeper understanding of how children and parents experience the intervention, including their engagement, acceptance, and any challenges related to the different components. The interviews and observations will also help identify unintended effects as well as factors influencing the implementation and use of digital tools.

In addition, qualitative interviews will be conducted with key gatekeepers and stakeholders involved in the recruitment and implementation of the intervention, such as school health nurses, social workers, and other relevant professionals. These interviews aim to explore gatekeepers' and stakeholders' perspectives on the recruitment process and their role in facilitating participation. Gatekeeper interviews will also provide insight into organizational, structural, and contextual factors that may influence recruitment, implementation, and reach.

All interviews will be semi-structured to allow for the exploration of themes that may emerge during the process. The analysis will be based on a thematic approach, identifying patterns and themes derived from the experiences of parents/guardians, children, gatekeepers and stakeholders.

8.10 Food frequency questionnaire (FFQ)

On behalf of their children, parents/guardians complete an FFQ, which has been developed in collaboration between the European project partners. The FFQ is used to assess the child's habitual dietary intake, focusing on food choices, dietary patterns, and changes over time. Since children aged 5–12 have limited ability to recall and evaluate their own intake, parents/guardians are considered the most reliable respondents.

The FFQ was validated in pilot studies of the project, where responses were compared with three 24-hour dietary recalls (3×24h recalls).

The questionnaire lists common foods and beverages, and parents/guardians report the frequency of consumption on a scale ranging from "6 times per day" to "never." At baseline, parents/guardians report on the child's dietary intake over the preceding period (the past year), while follow-up assessments at 6 and 12 months focus on changes since the previous measurement.

Data from the FFQ are used to calculate:

- Intake of food groups (e.g., fruits, vegetables, whole grains, dairy products, meat, fish, and sugary foods)
- Estimated nutrient intake, linked to a food composition database
- Overall dietary patterns and adherence to national dietary guidelines

The FFQ is administered at baseline, 6 months, and 12 months to assess changes in dietary habits, account for seasonal variation, and explore associations with physical activity, well-being, and biomarkers. The FFQ is completed in person with direct assistance from a project staff to ensure accurate and complete responses.

9. Safety and risks

Participation in a research study may cause minor disruptions to daily life and can be time-consuming. Participants in this study will be required to modify their usual health behaviour with respect to physical activity, diet and well-being. We estimate that participation will have only positive effects, and negative side effects are unlikely, however investigated through qualitative interviews with the participants. Participants will be provided with guidance on optimizing their diet in terms of macro- and micronutrients to prevent lifestyle-related diseases; however, they will not be asked to follow a specific or restrictive diet.

The risk of injury associated with physical activities such as dance, ball games, gymnastics, swimming, and movement-based play is considered low, and all study procedures are regarded as safe.

10. Adverse effects and inconveniences

Participation in this study may involve minor inconvenience and time commitment due to repeated visits, assessments, and data collection. Participants in the intervention group may be encouraged to make small adjustments to their usual diet and physical activity habits, but they will not be asked to follow any restrictive or specific dietary plan. Overall, the expected effects of participation are positive, and the risk of adverse effects is considered very low.

The intervention includes educational and practical components related to physical activity and nutrition. Participants will engage in activities such as dance, ball games, gymnastics, swimming, and movement-based exercises designed to improve physical skills, enjoyment, and physical activity literacy, that is, their knowledge, motivation, and confidence to engage in regular movement and healthy lifestyle habits. The risk of injury associated with these activities is considered minimal, and all study procedures are regarded as safe.

All study procedures are considered safe, including collection of the following biological samples and measurements::

- **Biological samples:**
  Urine, blood, saliva, and stool samples will be collected three times during the study:
  - *Urine, saliva, and stool samples* are non-invasive and not associated with any short- or long-term risks. Parents or guardians may assist children to reduce discomfort or insecurity during sample collection.

- *Blood samples* (capillary finger prick) are minimally invasive; based on experience from similar studies (e.g., OPUS), the risk of discomfort or complications is considered very low. The procedure may cause brief pain, minor bleeding, or slight bruising at the puncture site.
  To minimize discomfort and risks:
  - Sampling will be performed by trained personnel
  - Sterile, single-use lancets will be used
  - The finger will be disinfected with an alcohol swab prior to puncture
  - The number and frequency of samples are kept to a minimum

  The total amount of blood collected is very small and does not pose a risk of dizziness or physiological harm in the target population. In addition, the child can at any time withdraw from the blood sampling

- **Dietary assessments:**
  Completion of food frequency questionnaires (FFQ) is safe and without any expected side effects.

- **Anthropometric and physiological measurements:**
  Height, weight, waist, hip, and thigh circumferences, as well as body composition (via bioelectrical impedance analysis), resting blood pressure, and pulse, will be measured at multiple time points during the intervention. These procedures are safe, non-invasive, and well-tolerated. We will also perform DXA scans on some of the participants at the baseline and 12-month visits. The DXA scan involves a very low dose of ionizing radiation (approximately 0.001 mGy per scan), which is considered minimal and comparable to a very small proportion of natural background radiation. The risk of health harm is considered low.

- **Behavioral data:**
  Objective physical activity, sedentary behavior, and sleep patterns will be recorded three times using accelerometers (SENS Motion). The device is worn on the thigh and does not pose any physical risk.

- **Questionnaires:**
  Participants and their parents will complete standardized questionnaires covering demographics, lifestyle, physical activity, emotional wellbeing, quality of life, and other relevant factors. All questionnaires can be by study personnel to ensure understanding, accuracy, and data quality.

- **Interviews:**
  A subset of participants will participate in interviews after 6 months of intervention. The procedure does not pose any physiological risk.

Minor inconveniences may include temporary fatigue, mild discomfort from measurements, or time commitment related to visits and physical activity sessions. However, all study procedures are designed to minimize participant burden. Overall, the study is assessed to involve minimal risks and limited burden for the participants. The potential health and

scientific benefits are assessed to outweigh the disadvantages described, which is why the study is considered ethically sound.

There may be unforeseen risks or discomforts associated with participation that are currently unknown. If new information about risks emerges during the study, participants will be informed.

No financial compensation will be provided for participants.

11. Ethical considerations

11.1 General considerations

Participation in a research study will inevitably disrupt the daily life of study participants. In this trial, participants will be required to modify their behaviour with respect to diet and physical activity. Nevertheless, the study is considered ethically justifiable, as it is expected to have no or minimal negative consequences for participants.

The study will not commence before approval is obtained from the Danish National Committee on Health Research Ethics (DK: Den Videnskabsetiske Komité). All study procedures will be conducted in accordance with the Declaration of Helsinki, and the study is registered in the public database clinicaltrials.gov.

All personal data will be handled confidentially and stored in compliance with applicable legislation, including the General Data Protection Regulation (GDPR) and the Danish Data Protection Act (No. 502 of 23 May 2018). Participants will be informed about how their personal data are processed and about their rights under the GDPR, including the right to access, rectification, restriction of processing, and, where applicable, erasure of personal data, in accordance with the obligation to provide information.

Participants will also be required to sign a GDPR consent form to take part in the study (Appendix 3).

All participants will receive both written and oral information about the study. Only trained research personnel will provide information, oversee, and confirm the signing of the informed consent form. Potential participants will be informed about the background and significance of the study, as well as an overview of all study procedures requiring their participation and how these procedures will be conducted. Furthermore, research personnel will ensure that participants are aware of their rights as participants, including the right to withdraw from the study at any time without any consequences or reproach from the research staff.

11.2 Research involving children

This study includes children aged 5-12 years. The inclusion of children is necessary, as the study aims to investigate determinants of overweight and obesity and to evaluate intervention strategies specifically targeted at this age group.

11.2.1 Justification for inclusion of children

The study specifically concerns children within this age range, and the intervention cannot be meaningfully conducted in adults. The project is expected to generate knowledge that is directly relevant to children with overweight or at risk of overweight and may contribute to improved prevention and intervention strategies in this population. The study involves minimal risk and limited burden for participants.

11.2.2 Age group justification

The age group of 5-12 years has been selected as this is a critical period for the development of health behaviours related to diet and physical activity. Early intervention in this age group is considered essential for preventing overweight and obesity later in life. In contrast, older children in adolescence can be more difficult to reach and tend to exhibit less healthy behaviours; however, habits formed earlier in childhood are likely to persist and influence health later in life.

11.2.3 Minimization of discomfort

All study procedures are designed to minimize pain, discomfort, and inconvenience for the child.

- Non-invasive or minimally invasive methods are used whenever possible
- Biological sampling (e.g. finger prick) is kept to a minimum and performed by trained personnel
- The study setting is adapted to be child-friendly
- Parents will be present during procedures to support the child

11.2.4 Information and consent

i. Parental consent

Written informed consent will be obtained on behalf of the child from both parents in cases of shared custody. If both parents are not present at the time of consent, written authorization may be obtained from the non-present parent.

ii. Consent from minors

As the study includes children under 15 years of age, parental consent constitutes legally valid consent.

iii. Assent from the child

Children aged 5-12 years will be informed about the study in an age-appropriate manner and will be asked for their assent to participate. The child's wishes will be respected throughout the study.

iv. Age-appropriate information

Information provided to the child will be adapted to their age, level of understanding, and maturity.

v. Qualifications of staff

Information and involvement of the child will be carried out by trained research staff with knowledge of the study and experience in communicating with children and their parents.

12. Research biobank

In connection with the study, research biobanks will be established in accordance with applicable legislation for the purpose of storing biological material (saliva, urine and stool samples) for use in the analyses described in the protocol. Urine, saliva and faecal samples collected during the study will be stored in the research biobank until the planned analyses described in this protocol have been completed.

The research biobank established for the SuperKids study will cease no later than the completion of the project. At the end of the project, any remaining biological material will either be destroyed or transferred to a biobank for future research, provided that the participant's parents/legal guardians have provided separate consent for such storage.

Capillary blood samples are analysed immediately after collection and cannot be stored for later analysis. Blood samples are not stored in a research biobank, and any remaining material is discarded after completion of the analyses.

Only the analyses that are part of the study (and described in the protocol) will be performed during the project period, while non-specific future analyses will require new approval from the ethics committee.

12.1 Storage and duration

One urine sample (tube) will be collected from each child at both baseline, 6 months and 12 months (=3 urine samples). All these urine samples will be stored at the Technical University of Denmark (DTU) until portioned out into cryovials for analysis. Afterwards cryovials will be stored until they are analysed at DTU or shipped to collaborating and receiving institutions (partners of the HelathyW8 consortium) for specific analyses. These institutions include:

- Luxembourg Institute of Health (LIH), Luxembourg
- Institut d'Investigació Sanitària Illes Balears (IdISBa), Spain

One faeces sample (tube) will be collected from each child at both baseline, 6 months and 12 months (=3 faeces samples). All the faeces samples will be stored at the Technical University of Denmark (DTU) until shipped to collaborating and receiving institution (partners of the HelathyW8 consortium) for specific analyses. This institution is:

- Luxembourg Institute of Health (LIH), Luxembourg

Two saliva samples (tubes) will be collected from each child at both baseline, 6 months and 12 months (=6 saliva samples). All these saliva samples will be stored at the Technical

University of Denmark (DTU) until shipped to collaborating and receiving institution (partners of the HelathyW8 consortium) for specific analyses. This institution is:

- Institute for Agriculture, Environment and Development, Evora (UEV), Portugal

Data derived from the samples will be stored for at least 10 years after the end of the study (specifically 30th of April 2038). Data will be stored in secured folders on LIH servers, requiring a 2-stage permission procedure. All data stored will be pseudonymized.

12.2 Purpose of storage

The purpose of storage at DTU is to (1) analyse the samples together and (2) send the samples together for time and cost efficiency. The purpose of storage at collaborating institutions are likewise to analyze the samples together for time and cost efficiency. The storage enables completion of specific and planned analyses at DTU and collaborating institutions as described in this protocol.

12.3 Extent of stored material

Biological material may be stored at the collaborating institutions for varying periods of time, in accordance with local regulations and participant consent.

- Urine cryovials, saliva tubes and feces tubes stored at DTU and analyzed elsewhere will be shipped to collaborating institutions continuously until the end of the study (30th of April 2028). The collaborating research biobanks include Luxembourg Institute of Health (Luxembourg), Institut d'Investigació Sanitària Illes Balears (Spain), and Universidade de Évora (Portugal).
- Urine cryovials analyzed at DTU will be stored at DTU until after analysis (no later than the end of the study: 30th of April 2028) and then destroyed, however, excess material will be stored (subject to consent) for future unspecific analysis for up to 5 years after the end of the study (specifically 30th of April 2033) after which they will be destroyed
- Urine cryovials, saliva tubes and feces tubes analyzed and stored at collaborating institutions may be stored until after analysis (no later than the end of the study: 30th of April 2028) and then destroyed, however, excess material may be stored (subject to consent) at collaborating institutions for future unspecific analysis for up to 10 years after the end of the study (specifically 30th of April 2038) after which they will be destroyed.

Personal information that can be linked directly to an individual will be deleted at the end of the study (30th of April 2028).

The code key linking participant identity (e.g. name, email, and phone number) to study data (participantID) will be securely stored and deleted approximately 5 years after the end of the study (specifically 30th of April 2033), after which all data will be fully anonymized.

The end of the study is defined as the last participant's final visit.

12.4 Information about biobanks

Table 8. Biobank information

Partner	Responsible	Address	E-mail and phone number
LIH	Torsten Bohn	Luxembourg Institute of Health Department of Precision Health 1A-B rue Thomas Edison L-1445 Strassen Luxembourg	torsten.bohn@lih.lu +352 26970394 +352 621216637 +352 621763805
IdISBa	Margalida Monserrat	Guillem Colom Building Campus Universitat de les Illes Balears 07122 Palma de Mallorca Spain	margalida.monserrat@uib.es +34 971 17 2981 +34 971 17 3452
UEV	Elsa Lamy	Institute for Agriculture, Environment and Development (MED) Oral Biology and Salivary Proteomics Lab Universidade de Évora Polo da Mitra 7000-083 Évora Portugal	ecsl@uevora.pt +351 94 662 825

12.5 Future research

If separate consent has been obtained from the participant's parents/legal guardians, excess biological material may after completion of the SuperKids project be stored in research biobanks at Luxembourg Institute of Health (Luxembourg), Institut d'Investigació Sanitària Illes Balears (Spain), or Universidade de Évora (Portugal) for future research purposes.

Any future research use of stored excess biological material will require that the initiation institution of the future research receives an approval from the relevant ethical committee before analyses are conducted. Possible initiators include partners within the HealthyW8-consortium: Denmark, Germany, Luxembourg, Netherlands, Italy, Spain, Portugal and Bulgaria.

Future research use of excess biological material stored outside Denmark will be subject to the applicable national legislation of the receiving country. Future research projects will require review and approval by a competent research ethics committee or equivalent authority in the country where the research is initiated. Additional consent from participants may be required depending on applicable national legislation and the nature of the future research project.

12.6 Data protection

All stored material will remain pseudonymized and handled in compliance with GDPR and Danish data protection legislation.

Only authorized personnel will have access to identifiable data, and access to data will require a two-step authorization procedure where applicable.

13. Reporting Serious Adverse Events (SAEs)

In the event of unexpected serious adverse events (SAEs), the investigators will provide the ethics committee with the required information within 7 days of becoming aware of the event.

The study is expected to run from August 2026 to January 2028. At the conclusion of the study, the investigators will submit a list of all serious expected and unexpected adverse events, as well as all SAEs that occurred during the study period. This report will include an assessment of participant safety and will be submitted using the forms provided by the regulatory committee/system.

14. Confidential and private information

All personal data, including sociodemographic characteristics, health status, and clinical measurements, will be collected and processed in accordance with the EU General Data Protection Regulation (GDPR, 2016/679), the Danish Data Protection Act, and the rules outlined in the EU grand agreement (Appendix 11 section 15.2). Data will be pseudonymized using a unique participant ID, study number, and visit number. Only authorized personnel will have access to the key linking participant identities to study codes. The key will be retained securely for up to 5 years after the last participant completes the study and will then be destroyed.

Data will be processed only for the purposes of the study, following the principles of data minimization, integrity, and confidentiality. Data storage will use password-protected servers at each participating institution. Only pseudonymized data will be transferred, and no personal data will be sent outside the EU/EEA. Data will be anonymized prior to publication, and only aggregated data will be used for reporting.

15. Insurance

Study participants are covered by the Danish Patient Compensation (Patienterstatningen) in accordance with the Danish Act on the Right to Complain and Receive Compensation within the Healthcare System. Any injury resulting from participation in the study will be handled by the Danish Patient Compensation Association in accordance with applicable Danish legislation.

16. Financial support

The HealthyW8 study is financially supported by the European Union as part of the EU's research and innovation program. The Danish part of the project is conducted by the Technical University of Denmark (DTU, National Food Institute) in collaboration with local partners.

The total Danish budget amounts to €565,157.50, covering expenses for personnel, research activities, data collection, equipment, laboratory analyses, and dissemination of results.

16.1 Initiative for the study

The study is collectively initiated by the European HealthyW8 consortium, which the Technical University of Denmark (DTU) is a part of.

16.2 Financial management

Financial support for the study is provided through the HealthyW8 project funding structure.

Funding is administered by:

DTU Fødevareinstituttet

Adresse

Henrik Dams Allé
Bygning 202
2800 Kgs Lyngby

E-mail: food@food.dtu.dk
Phone: +45 35 88 70 00

16.3 Payments

Financial support is not paid directly to individual researchers but is allocated to the hosting institution (DTU) and managed according to institutional guidelines.

16.4 Conflicts of interest

The investigators have no financial ties to the funding bodies or other stakeholders that could influence the conduct or results of the study.

17. Publication of study results

The HealthyW8-study is registered on www.clinicaltrials.gov, an international registry for human clinical studies (NCT07011368).

The results of the study, whether positive, negative, or inconclusive, will be published in international peer-reviewed journals or presented at scientific meetings. In all publications or presentations, it will not be possible to identify the participants in any way.

The DTU team will lead and contribute to scientific publications based on data from the Danish intervention, as well as to joint publications involving data from HealthyW8 consortium partners. DTU will serve as lead institution for at least three publications based on Danish data.

In addition, the DTU team will participate in conferences and meetings focusing on social inequalities in health. Knowledge and insights gained from the study will also be shared with other municipalities that aim to reduce social inequalities in children's health. Dissemination will include various project outputs, such as videos produced as part of the study, to further communicate results and recommendations to a wider audience.

18. References

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19. Appendixes

- Participant Information Sheet (Appendix 1)
- Information from the Danish Research Ethics Committees on Health Research Ethics regarding participant rights (Appendix 2)
- Informed Consent Form (children) (Appendix 3a)
- Informed Consent Form (biobank) (Appendix 3b)
- Informed Consent Form (parents) (Appendix 3c)
- Power of Attorney Regarding Consent to Participation (Appendix 4)
- Protocol Summary (Danish) (Appendix 5)
- Questionnaires (Appendix 6)
- Advertising / Recruitment Materials (Appendix 7, 7a, 7b)
- HealthyW8 EU Protocol (Appendix 8)
- Information folders for the control group (Appendix 9)
- Information folders for the intervention group (Appendix 10)

- Chronic diseases for exclusion criteria (Appendix 11)
- Grant Agreement - GAP-101080645 (Appendix 12)
- Pre-screening Form (Appendix 13)
- Participant information for Parents (Appendix 14)