# PARTICIPANT INFORMATION SHEET

**Name of Investigators:** Teresa Grohmann  
Baukje de Roos

**Name of Study:** PRECISE - PRECISion nutrition approach to modulate metabolic health with Extracts

You are invited to take part in a research study. 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 (you can find the contact details on page 7 if anything is not clear or if you would like to have more information.

<table>
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<th>What is the purpose of this study?</th>
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<td>We want to test whether a commercially produced food supplement containing bilberry and grape seed extracts will lower your blood glucose and cholesterol levels. In addition, we want to understand if your response to this food supplement can be explained by the way you absorb and process the compounds in the food supplement or by differences in the type of microbiota in your gut, or other characteristics such as gender, age, body weight, genes and lifestyle factors.</td>
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### 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 45 years or older.
- You have a BMI higher than 28 \( \text{BMI} = \frac{\text{weight (kg)}}{\text{height}^2 (m^2)} \)
- You are either healthy or pre-diabetic
- You have an HbA1c (glycated haemoglobin) value at or above 5.5\% OR a Diabetes Risk Score in the Moderate Risk range (≥20 points)

You are not eligible to participate in this study if you:

- take the following medication regularly: any kind of medication affecting blood glucose metabolism, blood lipid metabolism, and blood pressure; antibiotics, aspirin and aspirin containing drugs
- have taken food supplements and/or vitamins in the past month
- are allergic/intolerant to certain food
- are diagnosed with diabetes, renal, hepatic, gastro-intestinal diseases
- are smoking

### Do I have to take part?

Participating in this study is voluntary. If you decide to participate, we will screen for eligibility and if eligible, provide you with a consent form to sign. Should you change your mind later, you can withdraw at any time without giving a reason. If you decide to withdraw from the study, your data/samples will be destroyed immediately. 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?

There will be a pre-study visit to see if you are eligible to take part. We will measure your height and weight and assess your Diabetes Risk Score. Further, this visit will include a
finger prick blood sample to analyse your HbA1c, and you will be asked to complete two short questionnaires – one about your health and one about your exercise pattern.

This study will take place over a period of 24 weeks. In these 24 weeks, you will receive a combination of bilberry and grape seed supplements for 12 weeks, and placebo supplements for 12 weeks, in random order. We will ask you to take the supplement twice a day – before your breakfast and before your dinner.

During this 24-week period, we will ask you to visit the Rowett Institute on 11 different occasions as indicated in the graph and the text below:

The study diagram: ♦ blood samples (from vein and finger), ▲ stool samples, ■ oral glucose tolerance test, • 24-hour blood pressure, ♠ buccal swab, * AGE Reader measurement. CGM=continuous glucose monitoring; FD=food diary

You will be given a diary, and we will send you regular (text) messages or emails, to remind you of the activities and measurements that are part of in this study.

The first visit (0w) will be just prior to you starting the study. During this visit we ask you to provide a faecal sample (which you can bring from home) to measure the type of microbiota in your gut. We will also collect a DNA sample by rubbing a buccal swab.
against the inside of your mouth. This sample will be analysed for three specific genetic markers, FTO, TCF7L2 and CEPT, which have been associated with obesity and diabetes, as well as with the responsiveness of glucose and lipid levels to diet. In addition, we will take a small blood sample (10mL, which is about 1 tablespoon) from the vein in your arm, as well as some finger prick blood, to assess your glucose and lipid levels, as well as how the compounds in the supplements are metabolised in your body. We will also perform an oral glucose tolerance test. This test involves drinking a glass of water that contains a set amount of sugar. We will sample your blood before drinking the sugar solution and two hours afterwards in order to determine how quickly your body lowers the glucose load.

The next five visits (at 8w, 9w, 10w, 11w and 12w), and the last five visits (at 20w, 21w, 22w, 23w, 24w), take place during the last 5 weeks of each 12-week intervention period, when you will be taking either the bilberry and grape seed supplement combination, or the placebo supplements. During these visits, which are one week apart, we will take a small blood sample of 10mL from the vein in your arm, and a finger prick blood sample, to measure your glucose and lipid levels, as well as how the compounds in the supplements are metabolised in your body. During the first of each of the 5 visits, we will fit you with an automated blood pressure sensor, which measures your blood pressure every 20 minutes during the day and hourly during the night for 24 hours. During the last of each of the 5 visits, we will take a faecal sample, and perform an oral glucose tolerance test, as described above.

During the last two weeks of each intervention period, we would like to assess the variability in your daily blood glucose concentrations using a continuous blood glucose measurement sensor (CGM). This sensor is going to be attached to the backside skin of your upper arm and will stay attached for two weeks. To obtain blood glucose data we will ask you to scan the sensor every 8 hours using either your mobile phone or the provided reader.
At the visits of week 8, week 12, week 20 and week 24 we will assess the level of AGEs (Advanced Glycation End products) in your skin. AGEs accumulate in cells over a person’s life time, but this process occurs more rapidly in people who have cardiovascular disease or diabetes. The AGE Reader measures the accumulation of AGEs in the tissue of the lower arm via non-invasive, painless ultra violet rays. We will ask you to press your lower arm into the foam cushion of an AGE Reader for 12 seconds.

The last thing we would like you to do is to record and weigh your foods, drinks and meals for a week in a food diary, just prior to providing a stool sample (i.e. before the first visit to the Rowett Institute, half way through the study and at the end of the study).

During all 11 visits to the Rowett we require you to be fasted. This means that we ask you not to eat or drink anything from 10pm the night before (although you will be allowed to drink water). A breakfast will be provided after the blood sampling.

The first, middle and last visit (at 0, 12 and 24 weeks) will take around 3 hours of your time. All the other visits should last 30-60 minutes. We will try to schedule the visits at a time that is convenient for you.

Throughout the period of this study we would like you to keep your dietary and exercise habits.

What will happen to the samples I give?
All samples we take are going to be coded to ensure anonymity. Samples will be stored in secured designated freezers for a maximum of 5 years. Samples and personal data from these samples (i.e. data on blood biomarkers, gut microbiota and DNA markers) are only accessible by the Aberdeen research team, and will not be shared with, or stored by, the companies that are funding the study, providing the supplements or are analysing the DNA samples.

**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. Original study records will only be kept for a maximum of five years from the study end date. Only the study team in Aberdeen will have access to your records and data. Any publications arising from these data will not identify the participants.

**Expenses and payments**

After your final visit you will receive £100 as a contribution towards any travel costs incurred.

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

This study might not help you personally, but you will receive detailed information about your personal health and diet. The information we obtain from this study will help us to develop individualised health interventions or guide future policy.

**What are the possible disadvantages and risks of taking part in this study?**

During the study you will be giving a small amounts of blood. There may be a slight discomfort during the drawing of blood from the vein. Other than this brief discomfort, the risks of having a small amount of blood taken should be minimal.

**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 (Teresa Grohmann 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 funded by the nutraceutical company By-Health.

CONTACTS FOR THE STUDY

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