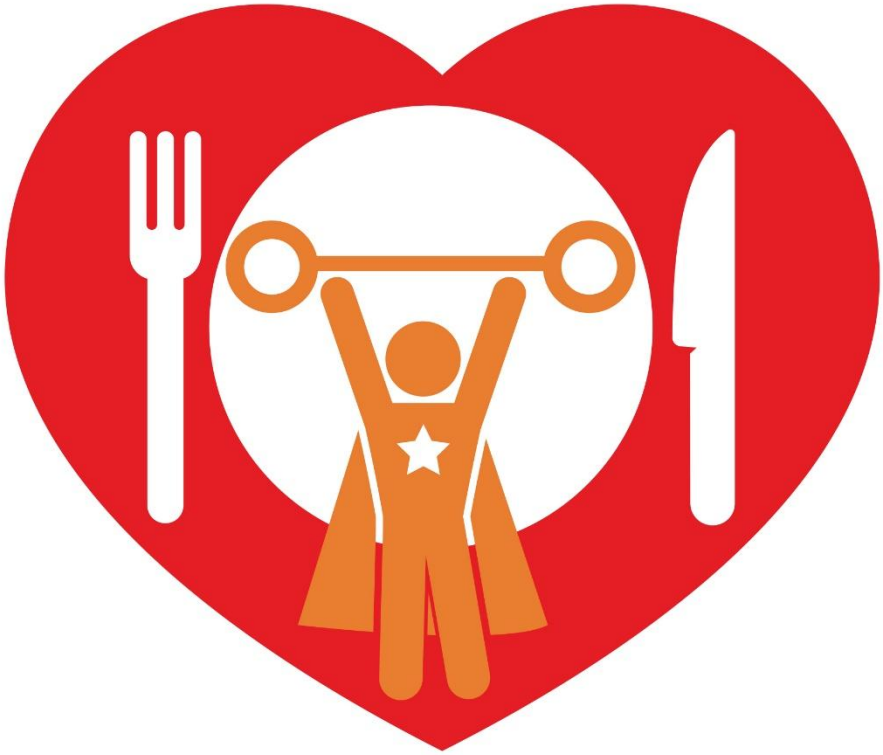

SUPERKIDS

Participant information

AUGUST 2026

For parents of children interested in taking part in the SuperKids study

We would like to ask whether you wish for your child to participate in the scientific study entitled: *Empowering Healthy Lifestyle Behaviour Through Personalized Intervention Portfolios to Prevent and Control Obesity During Vulnerable Stages of Life: The HealthyW8 Project.*

The project was initiated by the European HealthyW8 consortium. The Danish part of the project is conducted and led by the Technical University of Denmark (DTU).

The Danish part of the study is called *SuperKids*.

The study is conducted by researchers at the Technical University of Denmark (DTU National Food Institute) in collaboration with Fællesskabet Værebro, Social Balance and public health nursing in Gladsaxe Municipality, and several European partners.

Senior Researcher Gitte Ravn-Haren is the responsible lead researcher for the SuperKids study in Denmark.

Before you decide whether your child should participate in a scientific study, it is important that you have a full understanding of what the study is about and why we are conducting it.

The leaflet “The Rights of Research Participants in a Health Science Research Project.” is enclosed with this participant information sheet. We encourage you to read the leaflet carefully as it describes your rights as participants in a health research study.

You and your child will also be invited to an information meeting about the study, where this written information and participants’ rights will be reviewed. The information meeting will normally be conducted in Danish. If requested, it may be conducted in English. You will have the opportunity to ask questions if anything is unclear. You are also welcome to bring a companion to the meeting, for example a family member or a friend.

Please remember that you always have the right to take time to consider before deciding whether to sign the consent form.

Your child’s participation in the study is voluntary, and you may withdraw your consent at any time without giving a reason and without any consequences for you or your child.

Thank you for your interest in the study.

Table of content

1. About the SuperKids-study

1.1 Purpose

The purpose of the SuperKids study is to investigate whether a new digital health platform, in combination with local health-related activities, can support children in developing healthy habits related to diet, physical activity, and wellbeing, in order to prevent the development of obesity.

1.2 Background of the study

A recent report published by the World Health Organization (WHO) shows that one in three children in Europe is overweight. This development is partly because children grow up in societies designed in ways that make us move less, and where the easy availability of calorie-dense foods makes it easy to consume more calories than the body needs.

Children with overweight have an increased risk of developing type 2 diabetes, cardiovascular disease, and other chronic conditions later in life. In addition, overweight can affect a child's self-esteem and social wellbeing.

Because overweight in childhood often continues into adulthood, it is advantageous to prevent it early. However, many families find it difficult to establish and maintain healthy eating and exercise habits in a busy everyday life. Moreover, traditional approaches such as diet or exercise plans often have only short-term effects because they fail to consider the individual's daily life, motivation, and surroundings.

In SuperKids, you will have the opportunity to try out a digital tool that adapts to each user's needs and daily routines. Personalized recommendations, small challenges, games, and local activities are designed to make it more fun and easier to make healthy and enjoyable choices.

The goal is to determine whether this kind of personalized and digital support can help children (with support from their parents) establish and maintain healthy habits in a way that fits into everyday lives and thereby prevent the development of obesity.

1.3 Who can participate?

We invite children aged 5-12 with supports from their parent to participate in SuperKids. A child may participate if they meet inclusion criteria based on age and weight status. The overall assessment is based on screening:

- The child is overweight (based on BMI percentiles)
- The child drinks more than three glasses of soda or juice per week
- The child is physically active fewer than two times per week
- The child does not eat vegetables daily

To assess risk, we will also look at the child's waist-to-height ratio.

2. What does participation involve?

The study lasts for 12 months and includes a total of five main measurement time points: at baseline (0 months) and at 3, 6, 9, and 12 months. At baseline, 6 months, and 12 months, each time point is divided into two separate visits (R1 and R2). This means that you will attend a total of 8 physical visits during the 12-month study period (see Table 1 for an overview). Both children and parents are expected to participate in the visits.

Participation in the study involves both the child with the support of at least one parent. At several visits, both the child and a parent are required to be present, particularly in connection with measurements and questionnaires.

Parents will also be involved in completing questionnaires and, for the intervention group, in the use of the digital health platform.

Consent and/or power of attorney will be obtained from the parents who have custody of the child.

We will carry out measurements such as height, weight, blood pressure, body composition, and other relevant tests, which will be described in more detail below.

During the study, you will be asked to complete questionnaires about diet, physical activity, etc, and to collect biological samples from your child, including blood, urine, stool, and saliva. Children will be given an activity wristband that records physical activity.

We will schedule the visits at times that best fit your daily routine. More detailed information about the measurements and activities will be provided at the first visit.

Table 1: *Overview of the study visits and measurements for the child and parents.*

Measure points	Visit	Duration	What happens
0 months	R1	1,5 hours	Finger-prick blood sample, blood pressure, physical function test, collection of urine, saliva, and stool samples, distribution of accelerometer, completion of online questionnaires and food frequency questionnaire (FFQ).
	R2	1,5 hours (approx. 9 days later)	Return of accelerometer, completion of remaining online questionnaires, instruction in apps, activation of apps, distribution and synchronization of Garmin watch.
3 months	One visit	Short visit	Weight, height, waist, hip and thigh circumference, bioimpedance measurement, brief motivational talk about app use and participation.
6 months	R1	2 hours	Weight, height, bioimpedance measurement, blood pressure, physical function test, accelerometer worn

			for 9 days, completion of online questionnaires and FFQ, distribution of sample kits for urine and stool.
	R2	45 min (approx. 9 days later)	Finger-prick blood sample, collection of urine, saliva, and stool samples, return of accelerometer, completion of remaining online questionnaires.
9 months	One visit	Short visit	Repetition of weight, height, waist, hip and thigh circumference, bioimpedance measurement, brief follow-up on app use and participation.
12 months	R1	2 hours	Weight, height, bioimpedance measurement, blood pressure, physical function test, accelerometer, completion of online questionnaires and FFQ, distribution of sample kits for urine, saliva, and stool.
	R2	45 min (approx. 9 days later)	Finger-prick blood sample, collection of urine, saliva, and stool samples, return of accelerometer, completion of remaining online questionnaires.

2.1 Study design

The SuperKids study includes two groups. Participants are assigned to groups based on place of residence (i.e., not randomly). Group allocation determines which offers are available during the study:

2.1.1 If your child is in the intervention group

If you live in Værebro Park and surrounding areas, you will be part of the intervention group. This means that you:

- Will gain access to the digital health platform (apps)
- Will be offered local health activities focusing on movement, play, cooking, and community
- Will receive a Garmin smartwatch, which your child will wear during the study and may keep if you complete the study
- Will receive support and inspiration to work with diet, physical activity, and wellbeing

The local activities consist of organised sessions focusing on movement, play, cooking and community, led by research staff, trainers and students with relevant experience.

The purpose of these activities is to support the child in becoming more physically active in a motivating and safe way, and to provide inspiration for healthy and nutritious meals.

The digital platform includes small challenges and tools that the whole family can use together. For example, you can follow the child's activity, get inspiration for meals, and get support for everyday healthy choices.

2.1.2 If your child is in the control group

If you live in other areas of Gladsaxe Municipality (e.g., Høje Gladsaxe or Mørkhøj), you will be part of the control group. This means that you:

- Will participate in the same measurements, examinations, and questionnaires as the intervention group
- Will receive a Garmin smartwatch, which your child will wear during the study and may keep if the study is completed
- Will receive an information folder with official Danish recommendations on diet and physical activity

You will not have access to the digital health platform (apps) and will therefore not use them as part of the study.

You will also not be offered local health activities.

The material you receive may be used as inspiration in everyday life, but it is up to you how you choose to use it.

2.1.3 Common for both groups

Regardless of group assignment, you will:

- Participate in the same study visits
- Undergo the same measurements and provide the same samples
- Complete questionnaires about diet, physical activity, and wellbeing
- Contribute equally to the research

2.2 The study process

Before participating in the study, you and your child are invited to an information meeting, where you will receive verbal information about the study, including its purpose, procedures, and your rights as a study participant. There will be an opportunity to ask questions before you decide whether you wish to participate. Once the consent form is signed, the first visit will be scheduled.

At baseline, 3 months, 6 months and 12 months, participants in both the control and intervention group will undergo the measurements as shown in table 1. In addition, the intervention group will at baseline receive access to the digital health platform associated with the study, including apps providing recommendations and challenges.

The measurements and samples will be repeated to assess how your child's health and wellbeing have developed over the course of the year.

The examinations will primarily take place at Værebro Health Centre and in the Mørkhøj/Høje Gladsaxe area.

An overview of the study schedule and visit plan can be seen in Figure 1 below.

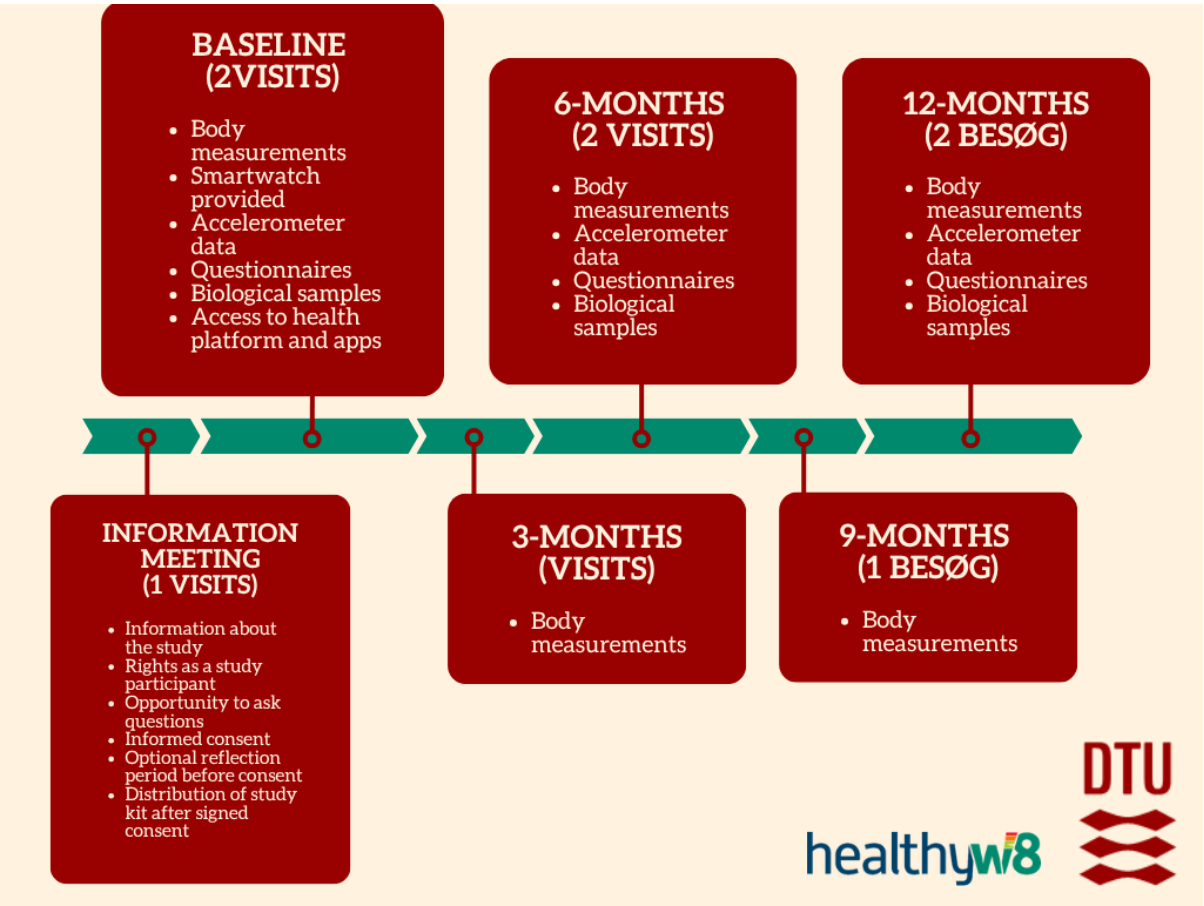

Figure 1: Overview of the Study Process and Visit Schedule (SuperKids)

3. Measurements and samples

3.1 Body weight and height

Your child's weight and height will be measured twice at each visit to ensure accuracy. Measurements are taken while the child is wearing no shoes and socks. Weight is measured using a digital bioimpedance scale, and height with a stadiometer, where the child stands upright with heels together.

From the height and weight, we calculate the child's Body Mass Index (BMI), which is weight in kilograms divided by height in meters squared (kg/m²). For children, BMI is not interpreted directly as for adults but is evaluated against age- and sex-specific BMI percentiles, which show how the child's weight compares with other children of the same age. It is important to note that BMI alone does not fully describe body composition. Therefore, we also perform more detailed measurements of body composition for a more accurate assessment.

3.2 Circumference measurements

At each visit, a few simple body measurements will be taken. The child will be asked to empty their bladder first. The measurements are taken with a soft, non-stretchable measuring tape.

- **Waist circumference:** Measured around the abdomen, approximately midway between the lowest rib and the top of the hip bone, while the child exhales calmly.
- **Hip circumference:** Measured around the widest part of the hips and buttocks.
- **Thigh circumference:** Measured midway between the groin and the upper edge of the knee.

These measurements are harmless and take only a few minutes. They help us assess body proportions and changes over time. Each measurement is repeated twice for accuracy and performed by trained staff.

3.3 Blood pressure

Your child's blood pressure will be measured to assess how the circulatory system is functioning and to check for any signs of elevated blood pressure. The measurement is taken with an automatic blood pressure monitor while the child sits relaxed with the arm supported on a table. To ensure an accurate result, the child will be allowed to sit quietly for a few minutes before the measurement is taken. Blood pressure is measured twice, with a short break in between, and the average of the two measurements is used as the result.
The procedure is completely harmless and takes only a few minutes.

3.4 Fat mass and body composition

To better understand your child's physical development, we will measure how body weight is distributed between fat mass, muscle mass (fat-free mass), and bone mineral content. This information provides a more detailed picture of the body's composition than BMI alone can offer.

3.4.1 Bioimpedance measurement

As a general method, body composition will be measured using bioelectrical impedance analyser (BIA). This is a safe and non-invasive technique that sends a very weak and harmless electrical current through the body to calculate how much of the body consists of water, fat, and muscle. The measurement takes only a few minutes and is performed while the child stands still on a scale-like platform.

3.4.2 DXA-scan

In some cases, we will also perform a DXA scan (Dual Energy X-ray Absorptiometry).
This method provides a highly precise image of the distribution of bone, muscle, and fat. A DXA scan takes about 10–15 minutes. During the scan, the child lies still on the scanning

platform while a movable arm slowly passes over the body. The child must wear light clothing without metal and remove any jewellery.

The radiation dose is approximately 0.001 mGy per scan, which is very low. If your child participates in both planned DXA scans, the total radiation dose will be approximately 0.002 mGy. The overall estimated lifetime risk of cancer is still considered to be very low. For comparison, natural background radiation in Denmark is approximately 3 mGy per year. The associated lifetime cancer risk is estimated to be very small (approximately 0.005%). DXA scanning uses ionising X-rays. Any exposure to ionising radiation may theoretically increase the risk of developing cancer later in life. However, the radiation dose used in this study is very low and the associated risk is considered very small. Overall, the method is considered safe with minimal risk.

3.5 Physical activity

Information on daily physical activity will be collected using an activity monitor called SENS Motion, which is designed to monitor physical activity. Your child will wear the activity monitor (SENS Motion) continuously for 9 consecutive days at baseline (0 months), and again after 6 and 12 months during the study. The activity monitor collects data automatically.

In addition, your child will wear a waterproof smartwatch (Garmin watch) throughout the entire study period (12 months) to record physical activity and sleep.

3.6 Handgrip strength

The handgrip measurement is performed using a handgrip dynamometer, which the child squeezes as hard as possible for a few seconds. The test is performed three times on the dominant hand, and the highest value is recorded. Handgrip strength provides information about the child's muscular strength and physical function. A strong handgrip is often associated with greater overall strength. The test is simple, quick, and causes no discomfort.

3.7 Step-up-test

To assess the child's physical fitness, a step-up test will be conducted. This test provides an indication of how efficiently the body can take in and use oxygen during physical activity. During the test, the child steps up and down from a bench at a steady pace for a few minutes. The test is adjusted to the child's age and fitness level so that it is neither too demanding nor too easy. After the test, the child's heart rate is measured to evaluate fitness. The test is safe and supervised by qualified health professionals.

3.8 Biological samples

To understand how diet and physical activity affect children's health, small biological samples will be collected from your child at selected study visits. The purpose of the biological samples is to examine how diet, physical activity, and wellbeing are related to the body's biological processes in children. The samples will be used to analyse various

biological and metabolic markers related to the risk of developing overweight, dietary intake, physical activity, and general health.

3.8.1 Samples to be collected from your child

The samples we collect at the study site are:

- Blood sample (finger prick)

The samples you will collect at home are:

- Urine sample (morning urine)
- Stool sample
- Saliva sample (collected in the morning)

3.8.2 Analyses of your child's samples

The analyses may include:

- Markers of metabolism (e.g. glucose and lipids in blood)
- Markers of dietary intake (e.g. in urine)
- Composition of gut bacteria (the microbiome) in stool samples
- Markers in saliva related to metabolism

The analyses are research-related and are not used for diagnosis or treatment.

The study is partly hypothesis-generating, meaning that the analyses may also be used to identify new relationships between lifestyle, environment, and biological processes.

3.8.3 Blood sample

At the study site, approximately two drops of blood will be taken from the fingertip (finger prick). The blood is used to analyse various health markers such as fats, sugars, and general indicators of the body's energy metabolism. The blood sample is taken by healthcare professionals experienced in blood sampling. Samples are collected at baseline (0 months), and after 6 and 12 months. The child will experience a small prick.

3.8.4 Urine sample

You will be asked to provide your child's morning urine sample in a sterile container provided by the study staff. Up to 120 mL of urine will be collected per sampling. A small portion of the sample may be divided into smaller aliquots for analysis. The sample is used to examine markers of dietary intake and metabolism. Urine samples are collected at baseline (0 months), and after 6 and 12 months.

3.8.5 Stool sample

The stool sample is collected at home using a special kit provided by the study staff. You will help your child collect a small amount (approximately the size of a pea) into a sealed tube containing a liquid that preserves the sample. The sample is used to analyse the composition of gut bacteria (the microbiome). Stool samples are submitted at baseline (0 months), and after 6 and 12 months.

3.8.6 Saliva sample

Saliva samples are collected at home using a special kit provided by the study staff. At each sampling time point, two saliva samples are collected (one at baseline and one approximately 30 minutes later - in collection tubes of approximately 50 mL). The samples are taken in the morning before breakfast and toothbrushing and are stored as instructed by the study staff until they are returned at the next visit. The samples are used to analyse biological markers related to metabolism. Saliva samples are collected at baseline (0 months), and after 6 and 12 months.

3.8.7 Results to participants

At the final study visit, participants will receive feedback on selected individual measurements obtained during the study, including for example body weight, body composition (bioimpedance), glucose measurements, and anthropometric measures. These results will reflect the participant's current health status based on the measurements performed in the study.

Results from the biological analyses will generally not be returned to individual participants, as these analyses are performed solely for research purposes and are not intended for clinical use.

Participants will have the opportunity to gain insight into the overall study results through scientific publications.

3.9 Interviews

As part of the project, some of the participating families will be invited to take part in an interview. The purpose is to gain a better understanding of how families experience the intervention - for example, what they find meaningful, motivating, or challenging, and how they use the digital tools and participate in the activities.

The interview takes place as an informal conversation, where you can freely share your experiences. Participation is voluntary, and it is completely acceptable to decline the invitation if you do not wish to take part.

4. What are the benefits?

4.1 For society?

This study has the potential to generate new knowledge about how digital, personally tailored solutions, in combination with local health-promoting activities, can affect children's health, well-being, and weight development. In clinical practice, the results may contribute to the development of more targeted and effective prevention strategies that consider each family's needs, daily routines, and life circumstances. Perhaps most importantly, the study has the potential to create a positive societal impact by providing parents and children with a practical and accessible tool to support healthy habits that can bring lifelong benefits.

4.2 What will you gain by participating?

Your child will receive a smartwatch to be worn on the wrist for the 12-month duration of the study, which you will be allowed to keep once the study ends. You will also gain valuable insight into your child's health and well-being, as well as their dietary and physical activity habits.

5. Are there any risks in participating?

There are no known significant risks associated with participation in the study, although unforeseen risks cannot be completely ruled out. During blood sampling, there may be mild discomfort and a very small risk of infection.

There may be unforeseen risks or inconveniences associated with participation that are currently unknown. If new information about risks becomes available during the study, you will be informed.

The study has been approved by the Scientific Ethics Committee of the Capital Region of Denmark (Journal No.: H-26002164) and is conducted in accordance with applicable ethical guideline.

If your child is selected for a DXA scan, he or she will be exposed to a very small amount of ionizing radiation (approximately 0.001 mGy per scan). The estimated lifetime risk of cancer is approximately 0.005% and is considered to be very low.

6. Participation in other studies

To ensure that the results of the SuperKids study are as reliable as possible, it is important that your child does not participate simultaneously in other research projects concerning diet, physical activity, well-being, or weight. If your child is already involved in another health-related study or program, please inform the research team before deciding whether to participate. This ensures that there is no overlap and that the results remain accurate and representative for this specific project.

7. Research biobank

The purpose of the biobank is to store biological material for use in the planned analyses in the study. The analyses will be completed no later than 30 April 2028.

Biological material is stored for different time periods depending on the storage location:

- Up to 5 years at the Technical University of Denmark (DTU)
- Up to 10 years at collaborating partners in Europe (Luxembourg Institute of Health (LIH), Universitat de les Illes Balears (IDISBA, Spain), and the Universidade de Évora (Portugal))

Urine, saliva, and stool samples will be collected three times during the study period and stored at -80°C at DTU until they are shipped to our collaborators for analysis in accordance with the SuperKids study protocol. The analyses will be conducted at DTU and at the designated European research centers affiliated with the study: the Luxembourg Institute of Health (Luxembourg), the Institut d'Investigació Sanitària Illes Balears (Spain), and the Universidade de Évora (Portugal).

Blood samples will be analyzed on an ongoing basis as part of the study. 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.

All biological material and associated data will be coded (pseudonymised) using a unique participant ID, group number, and visit number. The key will be stored securely at DTU and accessible only to authorized personnel at DTU for up to 5 years after the last participant visit, after which it will be destroyed. Personal data identifying participants (e.g. name and contact information) will be deleted at the end of the study.

Storage, handling, and any transfer of samples will comply with the Danish Data Protection Act and the EU General Data Protection Regulation (GDPR). No data or biological material will be transferred to countries outside the EU/EEA.

When the SuperKids study ends, the research biobank will be closed. Any remaining biological material will either be destroyed or, if you provide separate consent for this purpose, transferred to a research biobank at one of the project's collaborating institutions: the Luxembourg Institute of Health (Luxembourg), the Institut d'Investigació Sanitària Illes Balears (Spain), or the Universidade de Évora (Portugal), for future research.

If the material is used for future research in another European country, such use will be subject to the legislation applicable in that country. Future projects will normally require approval from a research ethics committee or equivalent authority and may in some cases require renewed consent.

8. Insurance and complaint procedure

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.

9. Financial aspects

The HealthyW8 study is funded by the EU's Research and Innovation Program.

The Danish part of the project is carried out by the Technical University of Denmark (DTU National Food Institute) in collaboration with local partners.

The total Danish budget amounts to €565,157.50 and covers costs related to staff, research activities, data collection, equipment, laboratory analyses, and dissemination of results.

The funds are not paid to individual researchers but are administered by DTU in accordance with applicable regulations. The investigators have no financial interests that could influence the conduct or results of the study.

10. Publication of results

This study is registered at www.clinicaltrials.gov, an international database for human clinical trials (NCT07011368). The study results, whether positive, negative, or inconclusive, will be published in international, peer-reviewed journals or presented at scientific conferences. When results are published, it will not be possible to identify your child in any way.

11. Ethical considerations and data handling

All personal data will be processed in accordance with the General Data Protection Regulation (GDPR) and the Danish Data Protection Act. Data will be pseudonymised and stored securely, and only authorized personnel will have access.

Responsibility for data processing is shared among the partners of the HealthyW8 consortium, all of which are based exclusively in European countries. As part of the HealthyW8 project, pseudonymized research data are therefore shared with collaborating partners in Luxembourg, Spain, Portugal, Germany, the Netherlands, Italy, and Bulgaria.

The purpose of this data sharing is to conduct joint research analyses and compare results across the participating countries.

Data sharing is carried out in accordance with data-sharing and data-processing agreements that ensure compliance with the General Data Protection Regulation (GDPR).

No personally identifiable information or data will be transferred to countries outside the EU/EEA.

Supplementary agreements on biological samples, biobanks, as well as with Gladsaxe Municipality and SENS exercise are also concluded in accordance with the GDPR.

12. If you would like to know more

If you would like your child to participate in SuperKids, or if you have any further questions or would like more detailed information, you are very welcome to contact us.

13. Withdrawal and interruption of the study

You may withdraw your consent and leave the study at any time without providing a reason and without any consequences.

If new, important information becomes available during the study, you will be informed. If this information is relevant to your child's safety, you will be asked to provide renewed consent to continue.

If you withdraw, you may voluntarily participate in a final visit and, if you wish, provide the reason for your withdrawal.

The study may also be stopped in whole or in part to protect the child's safety, if it is considered unethical to continue, or for organizational or financial reasons.

If the study is discontinued, this will not affect your future treatment options or your contact with the healthcare system.

14. Responsible investigators

Principal Investigator and Study Responsible: Gitte Ravn-Haren, Senior researcher

Medical Responsible: Jacob Borch, Medical doctor

15. Contact information

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16. Appendices

1. **"**Your rights as a participant in other trials involving humans, tissue, cells or trials with medicinal products approved under the directive (reported to The Regional Scientific Ethics Committees)"

2. Informed Consent Form
3. Power of Attorney