1495 UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

Name of Investigator:	Tilly Potter Baukje de Roos

Name of Study:	MI-DIET – Modelling Individual Determinants to Intervention using Ecological Tracking

You are invited to take part in a research 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.

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 aim of this study is to identify what factors, unique to you, affect whether you respond to a food intervention with wholegrains and nuts, by lowering your blood pressure or cholesterol levels. Your 'responsiveness' may be affected by, for example, your usual cholesterol levels or your weight, but may be related to other factors, including fluctuations in your sleep patterns or mood, or by the effect of others around you. Through measuring these factors, we aim to identify why people respond to interventions in different ways, despite consuming the same foods. The results from this study will hopefully help us to tailor dietary interventions to individual people in the future.

Why have I been chosen?

You have been chosen because you fulfil our inclusion criteria:

- You have expressed an interest in participating in this study
- You are aged 18-75 years
- Your systolic blood pressure (top number of a blood pressure reading) is in the mildly elevated range, between 120-140mmHg, **and/or**
- Your diastolic blood pressure (bottom number of a blood pressure reading) is in the mildly elevated range, between 80-90mmHg
- You have a BMI between 18-35 kg/m^2
- You typically eat fewer than 7 portions of wholegrain foods a week (such as brown bread, oatmeal and wholemeal pasta)
- You own a smartphone that is capable of running an app to measure your blood pressure during the study which you are happy to have installed on your phone.

Do I have to take part?

Participating in this study is voluntary. If you decide to participate, we will screen you to see whether you are eligible to take part and provide you with a consent form to sign. Should you change your mind later, you can withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard care you receive.

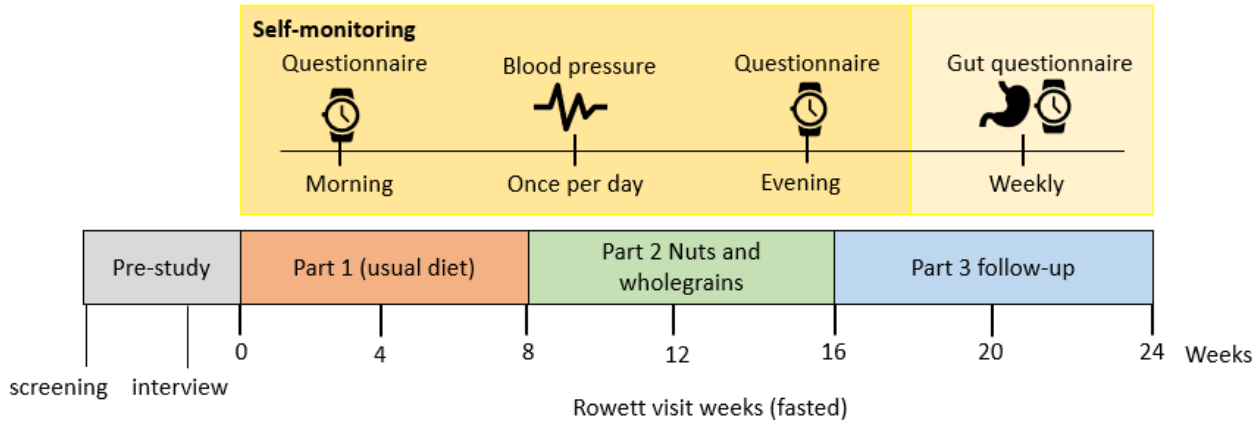
What does the study involve?

Screening and interview

There will be a pre-study screening visit to see if you are eligible to take part. Prior to your visit you will be contacted by a nurse from the human nutrition unit to inform you of the procedures that will be in place to mitigate coronavirus (COVID-19). During the screening visit we will measure your height, weight and blood pressure, and ask you about your consumption of wholegrains and any food allergies. If eligible, you will be given a series of questionnaires to complete at home about your typical eating behaviour, your general health (and a separate women's health questionnaire if you are female), typical activity levels and sleep quality. These questionnaires should take approximately 30-45 minutes to complete. Once you have sent us your questionnaires, we will then arrange an interview via videocall to find out more about your habits and discuss your preferences for the study, which will take a maximum of 1 hour. You do not have to provide responses to any questions you are unhappy or uncomfortable with. The personalised questions you receive during the study (more information below) will depend on your responses to the questionnaires you complete together with information you provide during the interview. Therefore, the more information you give the more we can tailor the questions delivered to you during the study.

Study schedule

The actual study will take place over a period of 24 weeks, split into three 8-week sections (see diagram below). For the first 8 weeks you are requested to maintain your usual diet and physical activity habits. During the following 8 weeks you will be provided with wholegrains and nuts to include in your diet. For the final 8 weeks we will stop providing you with these products. You will visit the Rowett institute for a total of 7 short visits every 4 weeks to provide a single blood sample. You will be given a calendar including the dates of visits and the activities and measurements that are part of this study. At the interview prior to the start of the study, we will arrange a time and preferred method with which to contact you each week, to ask how you are getting on with the measurements and answer any questions you may have.



Self-monitoring

During the whole study, you will be in control of monitoring your own blood pressure once a day at a time convenient to you. This will be done with an easy to use, wireless "QardioArm" blood pressure monitor that works with your phone (see image below left). We will show you how to use the device at the week 0 visit. You should be seated and rested for 5 minutes prior to taking each measurement, which takes approximately 3 minutes.

The Qardio blood pressure monitor (left) and PRO-Diary wrist device (right).

You will also wear a wrist-worn device each day, called a PRO-Diary (see image above right). The device monitors your activity levels and sleep quality through measuring movement. It also delivers personalised questionnaires to help identify what factors may affect your blood pressure and how you respond to the intervention. The questionnaires are answered by using the touch-sensitive bottom slider to make a response selection, and the top right button to confirm 'OK'. You will answer two short questionnaires each day: one in the morning (~1 minute) and one in the evening, at times convenient to you – the device will alert you with a beep or buzz. The evening questionnaire should take no longer than 3 minutes to complete, apart from one evening a week where a few extra questions will be asked about your gastrointestinal (gut) wellbeing. If you are unhappy or uncomfortable with any question(s), you do not have to continue providing responses to those questions, and any responses given to the question(s) will be removed from further

analysis. If this is the case, please let one of the research team know and we will remove the question from the PRO-Diary at your next visit to the Rowett institute.

Approximately 2 weeks into the study you will receive an email link to complete a 24-hour food intake questionnaire online, which will take approximately 30 minutes. This questionnaire will be repeated every 4 weeks (at weeks 6, 10, 14, 18 and 22). Please try to report your previous day's food intake as accurately as you can within 2 days of receiving a request to complete the questionnaire (this will be on a weekday).

Throughout **all** 24 weeks of the study and between each visit to the Rowett Institute (see section below), you should continue to measure your blood pressure and wear the PRO-Diary to respond to the questionnaires daily, or as often as you can. The more responses you give, the better we will be able to examine what personal factors affect your responses.

During the 24 weeks, your blood pressure readings are likely to vary from day to day and over time - this is perfectly normal (see example image from the Qardio app below). We are interested in these fluctuations over time, including during the wholegrains and nuts intervention. Do not be alarmed if you do not see a noticeable reduction in blood pressure during the intervention. It could take up to 8 weeks for any effects of the intervention foods to be shown, which may not be obvious just by looking at your results. You should therefore continue to consume the wholegrains and nuts for the full 8 weeks.

The Qardio app is built-in with an irregular heart rate detector, which may be triggered if you are moving or speaking during measurement. If you have any concerns about your blood pressure results please contact the study team at any time. If we feel that your blood pressure is too high or your heart rate is consistently irregular we will let you know. In this instance, we will monitor your results more closely or contact your doctor with your permission.

Visits to Rowett institute

The first visit after your interview (week 0) will mark your start of the study. During this visit we ask you to arrive fasted so we can take a small blood sample of 10ml from the vein of your arm to measure your cholesterol levels. This means that we ask you not to eat or drink anything except water from 10pm the night before. You will be given instant feedback on your cholesterol levels. We will also measure your weight and blood pressure, and you will be provided with a light breakfast that you can take away if you wish. We will then provide you with the devices you will use throughout the study with some guides for your reference. We will show you how to apply and use the blood pressure monitor in conjunction with the mobile app. We will also demonstrate how to answer questionnaires using the PRO-Diary wrist device. The device should remain charged for 4 weeks, but we will provide you with a charging cable just in case the battery runs flat. The whole visit should take no longer than an hour and a half.

For the following 6 visits (at weeks 4, 8, 12, 16, 20 and 24) we will also ask you to arrive fasted so we can collect another small blood sample of 10ml. Each visit should take no longer than half an hour. At each visit, your blood pressure and weight will be measured. We will ask you to send us your blood pressure measurements from the Qardio app on your phone to check how often you have taken your blood pressure, and compare that to the maximum number of measurements you could have taken. We will also briefly assess how often you completed the PRO-Diary questionnaires, before swapping the device to another fully-charged one for the next 4 weeks. The questions asked will remain the same (unless there are any questions you wish to be removed). If you have missed more than 30% of questionnaire responses or blood pressure readings, we will recommend extra prompts or reminders (e.g. text messages), or a change to the times you are prompted, to enable you to respond more easily. If your response rates are consistently below 50% we will be unable to keep you on the study. This is because we require multiple measurements and responses to be able to perform the personalised analysis.

After your third visit (week 8) you will begin the 8-week intervention period and will be provided with a variety of nuts (almonds, hazelnuts and walnuts) and a choice of wholegrain foods (agreed with you at the pre-study interview) to take home with you. You will also be provided with dietary advice about a blood-pressure lowering diet. We advise that you consume the nuts in place of another snack you would usually consume, and to eat wholegrains in place of refined grain foods (e.g. white bread and pasta). You are advised to consume 1 portion of nuts (30g or one handful) and 3 portions of wholegrains a day, all of which will be provided throughout the intervention alongside a portion size guide. You are welcome to swap to different wholegrain products during the intervention period if you let us know what products you would like in advance, from a list that we will provide. According to your preference, you can arrange to collect items from the Rowett Institute or receive delivery of the products for the remainder of the intervention period, though you will automatically be given products at your week 12 blood sampling visit.

From your fifth visit (week 16), we will stop providing you wholegrains and nuts, but you will need to continue measuring your blood pressure and providing questionnaire responses on the PRO-Diary device.

At your final visit (week 24), you will return the PRO-Diary device and after giving your final blood sample of 10ml, receive the same questionnaires you carried out after your screening visit to complete at home. This marks the end of the study.

What will happen to the samples and responses I give?

All samples we take and all questionnaire responses and activity data we receive from your device will be coded to ensure anonymity. Blood samples will be processed and stored in secured designated freezers for a maximum of 5 years. Samples, questionnaire responses and activity data are only accessible by the Aberdeen research team, and will not be shared with, or stored by, the company providing funding for this study.

Expenses and payments

You will receive a total of £100 upon completion of the study as a contribution towards travel costs and your time spent during the study. You will also get to keep the wireless Qardio blood pressure monitor you will use during the study (but not the PRO-Diary wrist device), which is worth £89.95.

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

By taking part in this study you will receive daily feedback on your blood pressure and monthly feedback on your cholesterol levels. At the end of the study you will receive a report detailing which factors unique to you are associated with fluctuations in your blood pressure levels. The information we obtain from this study will inform us about how personalised factors can affect health and wellbeing, and enable us to better tailor individual dietary interventions in the future.

What if there is a problem?

If you have any complaint about the way you have been dealt with during the study, or any possible harm you might suffer, please get in contact with one of the investigators (Tilly Potter or Baukje de Roos) as soon as possible and we will try to immediately address the problem. If you prefer to speak to an independent person please feel free to contact Mrs Sylvia Stephen, Human Nutrition Unit Manager, at 01224 438607 or sylvia.stephen@abdn.ac.uk

Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee and the Rowett Ethics Committee.

Who is organising and funding the research?

This study is organised by the Rowett Institute. The research is joint funded by the Biotechnology and Biological Sciences Research Council UK (BBSRC) and Unilever Research and Development, The Netherlands.

Will my taking part be kept confidential?

Yes. All of your data will be coded and stored in lockable cabinets or on password-protected computers. The code that can link the data to you will be kept separately. Any publications arising from these data will not identify you as a participant. Any individualised questions or responses will be referred to using minimal non-identifiable characteristics such as age and gender only.

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