**PARTICIPANT INFORMATION SHEET**

<table>
<thead>
<tr>
<th>Name of Investigator:</th>
<th>Dr Wendy Russell</th>
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<tr>
<td>Name of Study:</td>
<td>The MORINGA Study</td>
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You are invited to consider taking part in a research study, which investigates if the plant *Moringa oleifera* could be an important source of protein, vitamins and minerals in human diet. Before you decide whether to participate, 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.

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

**What is the purpose of this study?**

Lack of adequate nutrition is the single biggest contributor to child mortality. Malawi is amongst the countries most affected.

This human study is part of a wider collaborative project “MORINGA; delivering nutrition and economic value to the people of Malawi”, investigating the possibility of establishing *Moringa oleifera* as an economically viable crop which will contribute towards launching a resilient food supply chain in Malawi that will deliver essential nutrients across the population.

*Moringa Oleifera* (also known as the Miracle Tree) is common throughout in Malawi. Moringa leaves can be repeatedly cropped and are rich source of important for the human diet compounds. These nutritional characteristics give Moringa the potential to significantly contribute in Malawi’s battle against malnutrition.

The aim of this study is to evaluate the availability of key dietary components in the human body when Moringa is consumed.

**Who can participate?**

We are looking for healthy men and women, aged 18+. To qualify, the interested volunteers should fulfil the criteria listed below.

Subjects are not:
- Taking prescribed medication
- Pregnant / breastfeeding
- Given a blood donation in the last three months
- Unable to give written informed consent
- Experiencing eating disorders
- Taking vitamin or mineral supplements (unless they agree to discontinue supplementation 2 weeks before the start of the study)
- Experiencing food allergies / intolerances
What will happen to me if I take part?

Screening session

During this session, we will explain the study and give you the opportunity to ask any questions you may have. If you are happy to continue, we will ask you to complete a consent form. At this meeting, we will ask you some general questions about your health and get you to fill out a short questionnaire. If you fulfil all the criteria, you will be invited to participate in the study and will be offered to test some moringa powder sprinkled on a baguette. At this session, we will give you a food diary to complete over three days before entering into the study and we will explain to you how to keep the diary so that we can assess what foods you have consumed. We will ask you to avoid certain foods, which contain a high amount of the compounds in which we are interested (phytochemicals). Phytochemicals ("phyto" means "plant") are compounds that are produced by plants. They are found in fruits, vegetables, grains, beans, and other plants. The food diary will provide a list of foods that you can eat, and those that you should avoid. We will provide dinner for the evening before the intervention sessions and during the day of the intervention.

Your participation in the study will involve you coming for two intervention sessions (four study visits) to the Human Nutrition Unit (HNU) at the Rowett Institute on days selected by you - see Figure 1 below.

Figure 1.

Intervention sessions (study visits 1 & 3)

During the intervention sessions you will be asked to consume one of the two types of test meals:

1. **Corn Soya Porridge** (containing maize, soya and vitamin/mineral premix)
2. **Corn Moringa Porridge** – (containing maize and moringa but not soya and vitamin/mineral premix)

The ingredients for the test meals will be sourced from national suppliers. The Moringa powder will be supplied from Malawi. The meals will be delivered in form of a thick porridge (20g dry matter boiled in 125
ml of water). Both intervention sessions will be identical in all aspects except for the composition of the experimental meals.

The protocol for the intervention sessions is illustrated in Figure 2 bellow.

**Figure 2.**

![Figure 2](image)

On the day of the intervention session, you would have to attend the HNU in the morning in a fasted state (i.e. not having taken any food and drinks except water after 10 pm the previous evening). Upon your arrival, we will measure your height and weight and will calculate your BMI. We will also ask you to provide a urine sample. We will then insert a cannula in one of your arms. Following first blood sample collection, we will invite you to consume one of the test meals, following which period we will collect blood samples at 15min, 30min, 1h, 3h and 5h post-meal consumption. The total amount of blood sampled will be approximately 6 tablespoons. At time-points 1h, 3h and 5h we will also collect a urine sample (see Figure 2).

Five hours following the test meal, the cannula will be removed. We will provide you with lunch low on phytochemicals and you will be free to leave the HNU. We will ask you for the rest of the day to follow a diet low on phytochemicals. We will also ask you to collect all the urine you have void overnight.

**Post-intervention sessions** (study visits 2 & 4 - will last approximately 1 hour)

On the next day, following the intervention session, we will invite you to attend the HNU in the morning in a fasted state. We will ask you to provide a urine sample and we will collect the overnight urine sample you have brought. We will then take a blood sample (approximately 2 teaspoons). At the end of the session, breakfast will be provided and you will be free to leave the HNU.

Each treatment session will be followed by at least one-week washout period before crossing over to the second treatment.
Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. If you initially think you would like to participate but change your mind, you are free to withdraw at any time, without providing a reason. A decision to withdraw will not affect the standard of care you receive.

What will happen to the samples I give?

The University complies with the Data Protection Act and each participant will be assigned a unique anonymising code. All information will be treated with the strictest confidence. The University monitors research projects, so individual (anonymised) data may be accessed for this purpose. Your samples may be kept for up to ten years after the study is completed. After this period we will destroy your samples.

Expenses and payments

We will reimburse a maximum of £50 for any travel costs to and from the Rowett Institute.

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

This study may not be of direct benefit to you, but the information you provide will help us find out if Moringa could be an important source of protein, vitamins and minerals. The information will be used to develop strategies in adding a piece in the puzzle of tackling the hunger in Malawi.

What if there is a problem?

At anytime during the study, if you have a complaint or a concern that you have been unable to resolve with the Principal Investigator or Human Nutrition Unit Manager, Mrs Sylvia Stephen (01224 438607, sylvia.stephen@abdn.ac.uk), you may contact the Head of the Human Studies Management Committee, Professor Baukje de Roos, University of Aberdeen, Rowett Institute, Foresterhill, Aberdeen AB25 2ZD (01224 438636, b.deroos@abdn.ac.uk) or the Director of the Rowett Institute, Professor Peter Morgan (p.morgan@abdn.ac.uk, 01224 438642).

Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute, and received ethical approval from the Rowett Human Studies Ethical Review Panel.

Who is organising and funding the research?

The study is funded by a grant from the Biotechnology and Biological Sciences Research Council, sponsored by the University of Aberdeen and run by the Rowett Institute.

Will my taking part be kept confidential?

Your participation in the study will be kept confidential.
## CONTACTS FOR STUDY

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<th>Name: Dr Wendy Russell</th>
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