1495 UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

Name of Study:	**Assessing the nutritional sufficiency of HEmp food as part of a LOW CARBON footprint diet (HELOW CARBON study)**
Study Chief Investigator:	**Dr Madalina Neacsu**

You are invited to take part in a nutrition intervention study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. You must be able to understand English and the study documents to take part.

Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

The purpose of this study is to assess nutritional sufficiency of hemp rich diet as part of a low-carbon footprint diet in comparison with a high-carbon footprint diet.

Why have I been chosen?

You have been chosen because you are aged between 18-70 years old, BMI 18-35 kg m^{-2}, consuming meat and living in Scotland.

You cannot take part if:
- you have food allergies and/or are coeliac.
- you are not eating meat
-suffer with severe stomach or bowel conditions, diabetes, liver disease, cancer/on active cancer treatment, took antibiotics within the previous three months,
-are line managed or supervised by CI or study PI

Do I have to take part?

No. It is up to you to decide whether you want to participate.
If you do, you will be given this information sheet to keep and be asked to sign a consent form.

You can withdraw at any time without giving a reason. If you do withdraw from the study, any sample or data collected up to this point may still be used (unless you ask for your data to be destroyed).

What will happen if I take part?

If you agree to join, after signing a consent form, and passing the screening you will be invited to participate in a randomised crossover design human dietary intervention. This will involve two short visits and two six hours morning visits to the Human Intervention Studies Unit (HISU) at the Rowett Institute like described in the study diagram (Figure 1).

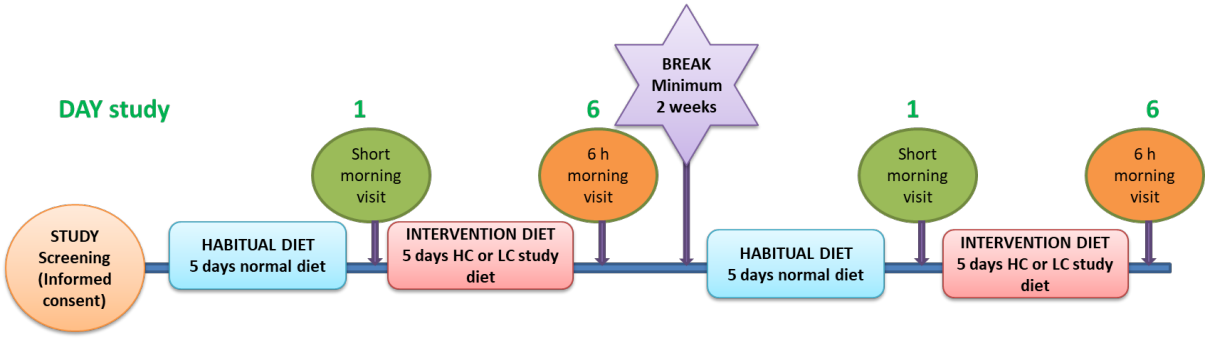

Figure 1: Study diagram

The screening: Comprises measurements of body weight, waist circumference and height, arm venous access check and the completion of a self-reported medical questionnaire.

Habitual diet: Comprises recording of a 5-day weighed dietary intake of your normal diet. You will follow your normal diet which you will record into a provided food diary combined with measurement of appetite during your usual waking hours.

The short morning visit: Consists of a short visit in the morning at HISU for providing a faecal sample (produced in the same morning or night before the visit), a urine and saliva sample and a blood sample of around 13 mL (less than a tablespoon).

The **INTERVENTION DIET:** consists of a 5-day high-carbon footprint diet (HC) and a 5-day low-carbon footprint diet (LC) which will have each a 3-day rotational menu of a balanced diet cooked entirely by the HISU.

The breakfast, lunch and dinner meals of both diets will contain 30% fat, 15% protein, 55% carbohydrate (~550 kcal per meal for females and ~750 kcal per meal for males, the deficit will comprise of drinks and snacks), representing a normal balanced diet with 2000 kcal/day for females and 2500 kcal/day for males, which reflects a typical UK meal/diet composition/intake.

For the LC diet we will replace part of the main food ingredients of a HC diet with hemp food ingredients (fat, carbohydrates and protein). During the INTERVENTION DIET you need to record all the food and drinks consumed (including the left over) in a food diary that will be provided.

In the food diary for the INTERVENTION DIET, will be included the questionnaires for the measurement (hourly) of hunger and appetite during your normal waking hours.

The six hours morning visit: On the morning of the sixth day following the **INTERVENTION DIET** you will visit the HISU for approximately six hours. You will be asked to come fasted (to not eat ten hours prior to this visit) and you will be served a low- or a high-carbon footprint breakfast.

You will bring with you a faecal sample (produced at your home same morning or night before the morning visit). Before you are served the study breakfast. A trained cannulist will insert a cannula into your arm for the blood collection. The sampling of urine, saliva and blood will be done as described in figure 2, below. A total of 72 mL (approximately five tablespoons) of blood will be collected during this visit. After the blood sampling period (five hours), the canula will be removed from your arm and you will be served a normal lunch. You will be served water during the five hours blood, urine and saliva collection.

Prior to each morning visit we advise drinking plenty of water. This will would reduce risk of blood sampling failure and potential withdrawal from the study.

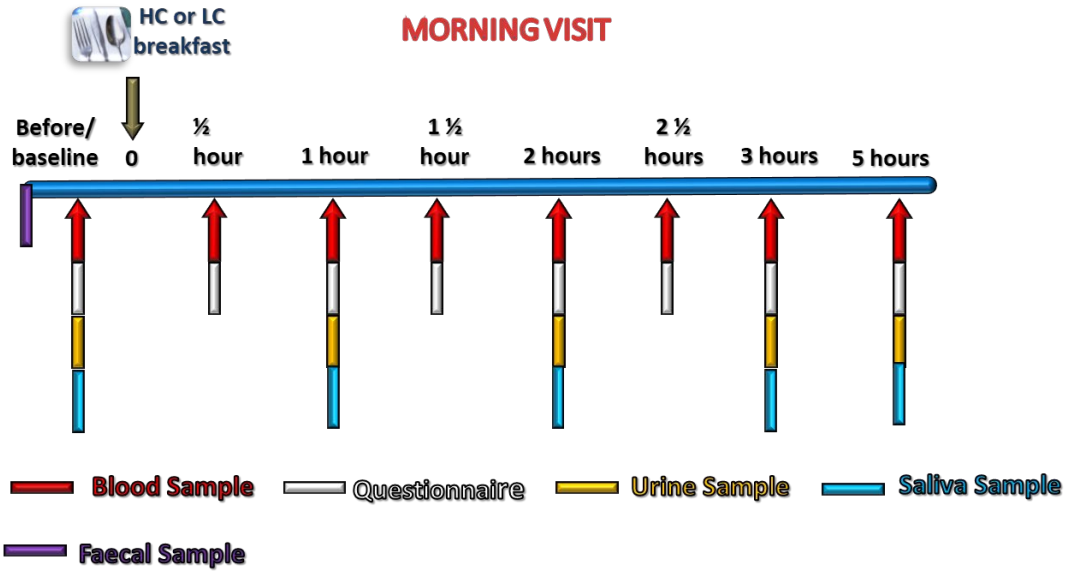

Figure 2: Six hours morning visit sampling diagram

During the INTERVENTION DIET periods you will be provided with coffee, juice and tea but you can drink water as much as you want. Alcoholic drinks are not allowed to be consumed during the INTERVENTION DIET periods.

You will be invited to come and collect all your food and drinks from the Rowett Institute during the INTERVENTION DIET period. You will be required to come only one time to collect your food as the food for the first days will be provided to you in the first short morning visit of each study intervention.

You will have a minimum break of two weeks between the INTERVENTION DIET periods (including your normal diet) as described in figure 1 (study diagram).

What will happen to the samples I give? What happens to my results?

Data will be collected using questionnaires, forms and food diaries and will be stored in secure electronic files on study-specific shared drives or locked cupboards and filing cabinets until and after the analysis. This data and the data collected during the measurements performed on the collected biological samples will be recorded in laboratory notebooks and secure electronic files on study-specific shared drives. All samples will be collected and stored in an anonymised form.

The biological samples collected will be anonymised and measured using specialised techniques for several metabolites of phytochemicals, fat, protein and carbohydrates. The bacterial DNA will be extracted from faecal samples to understand how the diet we provide will affect your gut microbiota.

We will inform your GP about your participation in the study only in case of out of clinical range parameters measured in any of the biological samples or the presence of blood in your stool. We will therefore ask for your consent to do this and ask you to provide your GP name and address at the time of recruitment.

All electronic data will be stored for 10 years after the end of the study in a secure University of Aberdeen Shared Drive. Archiving will only occur once all relevant paper data has been published, we estimate this will be for five years. The paper data will be archived for 10 years following publication of the project, in line with the institutional retention schedule.

Will any genetic testing be done?

No genetic testing of human DNA will be carried out on your samples at any time. We will only study the microbes that are present in the donated faecal samples.

What are the possible benefits of taking part in the study?

You will be provided with all the meals and drinks for 10 days (5 days of high carbon footprint diet and 5 days of low carbon footprint diet). The study may not help you personally, but the information we collect will help us understand if we can use hemp-based foods to reduce the carbon footprint of our diets while we can deliver a balanced diet and whether this will have additional health benefits.

"What are the possible disadvantages and risks of taking part?"

The inconvenience will be the time spent in the morning visits at the Rowett Institute; potentially if you will dislike some of the meals we provide and the very minor risk and /or discomfort associated with the blood sampling.

What if there is a problem?

Potentially for you the hemp-based foods are a new culinary experience. Hemp is not a listed allergen, and its protein has low allergenicity, which means it is well-tolerated by most people and not likely to cause an allergic reaction. However, people can develop an allergy to any food at any time.

If you notice potential side-effects (listed below) when consuming hemp-based food products, stop taking the products and to contact your GP or A&E department:
Irritation: itchiness, swelling, and puffiness of the eyes, and the skin in general.
Hives: in the forms of skin rash, plaques, or pale red bumps.
Allergic Rhinitis: sneezing, running nose, and nasal congestion.
Asthma: difficulty in breathing, tightness in the chest, and abnormal lung function.
Conjunctivitis: pink and/or red bloodshot eyes.
Anaphylaxis: skin rash, nausea, vomiting, difficulty in breathing, and shock. If you're having an allergic reaction with signs of anaphylaxis, you should immediately call 111 or your local medical emergency number.

At any time during the study, if you have a complaint or concern that you have been unable to resolve with the Chief or Principal Investigator, you can contact the Deputy Director Professor Frank Thies who is Head of the Human Studies Management Committee and independent of the study. You can be assured that Professor Thies will treat your concerns sympathetically and confidentially. He can be contacted by phone on 01224 437954, and email to: f.thies@abdn.ac.uk.

Expenses and payments

You will not receive any payment for your participation in this study. However, £50 will be paid to cover your travel costs during this study.

Who has reviewed this study?

This study has been reviewed by the University of Aberdeen, Rowett Institute's Human Studies Management Committee and ethically approved by their Ethical Review Panel.

Who is organising and funding the research?

The study is being run by the University of Aberdeen and is funded by Scottish Government, RESAS. The research team involved will not be paid for including you in this study.

Will my taking part be kept confidential?

All the information we collect about an individual will be kept strictly confidential within the research team. Information about the identities of the volunteers will be stored in locked facilities. Anonymised data will be stored on a computer database under the UK's data protection law guidelines. Your participation in the study will be kept confidential, and you will not be identified in any report or publication.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information by asking one of the research team and at www.abdn.ac.uk/about/privacy/.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If data will be used for future research: If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Paper study documents will be archived in line with the University of Aberdeen's archival policy. Archiving will only occur once all relevant paper data has been published. It is expected that paper data will be published within 5 years after collection and will be archived for 10 years after publication, in line with the institutional retention schedule. The chief investigator will hold an electronic copy of the generated data indefinitely, on one of the University's backed-up Shared Drives.

More on the University's policy: Data Protection policy.pdf (abdn.ac.uk)

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