

# Information sheet

## REVAMP Study

# Participant Information for Participation in Scientific Research

## Revamp study

Research on Protein and Digestion

## Introduction

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a scientific study. Participation is voluntary. You can read about the scientific study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, complete the form in Appendix C.

## Ask your questions

You can take your decision based on the information in this information sheet. We also suggest that you do this:

- Put your questions to the investigator who gave you this information.
- Talk to your partner, family or friends about this study.
- Ask questions to the independent expert, Dr. Muhsen. For contact details, go to appendix A.
- Read the information on [www.rijksoverheid.nl/mensenonderzoek](http://www.rijksoverheid.nl/mensenonderzoek).

## 1. General information

The Division of Human Nutrition and Health at Wageningen University has set up this study. Researchers are conducting the study in the Helix building on the campus of Wageningen University. Participants in scientific research are often referred to as subjects. This study requires 39 subjects. The medical-ethical review board of the eastern region of the Netherlands, (Kamer 4) has approved this research.

## **2. What is the purpose of the study?**

The purpose of this study is to investigate the effect of proteins on digestion, body composition, and hormones. This study is not a weight loss study.

## **3. Wat is the background of the study?**

After the consumption of food, carbohydrates, fats, and proteins are broken down in the stomach and intestines and then absorbed. The composition of added proteins in food can influence this digestion processes. However, less is known about proteins that are naturally present in foods. Therefore, with this study, we aim to investigate whether proteins naturally present in food affect digestion, body composition and other physical responses such as hormones.

## **4. What happens during the study?**

Are you taking part in the study? It will take 7 weeks ( $\pm 70$  hours) in total.

*Step 1: Are you eligible to take part?*

First, we want to know if you are eligible to take part. For this study, we are looking for men and women who meet the following criteria:

- Between 21-50 years old
- Being able to read and understand English
- BMI between 21-27 kg/m<sup>2</sup>.
- Good general and mental health and appetite
- Commonly (5 out of 7 days a week) eating three meals a day approximately around the same times.

You cannot participate in the study if you:

- Have difficulties with swallowing, chewing, and/or eating in general
- Suffer from a disorder and/or (chronic) illness
- Have a history of low blood pressure
- Have unsuitable veins for blood sampling (as assessed by a trained nurse)
- Have no or reduced taste and/or smell, or have a taste/smell disorder
- Have braces or a mouth piercing (except for a dental wire)
- Have followed an energy-restricted diet in the last 2 months

- Currently use or in the past 3 months used prebiotics, probiotics, and/or antibiotics
- Gained or lost more than 5 kg body weight in the last six months
- Use medication that could affect study outcomes
- Underwent radiological examination in the last 7 days using iodine- or barium-containing contrast agents
- Underwent nuclear medical examination with isotopes in the last 7 days
- Consume on average more than 21 (men) or 14 (women) glasses of alcohol per week
- Are pregnant or planning to become pregnant
- Are breastfeeding
- Smoke (daily)
- Are not willing to stop using drugs during the entire research period (from Monday of week 1 to Monday of week 8)
- Are not willing to stop consuming alcohol during the test weeks (weeks 2+3 and 6+7)
- Engage in more than 4 hours of physical activity per week (except for cycling and walking at a normal pace and distance)
- Follow a vegetarian or vegan diet
- Have allergies or intolerances to any of the ingredients of the test meals
- Do not want to consume the test meals due to dietary habits, beliefs, or religion
- Signed up for participating in another research study
- Are an employee, thesis student, or intern in the Human Nutrition and Health department at Wageningen University.

After reading this information brochure, you can indicate whether you want to participate in this study. We will invite you to an information session on the campus (Helix, building 124, Wageningen University, see Attachment A). After the information session, we will let you know if you can participate in the study. If you are eligible, we will invite you to a screening morning.

In summary:

- You will attend one information session (approximately 2 hours). After this, we will determine if you can participate in the screening.
- You will attend one screening session (approximately 1.5 hours). After this, we will determine if you can participate in the study and discuss the schedule with you.

### **Information Meeting**

The information meetings will be held every 6-7 weeks. During these meetings, we will provide you with a detailed explanation of the study. If you decide to participate in the study, we will ask you to fill out and sign the informed consent form (Attachment C). If you need time to think about your participation, you can schedule a new appointment when you decide to join. You have a two weeks to consider whether you want to participate in the study. After signing the informed consent form, you will complete questionnaires which includes questions about your health, age, gender, eating habits, and dietary intake. In the questionnaire, we will also ask you to rate how much you enjoy certain food products and meals. Then, we will measure your height and weight. The meeting lasts approximately two hours. Afterwards, we will contact you via email or phone to inform you whether you can participate in the screening.

### **Screening**

When you have signed the informed consent and when you are eligible to participate according to the questionnaires in the information meeting, you will attend a screening session. The screening takes place at the Helix building in Wageningen. You will be asked to arrive at this session in fasted state. During the screening, your glucose and hemoglobin levels are determined using a finger prick, performed by a nurse. In addition, your blood pressure, salivary flow and eating behavior (carrot-test) will be measured. After which you will consume a full meal while being recorded on camera. Lastly, you will assess liking and familiarity of seven one-bite samples of the foods used in the study. This screening will last approximately 1.5 hours.

You have at least two weeks to decide if you want to participate. If you still wish to participate and the screening indicates that you are eligible, we will contact you to schedule the start of your 7-week test period.

Please note: It is possible that you are healthy but still not suitable to participate. The researcher will provide more information about this.

### *Step 2: Study procedure and measurements*

If you are eligible based on the screening, we will schedule your 7-week study period. The duration of the research is 7 weeks. In the first week, you will come to the Helix building three times, track your food intake in an application for 3 days, and wear two activity trackers, one on your leg and one on your hip. Afterwards, a 2-week test period follows. During these test periods, you will be asked to come to the Helix building on work days three times a day to consume your breakfast, lunch, and dinner. On the weekends, you do not need to come to the test location, but you will eat the meals provided by the researchers at home. You will return all leftover food to the researchers on Monday. Throughout the test periods, we will ask you to only

consume the food provided by the researchers. Once in these two weeks, you will come for a longer session (whole morning) in which blood will be drawn and you will lie in a reclined position with a hood placed over your head (ventilated hood). In addition, before and after each two-week study period, you will come for a longer measurement morning in which you will be asked to sit in the BODPOD and lay down for the DEXA scan. Furthermore, your fluid balance will be measured using Bio Impedance Analysis (BIA). Your weight, hip and waist circumference, and skinfold measurements will also be taken. More information about these measurements can be found in the Extra Measurement Information section below (page 9). After the first two-week test period, there is a less busy period of 2 weeks in which you will come to the research location three times and you will do the same as in the first week (tracking your diet in an app, wearing activity trackers). In this period, you will come to the research location two times for the following measurements of your body composition: DEXA scan, BODPOD, BIA, body weight, hip and waist circumference, and skinfold measurements (more information on page 9). After this period, you will participate in a second 2-week test period, which looks the same as the first test period. Throughout the entire 7-week test period, we will ask you to eat blue muffins four times, collect a stool sample six times, and collect urine for five Sundays.

All food products and meals we provide are available in supermarkets and will be prepared according to safety and hygiene rules. Examples of meals you can expect are listed in Attachment D. This is not a weight loss study, so you don't need to worry about getting hungry.

In summary:

- If you participate in the study, during two study periods of 14 days (a total of 28 days), you will:

- Only consume the food we provide;
- Come to the Helix building on work days to eat your breakfast, lunch, and dinner while being recorded on video (approximately 45 minutes per session). Before and after the meal, we will ask questions about your appetite and your liking of the meal;
- On weekends, consume the food we provide and return the leftover foods and packaging to the research location on Monday;
- Attend two longer study mornings where blood is drawn, and you lay down for the ventilated hood measurement;
- Attend four measurement mornings where your fluid balance is measured using BIA, a BODPOD and DEXA scan are conducted, and your body weight, hip and waist circumference, skinfolds and blood pressure is measured;

- Wear a glucose monitor and activity trackers
- If you participate in the study, in the week before the test periods, you will:
- Come to the university for a practice breakfast and dinner session;
  - Attend one longer study morning where blood is drawn and you lay down for the ventilated hood measurement;
  - Track your diet for 3 days using an app.
  - Wear activity trackers

The Breakfast, Lunch, and Dinner Sessions—replacing the preparation and consumption of your regular breakfast and dinner at home—align with regular working hours. This makes it easy to combine with activities at Wageningen University or nearby locations.

### **Test Period**

#### Week 1

During the first week, you will come to the Helix building three times. On Monday, you will have a training day to become familiar with the procedures during the test periods. You will consume breakfast and dinner at the research location, and you will receive lunch to-go, to familiarize yourself with the procedures for weekend meals. Additionally, we will provide you with two activity trackers, one to wear on your hip and another on your leg. You will also be asked to complete a questionnaire about your current dietary patterns. On Thursday, you will have a 'measurement test morning.' During this session, you will eat a standardized meal, and your blood will be drawn over 3 hours. This is explained further below (page 12). On Friday, we will measure your body weight, body composition and blood pressure. We will also arrange with you a day and time for a researcher to visit your home to deliver the items you need for the weekend package. The researcher will provide advice on how to follow the weekend procedure and how to prepare the weekend meals at home.

You will also be asked to collect urine for one day and take a stool sample. On three days, you will be asked to track what you eat in an application (Traqq app). These days will be spread over 2 work days and 1 weekend day.

#### Week 2 + 3

During 10 working days, you will consume breakfast, lunch, and dinner in the Helix building at Wageningen University. Each meal will last approximately 45 minutes. You can come to eat within the following times: breakfast: 8:00 – 8:45, lunch: 12:30 – 13:15, and dinner: 17:00 – 17:45. During these sessions, you will be recorded with a video camera, and you will fill out questions about the meal. Additionally, the following measurements will be taken:

- On Mondays, Wednesdays, and Fridays, your body weight will be measured
- Throughout the study period, you will wear a glucose monitor on your upper arm. This will be applied during the breakfast session on the Monday of week 2.
- Throughout the study period, you will wear two activity trackers, one on your leg and one on your hip.
- On the Thursday or Friday of week 3, you will have a 'measurement test morning' where you will eat a standardized meal, and your blood will be drawn over 3 hours. This is explained further below (page 13).

During the weekends, you do not need to come to the study location. During the baseline week (week 1), a researcher will deliver the materials needed for the weekend procedure. The day and time will be determined in consultation with you. On Friday, you will receive a package with your breakfast, lunch, and dinner for the weekend, divided into two crates (one with items for the fridge and one with items for outside the fridge). You will prepare these meals yourself with the help of the provided instructions. The preparation methods will be simple, and they will take into account the limited availability of kitchen equipment. We will ask you to take photos of the meals you prepare over the weekend. Additionally, we will ask you to bring back any leftover food and packaging to the research location on Monday. Furthermore, we will ask you to collect your urine over the weekend, which you will take back on Monday.

During the 14 days, you will only eat food products and meals that we provide, and you are not allowed to share your food with others. In addition to the food and water provided by us, you may consume water, coffee, and tea (without sugar and milk). You will need to keep track of these consumables. Please note: You can consume as much or as little of the food we provide. This is not a weight loss study, so you don't need to worry about getting hungry.

#### Week 4 + 5

During these two weeks, you may follow your own diet again. On the Monday of week 4, you will only come in the morning to return leftovers and empty packaging from the weekend. In addition, your body weight, body composition and blood pressure will be measured. In week 5, you will come to the Helix building twice. On Monday, your activity tracker on your leg will be replaced and on Friday, we will measure your body weight and body composition again. You will also take a stool sample on Friday.



Throughout both weeks, you will wear two activity trackers. Additionally, you will be asked to track what you eat in an app (Traqq app) on three days. These days will be spread over 2 work days and 1 weekend day.

Week 6 + 7

These weeks will be the same as week 2 + 3.

Week 8

The very last day takes place on Monday. During this Monday, you will return any remaining leftovers and packaging from the weekend, and we will measure your body weight and body composition one final time.

## **Extra Information about Measurements**

### Activity Trackers

During the study, you will be asked to wear two activity trackers: an ActivPal™ on your leg and an Actigraph™ on your hip. Below, you can see a photo of the activity trackers. The ActivPal will be pasted on your leg. Both activity trackers accurately record movement and store this data. By downloading the data with a computer afterwards, it will be possible to estimate the amount of activity you performed during the time you wore the device. It is not possible to exactly track what activities you did, only how much movements you made. There is **no** GPS receiver or any other form of location tracking. Therefore, we cannot determine your whereabouts. You are not allowed to swim with them, but you can shower while wearing them.



Source: Griffiths, B., Diment, L., & Granat, M. H. (2021). A machine learning classification model for monitoring the daily physical behavior of lower-limb amputees. *Sensors*, 21(22), 7458.



### Glucose Monitor

To monitor your blood sugar levels throughout the day, you will wear a continuous glucose monitor on your upper arm, which will be placed by a trained nurse. The monitor is a small device that you won't feel once it's in place. Below, you can see a photo of the monitor. You are not allowed to swim with it, but you can shower while wearing it.



Source: navorolphotography; <https://www.istockphoto.com/nl/foto/freestyle-libre-sensor-op-een-arm-gm1225965402-361046714>

### Urine and Stool

To gain insight in your digestion, urine and stool samples will be examined. You will be asked to collect urine and stool samples multiple times during the study period. You will collect your urine in urine collector containers provided by the researchers. We will provide you with instructions for collecting the stool sample, and you will receive these instructions to review at home. For collecting stool, we will provide the necessary materials, including a small tube with a cap and an attached spoon, as well as gloves. You should deliver your stool sample within two hours to the research location. Additionally, we will measure the transit time of your digestion by asking you to eat blue muffins four times. This will color your stool. We will ask you to report when your stool is colored blue/green after eating the muffins.

### Body Composition Measurement

To measure your body composition, we use the following methods: weighing with a scale, measuring hip and waist circumference with a measuring tape, determining fat and fat free mass with the DEXA scanner and BODPOD, and assessing fluid balance with Bio Impedance Analysis (BIA).

The DEXA scanner is often used to determine bone mass. In this study, we use the scanner to measure body composition. The DEXA scanner can measure your body composition using a small amount of X-ray radiation. The scanner detects what is absorbed by X-ray radiation and what passes through the human body. Differences in absorption by muscles, fat tissue, and bones allow for the measurement of body composition.



Source: National Health Service; <https://www.nhs.uk/conditions/dexa-scan/what-happens/>

The BODPOD is used to measure your body composition. During this measurement, you will wear bathing clothes and will spend 15 minutes inside a BODPOD cabin. By measuring differences in air pressure, the BODPOD can determine your body volume within minutes.



Source: Nutritional Assessment Platform; <https://nutritionalassessment.nl/bodpod/>

BIA is used to measure your body's fluid balance. By using electrodes placed on your hand and foot, a weak electric current is sent through your body. This measures your body's resistance. You will not feel the weak electric current and this current is not dangerous. In the figure down below the set-up of the BIA is displayed.



Source: Fresenius Medical Care; <https://5.imimg.com/data5/SJ/UA/MY-8488004/electrode-cable-bcm-m351351.pdf>

### Measurement Test Mornings

Three times (Tuesday or Wednesday of week 1, Thursday or Friday of week 3 and week 7), you will have a "measurement test morning." During this morning, you will consume a fixed portion meal while being recorded with a video camera, and blood will be drawn at different timepoints. Early morning, a cannula (tube) will be inserted by a trained nurse. 10 and 5 minutes before the meal, and on different timepoints 3 hours after consuming the meal, we will collect blood from you 10 times via the cannula. This will amount to a total of 99 mL blood on the first measurement test morning, and for the other sessions, it will be 97 mL blood per morning. These blood samples are necessary to measure substances in your blood, such as hormones. During the measurement, for 30 minutes before and after the meal, you will lay on a bed with a transparent hood (ventilated hood) connected to a breathing tube over your head to measure your breath composition. This provides more information about your digestion.



Source: Wageningen University & Research; <https://www.wur.nl/nl/product/MAX-II-metabolic-cart-including-ventilated-hood.htm>

## **5. What agreements do we make with you?**

We want the study to go well. That is why we want to make the following agreements with you:

- You will keep your physical activity levels consistent throughout the test periods, not engaging in intense sports;
- You will have the same dinner and evening snack on Sunday in week 1 and week 5;
- You will not swim while wearing the glucose monitor and activity trackers;
- You will consume only the food provided in the study and will not share it with others;
- You will only consume beverages such as water, coffee, and tea (without milk and sugar) during the test periods;
- You will not use any drugs throughout the entire study period (7 weeks);
- You will arrive and attend all planned test sessions.

It's important that you contact the researchers if:

- You test positive for Covid-19, experience Covid-19-like symptoms, or have been in close contact with someone who has tested positive.
- You feel unwell or have a cold;
- You intend to start using medications, including homeopathic remedies, natural remedies, vitamins, or over-the-counter medications;
- You no longer wish to participate in the study;
- Your contact information changes (e.g., your phone number or email address).

## **6. What side effects, adverse effects or discomforts could you experience?**

The products offered to you are available in the supermarket and may contain (traces of) meat, wheat, rye, barley, oats (gluten), soy, sesame, egg, milk, lactose, nuts, peanuts, and lupine. We do not expect any risks or side effects from your participation in the study, since all products will be produced according to hygiene standards. If you experience side effects from the products provided in the study, please report this to the researcher. The meals will comply with Dutch dietary guidelines, and you can receive dietary advice from an experienced dietitian after the study, if desired.

The measurements performed are safe and have few disadvantages. The measurements with the DEXA and BIA are safe. The X-ray radiation used with the DEXA scanner is <math><1 \mu\text{Sv}</math> and <math><4 \mu\text{Sv}</math> over the entire study period. For comparison, the radiation exposure from a standard chest X-ray is about 1000  $\mu\text{Sv}$ .

*What are the possible discomforts you may experience with checks or measurements during the study?*

Collecting your stool and urine samples may be perceived as unhygienic or unpleasant. If you are not comfortable with this, you can stop participating in the study at any time. The measurement test morning may involve inconveniences. You must lay still on a bed under a transparent hood for 60 minutes. You are allowed to listen to music to alleviate boredom. If you feel uncomfortable under the hood, you also have the right to stop participating in the study at any time. The placement of the cannula can be painful or cause a local bruise. It may also happen that placing the cannula does not work immediately, in which case we will make a second attempt in consultation with you. If you are not comfortable with it, you can stop participating in the study at any time. It can also happen that the cannula no longer functions correctly and blood cannot be drawn. In that case, we will decide, in consultation with you, whether a new cannula can be placed. However, this occurs sporadically. In total, we will collect 97-99 ml of blood per session from you. This quantity does not pose problems for adults. For comparison, the blood bank collects 500 ml of blood at a time.

## **7. What are the pros and cons if you take part in the study?**

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.

You yourself do not benefit from taking part in this study. But if you take part you will help the investigators to get more insight into the effects of proteins on digestion, body composition, and hormones. Upon completion of the study, you will receive compensation (see Section 11).

Taking part in the study can have these cons:

- You may feel uncomfortable during the measurements.
- The continuous glucose monitor may cause discomfort.
- You may gain or lose weight.
- The time required to participate.
- The agreements you must follow.

*You do not wish to participate in the study?*

It is up to you to decide if you wish to participate in the study.

## **8. When does the study end?**

In these situations, the study will stop for you:

- You have completed the 7-week test period;
- You choose to stop participating in the study. You can do this at any time. Please notify the researcher immediately. You do not need to provide a reason;
- The researcher believes it is in your best interest to stop, for example, because you cannot or will not adhere to the study rules;
- One of the following authorities decides that the study must stop:
  - Wageningen University;
  - The government, or;
  - The medical ethics committee evaluating the study.

*What happens if you stop participating in the study?*

The investigators use the data and body material that have been collected up to the moment that you decide to stop participating in the study.

## **9. What happens after the study has ended?**

*Will you get the results of the study?*

About one year after the study has ended, the investigator will inform you about the most important results of the study.

## **10. What will be done with your data and body material?**

Are you taking part in the study? Then you also give your consent to collect, use and store your data and body material.

*What data do we store?*

We store the following data: your name, address, date of birth, and information about your health. Additionally, we collect, use, and store your video recordings.

*What body material do we store?*

We collect, use, and store your blood, stool, and urine samples.

*Why do we collect, use and store your data and body material?*

We collect, use and store your data and your body material to answer the questions of this study. And to be able to publish the results.

*How do we protect your privacy?*

To protect your privacy, we give a code to your data and your body material. We only put this code on your data and body material. We keep the key to the code in a safe place in Helix. When we process your data and body material, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.



The code will also be used for video recordings. However, it is not possible to fully anonymize the videos. Video recordings will not be (digitally) published or shared with individuals not directly involved in this research. Researchers will ask for your permission to use your video for presentations. Only with your written and oral consent the researchers can use them.

*Who can see your data?*

Some people can see your name and other personal information without a code. This could include data specifically collected for this study, but also data from your medical file. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- Members of the committee that keeps an eye on the safety of the study.
- The members of the research team can access your data. These individuals will keep your data confidential.

We ask for your permission to allow access to these individuals. If you sign the informed consent form, you agree to the collection, storage, and access of your personal data and video recordings. The Healthcare and Youth Inspectorate can access your data without your consent. Your collected data will be made available online in anonymous form on Open Science Framework (osf.io). This is done to comply with the FAIR principles (Findable, Accessible, Interoperable, Reusable). You will not be traceable. If you sign the informed consent form, you agree to this.

*For how long do we store your data and body material?*

We store your data for 15 years in a digital database on an internal network, which is secured with a personal password known only to the researchers. The code key is kept for 5 years.

We store your body materials in the research location. They will be stored for 10 years in order to be able to make new assessments related to this study in the course of this study. If no longer needed, we will destroy your body material.

We will keep your video recordings for up to 5 years after the publication of the study results. You can indicate on the informed consent form whether you agree with this. You can withdraw your consent at any time. Your video recordings will then be destroyed, but if your video has already been analyzed, the results will be used for publication/research purposes.

*What Happens with Unexpected Findings?*

During the study, we may incidentally discover something that is not directly relevant to the study but may be important for your health. The researcher will then contact your general practitioner. You will discuss with your general practitioner or specialist

what should be done. The costs of this fall under your own health insurance. You give consent with the form to inform your general practitioner or specialist. Please note that the measurements we conduct are for research purposes, not for making a medical diagnosis.

*Can You Withdraw Your Consent for the Use of Your Data?*

You can withdraw your consent for the use of your data at any time. Inform the researcher of your decision. However, be aware that if you withdraw your consent and the researchers have already collected data for a study, they may still use that data.

*Can we use your data and body material for other research?*

Your collected data and your (remaining) body material may also be important for other research. For this purpose, your data and body material will be stored in the research centre for 10 years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent? Then you can still take part in this study.

*What happens if there are coincidental findings?*

It is possible that during the study we discover something that is not directly relevant to the study but is important to your health. In that case, the independent doctor will ask you to contact your doctor. You will then discuss what needs to be done with your doctor or specialist. The cost of this will fall under your own insurance policy. With the form, you give consent to inform your doctor or specialist.

*Can you take back your consent for the use of your data?*

You can take back your consent for the use of your data at any time. Please tell the investigator if you wish to do so. This applies both to the use in this study and to the use in other research. But please note: if you take back your consent, and the investigators have already collected data for research, they are still allowed to use this information. The investigators will destroy your body material after you take back your consent. But if assessments with your body material have been carried out, the investigator can continue to use the results.

*Do you want to know more about your privacy?*

- Do you want to know more about your rights when processing personal data? Visit [www.autoriteitpersoonsgegevens.nl](http://www.autoriteitpersoonsgegevens.nl).
- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this

is For your study, that would be Mr. WFEM (Frans) Pingen. Email: [privacy@wur.nl](mailto:privacy@wur.nl) (Appendix A).

- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Data Protection Officer of the institution (Appendix A) or the Dutch Data Protection Authority. Or you can submit a complaint to the Dutch Data Protection Authority.

*Where can you find more information about the study?*

You can find more information about the study on the following website: [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). After the study, the website may display a summary of the results of this research. To locate the study, search by the study number (to be filled in after registering with [ClinicalTrials.gov](http://ClinicalTrials.gov) before the start of the study).

## **11. Will you receive compensation if you participate in the study?**

The 84 meals for the study will cost you nothing. In addition, you will receive compensation of €1200 gross and an additional €300 upon completing the entire study. So, the total compensation is €1500, including travel expenses. If you discontinue participation during the testing period (the 7 weeks), you will receive compensation based on the duration of your participation, calculated from the €1200. If you cannot participate after the screening session, you will receive €50.

Wageningen University is obligated to report the compensation you receive for your participation in this study to the Tax Authority (Belastingdienst). You are also required to declare this compensation in your Income Tax return. We will provide the following details to the Belastingdienst: the compensation you have received, your Citizen Service Number (BSN), name, address, and date of birth. We will not disclose the purpose of this compensation. Consequently, the Belastingdienst will not know that you participated in research, nor to which study it pertains. More information can be found on the website of the Belastingdienst.

Please note that you are allowed to receive a maximum of €1900 in volunteer compensation per year without incurring tax. Keep this in mind if you receive other compensations in addition to this study. For more information, see [https://www.belastingdienst.nl/wps/wcm/connect/bldcontentnl/belastingdienst/privewerk\\_en\\_inkomen/werken/werken-als-vrijwilliger/vrijwilligersvergoedingen/vrijwilligersvergoedingen](https://www.belastingdienst.nl/wps/wcm/connect/bldcontentnl/belastingdienst/privewerk_en_inkomen/werken/werken-als-vrijwilliger/vrijwilligersvergoedingen/vrijwilligersvergoedingen).

## **12. Are you insured during the study?**

Insurance has been taken out for everyone who takes part in this study. The insurance pays for damage caused by the study. But not for all damage. You can find more information about this insurance and any exceptions in **Appendix B**. It also says who you can report damage to.

### **13. Do you have any questions?**

You can ask questions about the study to the research team. Would you like to get advice from someone who is independent from the study? Then contact the independent expert Dr. Naguib Muhsen, for contact details go to appendix A. He knows a lot about the study, but is not a part of this study.

Do you have a complaint? Discuss it with the investigator or the doctor who is treating you. If you prefer not to do so, please visit the complaints officer of Wageningen University and Research. Appendix A tells you where to find this.

### **14. How do you give consent for the study?**

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, fill in the consent form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

### **16. Appendices to this information**

- A. Contact Information
- B. Insurance Information
- C. Informed Consent Form
- D. Examples of Meals

**Attachment A: Contact Information**

**Principal Investigator:**

Prof. dr. Ciarán Forde  
Wageningen University  
Division of Human Nutrition and Health  
Helix building 124, room 1057  
6708 WE Wageningen  
Phone: +31317487120  
Email: Ciaran.Forde@wur.nl

**Coordinating Investigator:**

dr. Marlou Lasschuijt  
Wageningen University  
Division of Human Nutrition and Health  
Helix building 124, room 1062  
6708 WE Wageningen  
Phone: +31631089704  
Email: Marlou.lasschuijt@wur.nl

**Independent Physician:**

Dr. Naguib Muhsen,  
PRA Health sciences  
Euclideslaan 1  
3584 BL Utrecht  
Email: nmuhsen@hotmail.com

**Complaints:**

Eveline Waterham  
Division of Human Nutrition and Health  
Wageningen University  
Helix (building number 124)  
Stippeneng 4  
6708 WE Wageningen  
Email: eveline.waterham@wur.nl

**Institutional Data Protection Officer:**

Wageningen University & Research Data Protection Officer  
Mr. WFEM (Frans) Pingen  
E-mail: privacy@wur.nl

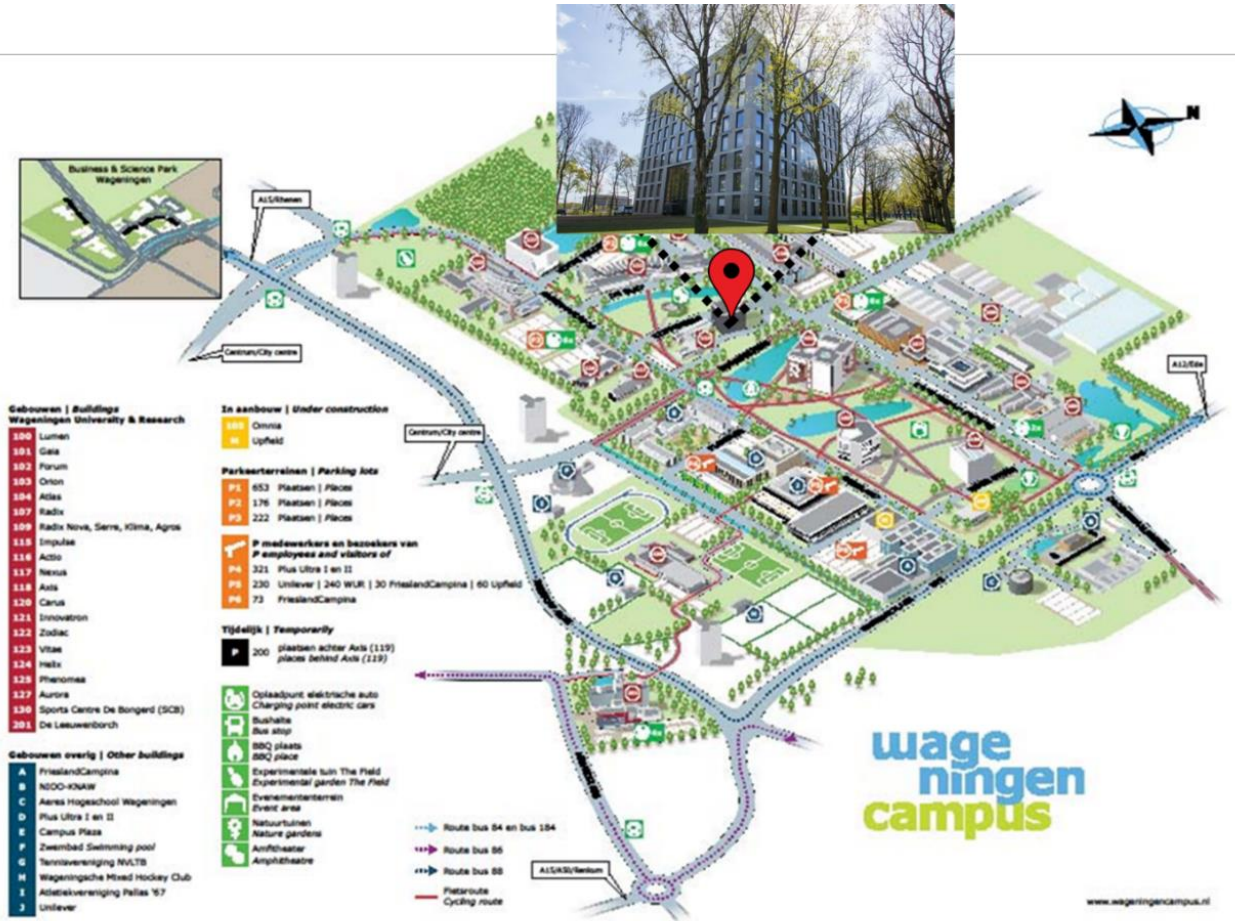
### Investigation site

Wageningen University

Helix (building 124)

Stippeneng 4

6708 WE Wageningen



## Attachment B: Information about Insurance

Wageningen University has taken out insurance for everyone who takes part in the study. The insurance pays for the damage you have suffered because you participated in the study. This concerns damage you suffer during the study or within 4 years after you participated in the study. You must report damage to the insurer within 4 years.

The insurance does not cover all types of damage. At the bottom of this text, a brief explanation is provided of the types of damage that are not covered.

These provisions are stated in the Medical Research Involving Human Subjects Act. This decree can be found on [www.ccmo.nl](http://www.ccmo.nl), the website of the Central Committee on Research Involving Human Subjects (see 'Library,' and then 'Laws and Regulations').

Have you suffered damage as a result of the study? Please report this to this insurer:

**The insurer for the research is:**

Name insurer:	HDI – Global SE
Address:	Postbus 925, 3000 AX Rotterdam
Telephone number:	+31 (0) 10 40 36 100
Email:	<a href="mailto:info@nl.hdi.global">info@nl.hdi.global</a>
Policy number:	V-055-862-396-3 / V0100109572

The insurance pays a maximum of € 650,000 per person and a maximum of € 5,000,000 for the entire study. There is a maximum of € 7,500,000 for all research conducted by Wageningen University per insurance year.

Please note: The insurance does **not** cover the following types of damage:

- Damage due to a risk about which we have given you information in this sheet. But this does not apply if the risk turned out to be greater than we previously thought. Or if the risk was very unlikely.
- Damage to your health that would also have happened if you had not taken part in the study.
- Damage that happens because you did not follow directions or instructions or did not follow them properly.
- Damage to the health of your children or grandchildren.
- Damage caused by a treatment method that already exists. Or by research into a treatment method that already exists.

## Attachment C: Informed Consent Form for Study Participants

Belonging to Revamp

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give consent to collect and use my data and blood, urine and stool. The investigators only do this to answer the research questions of this study.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- I give consent for the researcher to provide me and my general practitioner with information on unexpected findings from the study that are relevant to my health.
- I understand that the measurements collected as part of this study are not intended for diagnostic purposes.
- I give consent for my data to be stored for up to 15 years after this study.
- I give consent for my body materials to be collected, used, and stored for up to 10 years.
- I give consent for video recordings of me to be made and for these videos to be used as described in the information brochure.
- I give consent for my video recordings to be stored and kept for up to 5 years after the publication of the results.
- My data may be used for follow-up research that aligns with the current study.
- I give consent for my anonymous, unidentifiable data to be made available online.
- I want to participate in this study.

I give consent to store my data to use for other research, as stated in the information sheet. Yes  No

I give consent to have my (remaining) body material stored for use in answering research questions directly related to the current study, as stated in the information sheet. The body material is stored for this purpose for another 10 Yes  No

I consent to the storage of my video recordings for use in other research, as outlined in the information brochure. The video recordings will be stored for a maximum of 5 years after the publication of the results. Yes  No



I give consent to ask me after this study if I want to participate in a follow-up study. Yes  No

I consent to having my anonymous data made available online. Yes  No

My name is (participant):

Signature:

Date: \_\_/\_\_/\_\_

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I declare that I have fully informed this subject about the study mentioned.

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative): .....

Signature:.....

Date: \_\_/\_\_/\_\_

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## **Bijlage D: Examples of the meals**

### Breakfast:

- Smoothies
- Yogurt (with cereal)
- Breakfast rolls and bagels
- Sandwiches
- Topped crackers, rice cakes, and crispbreads
- Scrambled eggs
- American pancakes

### Lunch:

- Breakfast rolls and bagels
- Sandwiches
- Salads
- Soups
- Savory pancakes

### Dinner:

- Mashed potatoes, meat, and vegetables
- Stew
- Pasta and gnocchi
- Fried rice and noodles (Bami/nasi)
- Rice dishes
- Stuffed wraps
- Topped flatbread
- Flammkuchen
- Salads