Quadram Institute Science Health Food Innovation

The BETA Study

Broccoli Effect on Glycated Haemoglobin (HbA1c) Study

NHS
Norfolk and Norwich University Hospitals
NHS Foundation Trust

IRAS ID: 281010

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Broccoli Effect on Glycated Haemoglobin (HbA1c)

You are being invited to participate in a research study lead by researchers at the Quadram Institute Bioscience (QIB). To help in your decision to participate in this study, this information booklet has been provided. It contains important information about why this research is being done and what activities you will be asked to do while you are on this study. We understand that this booklet contains a lot of information so please take your time to read through the information. Before you commence on the study, you would also have the details explained to you carefully in a study talk over the phone. Because your decision to participate is important, please feel free to discuss the study with family and friends. You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you receive from your own doctors. This information is yours to keep. Thank you for time in reading this information.

The Study Team:

Dr Paul Kroon
Chief Investigator

Dr Jennifer Ahn-Jarvis
Principal Investigator

The Study Facility:

Quadram Institute Clinical Research Facility (CRF) is an NHS facility managed by Norfolk and Norwich University Hospital (NNUH) staff.

Please do not hesitate to ask if there is anything contained within this booklet that is not clear, or if you would like more information.

Tel: **07733 699117,** QI Study Webpage: **www.quadram.ac.uk/BETAstudy**

Email: **BETA@quadram.ac.uk**

Brief summary of the study

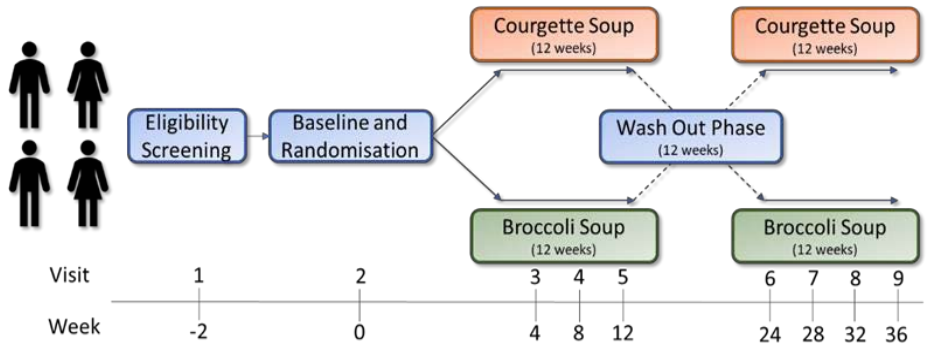
The BETA study is investigating how eating broccoli, when eaten as a soup, affects sugar (glucose) accumulation in the blood of individuals with pre-diabetes.
During the 36-week study duration, you will be asked to consume two vegetable soups containing broccoli or courgette. We will collect:

- Fasting blood at multiple times and during oral sugar tolerance tests
- 24-hour urine collections
- Dietary questionnaires.

Further details are included in this booklet.

What is the purpose of the study?

Individuals with pre-diabetes have higher than normal blood sugar levels which can be managed through behaviour modification (diet, exercise), and has not developed into diabetes which requires medical treatment. Broccoli has shown to normalise elevated blood sugars when eaten over long period of time. Therefore, in this study we are trying to understand how broccoli, when eaten as a soup, affects blood sugar levels in individuals with pre-diabetes. We plan to look at blood sugar levels in two ways. One way, we will look at the long-term build-up of sugar on your red blood cells using a marker called glycated haemoglobin (HbA1c). The HbA1c test evaluates if the sugar build-up on your red blood cells has been normal over the last 2 to 3 months. If your blood sugars have been high over this period your HbA1c will be above normal levels. The second way, we will measure how your body absorbs sugar during an oral glucose tolerance test. In an oral glucose tolerance test (OGTT), you will be asked to fast overnight for 10 hours and the following day you will quickly drink a very sugary drink. Blood sugar levels will be measured before and after you have eaten the sugary drink over a few hours. For the study, you will be asked to complete 4 OGTT. During this 36-week study, you will be consuming two types of vegetable soup for 12 weeks for each soup. These contain either broccoli or courgette and were developed at QIB. Additionally, you will be asked to restrict your diet by only eating 3 portions a week of cruciferous (i.e., broccoli, cauliflower, cabbage) and alliaceous (i.e., garlic, onions) vegetables during the soup intervention periods.



Who can take part in the study?

For this study, we are aiming to recruit participants aged 18 years or over with prediabetes. Eligible participants will have a body mass index between 18.5 to 35 kg/m^2 (healthy to slightly obese) and live within 40 miles from Norwich Research Park (NR4 7UQ).

You will not be able to participate in the study if you(r):

- Screening test results indicate you are not suitable to take part in this study.
- Have a known allergy to any of the components (broccoli, courgettes, milk, or gluten) of the test soups.
- Have been diagnosed or have a history of blood or clotting disorders such as anaemia or thrombosis.
- Have been treated for heart disease, cancer, or diabetes.
- Are immunocompromised due to medications or viral infection such human immunodeficiency virus (HIV).
- Have low or high blood pressure with hypertension medication (≤90/60, ≥160/100 respectively would be classed as abnormal).
- Have any acute or chronic illnesses that affects the outcome of the study such as a gastrointestinal disorder. This will be assessed on a case by case basis by QI medical advisor.
- Plan to become pregnant during the study duration, pregnant or breastfeeding.
- Frequently take medications that may interfere with sugar metabolism or absorption such as laxatives, steroids, dietary supplements, or anti-inflammatory medications. This will be assessed on a case by case basis by QI medical advisor.
- Drink more than 14 alcohol units/week.
- Smoke socially or on occasion more than 12.5 grams or 20 cigarettes/week
- Vegan or any dietary restrictions that prevent the consumption of study soups or follow a diet programme which requires fasting for multiple days.
- Are a registered blood donor and have donated a large quantity of blood within the last 16 weeks. Registered blood donors should abstain from blood donations for the duration of the study.
- Are unable to give written or verbal informed consent
- Unable to provide your GP contact details.
- Are participating in another dietary intervention study nor given blood in another dietary study in the last 3 months.
- Are related to or living with any member of the study team or part of the management/supervisory structure of the Chief Investigator.
- Have symptoms of COVID-19, been asked to self-isolate, or have been diagnosed with COVID-19 in the last 14 days.

About the BETA study

There is a total of 9 visits. With the exception of the first two visits, visits will be every month. We will make every effort to schedule visits according to your availability and visits typically will occur in the morning. We hope each participant will complete the study in 36 weeks.

Pre-Study Talk (no visit)
Study team member will contact participant expressing interest and study details will be discussed

Screening Visit
Sign consent, medical questionnaire, physical examination (height, weight, body measurements, blood pressure, and pulse), and blood collected.
Breakfast, 24-hour urine container given and study soups will be provided

Baseline Visit
Submit 24-hour urine collection, physical examination, medical questionnaire review. Fasting blood collected, oral glucose tolerance testing, and lifestyle questionnaires. Lunch and study soups will be provided.

Intervention 1 – Early Visit
Physical examination, medical questionnaire review. Fasting blood collected.
Breakfast and study soups will be provided.

Intervention 1 – Midpoint Visit
Physical examination, medical questionnaire review. Fasting blood collected.
Breakfast, 24-hour urine container given, and study soups will be provided.

Intervention 1 – End Visit
Submit 24-hour urine collection, physical examination, medical questionnaire review. Fasting blood collected, oral glucose tolerance testing, and lifestyle questionnaires. Lunch will be provided.

Soup Consumption

Washout phase –no visit
Continue with normal diet. No soups are eaten during this 12-week washout period.

Intervention 2 – Early Visit
Physical examination, medical questionnaire review. Fasting blood collected.
Breakfast, 24-hour urine container given and study soups will be provided.

Intervention 2 – Midpoint Visit
Physical examination, medical questionnaire review. Fasting blood collected.
Breakfast, 24-hour urine container given, and study soups will be provided.

Intervention 2 – End Visit
Submit 24-hour urine collection, physical examination, medical questionnaire review. Fasting blood collected, oral glucose tolerance testing as well as lifestyle and follow-up questionnaires. Lunch will be provided.

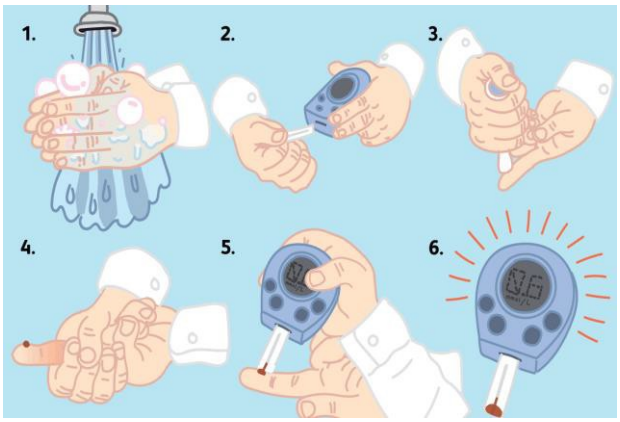
Soup Consumption

What will happen if I take part?

Once we have received your expression of interest to participate for the BETA study, a study team member will contact you by telephone at a convenient time. This **study talk** will be between 10 to 30 minutes in duration. At the end of the discussion, you will be given at least 24 hours to decide whether you would like to participate. During this time, you can contact the study team with any questions or concerns that may arise.

You will be invited for a **screening visit** (visit 1) if you decide to participate in the study. You do not have to fast for this visit. At this visit you will be asked to complete a medical questionnaire. Therefore, please remember to bring details of any medication you are taking when you come for your screening visit. The screening visit will last 30 to 60 minutes. We will review the consent form and ask you to sign the form to enrol you onto the study. A nurse will complete a physical exam which will include height, weight, BMI, waist and hip circumference, blood pressure and pulse. The research nurse will collect no more than 20mL (4 teaspoons) of blood from a vein in your arm. At the end of your visit you will be provided with breakfast to eat in the QI CRF lounge area, a container for a 24-hour urine collection prior to the next visit, and study soups.

At the **baseline visit** (visit 2), you would have fasted for 10 hours and have completed a 24-hour urine collection which you will bring to this visit. ***Notably, for every visit on this study, you will be asked to fast for 10 hours prior to your visit.*** The baseline visit will be used to assess your normal starting blood sugar levels. This visit will be 4 to 5 hours in duration. We will ask if there was any change to your medication or health since visit 1 and then 35 mL (7 teaspoons) of blood will be collected from a vein. This will be used for blood sugar, fat, and gene expression analysis. You will be asked to collect a series of blood drops from the tip of your fingers using a fine lancet this is called a finger prick. In the oral glucose tolerance test (OGTT), you will be asked to collect blood before and after you drink your sugary glucose drink by finger prick using a glucose meter. A maximum of twelve finger pricks will be needed to complete the OGTT. You will be asked to consume 250 mL (8 cups) of the sugary beverage within 15 minutes. A member of the study team will be there to support you with this. There will be idle times during the OGTT, and we will ask you to complete three questionnaires regarding your physical activity and dietary pattern. You will be provided with a sterilised tablet and correct pencil to complete the questionnaires during the visit. At the completion of this visit, the type of soup will be randomly selected, and you will be provided 1-month worth of soups as well as lunch to eat in the QI CRF lounge area before leaving the CRF.



After consuming the study soups for 1 month either during intervention 1 or 2, you will return for an **early visit.** This visit is to measure your initial progress on the study. This visit is a relatively short visit (30 to 60-minute duration) where we will check if there have been any changes to your medications and general health. A research nurse will conduct a quick physical examination where body measurements will be measured and 25ml (5 teaspoons) of fasting blood will be collected. You will be provided breakfast to eat in the QI CRF lounge area, and another month's supply of soups.

You will be asked to return in another month. This will be called your **midpoint visit** and similar to the early visit, we will again check if there have been any changes to your medications and general health. A research nurse will conduct a quick physical examination where body measurements will be measured and 25ml (5 teaspoons) of fasting blood will be collected. You will be provided breakfast to eat in the QI CRF lounge area, a container for a 24-hour urine collection prior to the next visit, and your third month's supply of soups.

The **end visit** marks the completion of an intervention period. This visit will be 4 to 5 hours in duration and will be used to evaluate the effects of the vegetable soup on your blood sugar levels. We will ask if you had any changes to your medication or health. Similar to the baseline visit (visit 2), 35 mL (7 teaspoons) of blood will be collected. You will be asked once again to participate in an oral glucose tolerance test by collecting a series of blood drops from the tip of your fingers using a fine lancet. You will again consume the sugary drink. We will ask you to complete two questionnaires regarding your physical activity and dietary pattern. Additionally, if this is an end study visit during the second intervention period, you will be asked to complete a follow-up questionnaire. At the completion of this visit, you will be provided lunch to eat in the QI CRF lounge area before leaving the CRF.

After completion of intervention period 1, you will conduct a **washout phase** for 12 weeks prior to intervention period 2. During this washout phase, you will be asked to continue with your normal diet. During this period, you are still on the study so you can contact the study team if you have any questions or concerns that may arise during this period. You will receive a summary of results at the end of the study when all the samples and questionnaires have been collected from all the participants, and your personal data (contact details) will be used for this purpose.

BETA study foods & diet control

The **two vegetable soups** containing broccoli or courgette for this study was developed at QIB and it is produced in the QI Clinical Research Facility Research kitchen. The research kitchen is fully equipped commercial kitchen where food preparation is done in a safe and hygienic manner in accordance to the Food Standards Agency of England (https://www.food.gov.uk/); regularly inspected similar to catering establishments in England; and food preparation is restricted only to individuals with Food Safety and Hygiene Level 2 Certificate for Catering.

You will receive 14 soups (12 soups for the intervention and 2 spare), at the end of each early and midpoint visits. At the completion of this study, you will have eaten both soups but the type of soups that will be provided at intervention 1 or 2 will be randomly selected. The soups are designed to be eaten as part of your usual diet. **You will be asked to eat 3 soups per week, for each 12-week period.** You will be asked to return unused soup packets and soup record sheet at the completion of each intervention period. If you accidentally miss a dose, please contact the study team immediately to provide alternative advice. Additionally, if you lose your soups and do not have enough before your next visit, please notify the study team immediately. If for any reason, you are unable to eat at least 75% of the study soups, in a given month, you can elect to withdraw from the study. We will provide written information about ingredients, allergens, storage, and cooking of the soups and a soup record sheet to record when you eat the soups. The test soups do contain monosodium glutamate (MSG) as a flavour enhancer. Ingredients to produce the soup are sourced from commercial food manufacturers and safe for human consumption in the UK.

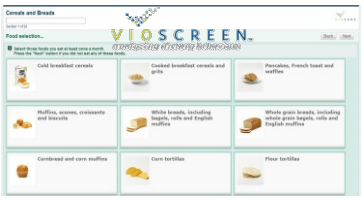
Both soups are individually portioned for your convenience and to make sure you are eating the correct amount at any given day during the week. Both soups provide ~564kJ or 134kcal /serving. The soups are a dry soup mix and should be made up with 250 mL of boiling water. They taste like a standard vegetable cup of soup with similar colour and texture. We ask that you do not reheat the soup once it has been made up with boiling water. The soups should be stored in a cool, dry place and away from direct sunlight. **We do ask if you could please not eat more than 3 portions per week of the vegetables listed on your instruction sheet during the soup intervention periods.**

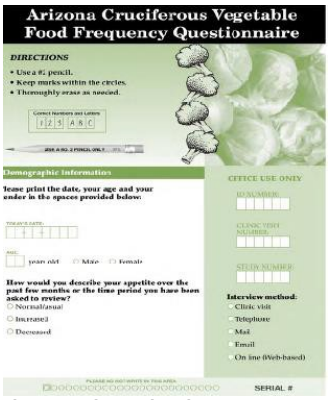
The **sugary beverage** (glucose drink) is purchased from a medical supplier since the amount of glucose needs to be prepared under strict pharmaceutical standards. GlucosePro, is a pleasant raspberry-flavoured beverage. The level of sweetness is similar to that of a fizzy drink or hot chocolate. You have the choice to consume the beverage chilled (recommended) or at room temperature. The key to a successful OGTT is for the sugar drink to be consumed quickly as possible so a straw will be provided. As mentioned earlier you will need to consume the entire 250 mL (8 cups) within 15 minutes.

Since this study involves looking at the effects of broccoli on your blood sugars, we want to make sure that everyone on the study consumes similar amounts of broccoli and foods that contain naturally occurring chemicals that are similar to broccoli. Therefore, we ask that you **limit your diet** of cruciferous and alliaceous vegetables to a maximum of 3 servings/week during the soup intervention periods. A comprehensive list of vegetables will be provided at the start of the study. You can eat all other fruits and vegetables such as apples, carrots, peppers, and peas. If you don't cook for yourself or go out for a meal, it will be more difficult to track what vegetables you have eaten, however we suggest for you to read the ingredient list or ask the restaurant what dishes contain cruciferous and alliaceous vegetables.

The BETA study questionnaires

There are many factors that affect your blood sugar in any given day and among different individuals. These can include differences in physical activity, lifestyle, diet, and food preferences (personal taste of food). Accordingly, we will be using 5 different questionnaires. The following is a summary of the questionnaires used for the study:

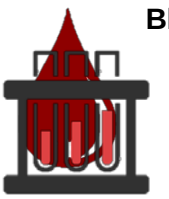




- **International physical activity questionnaire** (IPAQ) collects information of physical activity from lifestyle behaviours and from exercise (20 to 25-minute duration).
- **Vioscreen food frequency questionnaire** collects information about foods that make up your habitual diet over 90-day intervals for this study (20 to 30-minute duration).
- **Arizona cruciferous vegetable food frequency questionnaire** collects specific information regarding your habitual consumption of cruciferous vegetables for 90 days before the enrolment in the study (20 to 25-minute duration).
- **Sensory evaluation questionnaire** collects information on your impressions of the study soups in how they taste. This will be completed at home (5 to 10-minute duration).
- **Follow-up questionnaire** will collect your anonymous comments on the soups and the study during the final study visit (visit 9, 10 to 15-minute duration)

The international physical activity questionnaire (IPAQ) and Vioscreen food frequency questionnaire (FFQ) will be completed during your study visits using a tablet whereas the Arizona cruciferous vegetable food frequency questionnaire and follow-up questionnaire will be completed using paper surveys. The Arizona questionnaire has been specifically developed by the University of Arizona to assess cruciferous vegetable intake over the time period you have been asked to review. In your case this will be 90 days before the enrolment in the study. You will be provided with a clean, sanitised tablet and pencil to complete the questionnaires during the visit. The sensory evaluation questionnaires will be completed at home during the first week of eating the soups. All questionnaires are anonymised so the data collected will be analysed without any of your personal or contact details. The IPAQ and FFQ will be completed using software provided by Viocare®. At your first visit (screening visit), you will be assigned with a unique study-specific code. This code will be used throughout the study and used to create your account to identify your questionnaires but no personal information will be held by this software, as data will be fully anonymised.

What happens to my samples?



Blood samples from the finger prick will be analysed immediately using a glucose analyser device. The blood samples you provide during the study visits will be analysed by study scientists at QIB or at the Norfolk and Norwich University Hospital (NNUH). The results will be logged on the hospital electronic system where your GP can access them. The remaining blood samples will be kept frozen until analysis and discarded when this study is completed. The stored samples will not carry any personal information and assigned a unique code.

The blood samples will be analysed for blood sugar and fat analysis, and for analysis of gene expression in your RNA. This will look at a snapshot of your genes at a given moment in time. ***It is important to stress that this genetic analysis has no clinical relevance to you or your relatives.***

Supplies to help you successfully complete a **24-hour urine collection** will be provided. You will be reminded the day before your visit to start collecting your urine at home. You will need to collect urine throughout the day and bring it with you to your study visit. Only a very small fraction of the larger urine collection will be stored for analysis for study scientist at QIB. Urine is being collected because the compounds of interest from the soups are found in the urine.

Reimbursement for expenses

Your participation in these clinical studies are voluntary. However, we do appreciate your time and the inconvenience of participating in the study has created some expenses. For this reason, you will receive an inconvenience payment. The total payment £210.00 for participation. If you are excluded from the study or you withdraw from the study, the inconvenience payment you receive will be adjusted according to how much of the study you completed before exclusion/withdrawal. Travel expenses to and from the CRF are reimbursed at the current QIB mileage rate for private cars upon presentation of a bus or train receipt. Please note that payments are liable to tax and you are personally liable for your own tax assessment. QIB and NBI employees will be taxed via the payroll.

Contact Us

If at any time you have any questions or concerns, please do not hesitate to call, or send an email to a member of the BETA study team. *For your safety and the success of the study, it is important that you let us know if your health changes no matter if they seem small.*

07733 699117

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Norwich, Norfolk, NR4 7UQ

Frequently Asked Questions

What COVID-19 precautions and safety measures will be implemented?

Before your face to face appointment:

- You will be given the option to decline your appointments if they are worried about associated increased risk of COVID19 infection.
- You will be contacted within 7 days of any scheduled appointments at QI CRF. If you respond "yes" to any of the following questions, please do not attend your appointment:
  - a) Have you been advised that you are extremely vulnerable from COVID-19 infection and are therefore shielding?
  - b) Have you or has anyone in your household received a positive test for COVID-19, or awaiting results of a test?
  - c) Have you or has anyone in your household had any of the symptoms of coronavirus in the last 14 days? (a high temperature, a new continuous cough, a loss or change to your sense of smell or taste)
  - d) Are you or is anyone in your household self-isolating as a result of the NHS test and trace programme?
- Responses to the questions above will be recorded in the study log with the initials of the research team member who contacted you and the date you were contacted.
- You will also be sent these questions in a reminder message or by email the day before your appointment and asked to review your responses before attending your appointment.
- Appointments will be scheduled to reduce contact with other participants and members of staff.

At the appointment:

- Before each scheduled appointment, the research team will disinfect the common surfaces of the appointment room that you may come into contact with during your visit (chair, desk, door handles). Disinfectants will be provided by the CRF team in line with NNUH Infection control guideline.
- You will not be allowed to wait at the QI CRF reception for more than 10 minutes before your scheduled appointments.
- You will be given the choice to wear personal protective equipment (PPE)you're your appointments. If you have not brought your personal PPE items then we can provide them. Research staff will wear PPE in accordance with NNUH guidelines.
- Research staff will adhere to current government social distancing guidelines wherever possible. However, it is acknowledged that during physical measurements and when blood is being collected, this may not be possible. Staff conducting this aspect of the appointment will be NNUH staff and will be adhering to the latest NHS guidelines on how to conduct this aspect of the study as safely as possible.

Further information and current COVID-19 guidance can be found on the NHS and GOV websites.

What happens if I fail the screening?

You will be invited for another screening (re-screening) 8 weeks later. Similarly, if you do not commence the study within 8 weeks of your screening, you will have to be re-screened should you wish to take part.

Do I have to take part in the study, or can I stop participating in the study?

Participation in this study is completely voluntary. Therefore, you are free to withdraw from the study at any time without giving reason. Once you have informed a member of the BETA study team of your decision to withdraw, all personal and identifiable data will be removed, and the study data will be fully anonymised. With your consent, samples that have been collected until the point of withdrawal will be retained and used in the study. You will receive payment pro rata for samples given up to the point of withdrawal. If you are on the QIB participant database, a decision to withdraw or not to take part will not affect your participation in future studies.

What are the risks and benefits for participating in the study?

Benefits: There are no direct benefits to you by taking part of the study. However, the information we obtain from this study will expand the current scientific knowledge which may help develop prevention and treatment strategies for diabetes and cancer in the future.

Risks: There is a potential risk of COVID-19 infection during your participation in the study such as use of public transport to attend a study visit at the QI CRF and visiting an NHS facility.
All soups used in this study are made from commercially available products which are safe for human consumption. The ingredients have no reported adverse events or reactions unless an individual is allergic to any of the ingredients in the soup or glucose drink. Before you participate, information on the ingredients will be provided in case this is relevant to dietary or allergy concerns.

Side Effects: There can be slight discomfort associated with taking blood from a vein and by finger prick. You may develop a small bruise at the site of the blood sample and should fade over a few days but if the site because increasingly more painful or red, please notify the study team as soon as possible.

What if new information becomes available or study changes?

If there are changes to the study or new information becomes available, we will contact study participants. If these changes are significant, you may be asked to sign another consent form. Due to COVID-19, if a full UK lockdown is announced and you are 10-12 weeks through an intervention period, we may ask you to come in earlier to complete the study. If you have just started an intervention period, we may ask you to restart the intervention period once lockdown is lifted.

What if a problem arises while I am at home or in clinic?

While you are on study and you have any concerns or complaints about the study, you can speak to the principal investigator, Dr Jennifer Ahn-Jarvis, who can address any queries. If you are

still unhappy, and wish to complain formally, please contact the chairperson of the QIB Human Research Governance Committee (HRGC) – Dr Antonietta Hayhoe by telephone 01603 255030 or email antonietta.hayhoe@quadram.ac.uk

What do I do if I'm unwell on the study? You should seek medical advice from your GP or got to A&E if you require medical attention. If you are able to contact the study team, please do so. We may ask you to stop eating the soups. We will suspend all your study activities until you are feeling better. Once you are well, we may request that you repeat the intervention phase but depends on the nature of your illness and whether it will affect the study outcome. In a medical emergency, you should contact the emergency service (via 999). Please ensure that your GP and the study team are informed as soon as practicably possible if this occurs.

What if something happens to me while I am on the study? QIB accepts responsibility when conducting clinical studies and as such will give consideration to claims from participants for any harm suffered by them as a result of participating in the trial, with the exception of those claims arising out of negligence by the participants. QIB has liability insurance in respect of research work involving human participants. Please note that the Institute will not fund any legal costs arising from any action unless awarded by a court. If you have any concerns or complaints about the way you have been treated whilst taking part in this study at the QI CRF, there will be a local hospital complaints procedure that you can follow. If you wish to complain you should contact the **Patient Advice and Liaison Service** (PALS) at the NNUH on 01603 289036 (email: pals@nnuh.nhs.uk).Their offices are located next to Kimberley Ward, East Block Level 2 or please ask at the main reception desks at the Inpatient and Outpatient NNUH hospital entrances. The office has an answerphone which is available 24 hours a day and messages will be responded to as quickly as possible. As this study involves the QI CRF, which is an NHS facility, indemnity is provided through NHS

Will my GP be informed?

Yes, it is routine practice to inform your GP of your participation in a study at QIB. When you give your consent by signing the informed consent form you have agreed that we are allowed to contact your GP.

How will my data be protected and kept confidential?

In accordance to Good Clinical Practice (GCP) we will follow strict ethical and research governance rules. All information and data about you will be handled in confidence. All information collected about you during the study will be kept strictly confidential. Any information leaving QIB, will be anonymous. Study information will be stored in locked filing cabinets at the QIB and only accessible by the study team. Personal data collected will be processed by computer which is password protected and personal information that is essential for the study will be collected. To safeguard your identity, at your first visit (screening visit) you will be assigned to unique numerical code (participant code number). This number will be used to identify your samples but by no means can it be linked to any personally identifiable information. Hard copies of the clinical data will be archived separately from your personal information. Your personal records are accessible only to the study team, members of the CRF team and your GP.

The data collected from the blood samples will be identifiable by the NNUH team at the QI CRF and will be transferred from NNUH Pathology department to QIB for analysis. The data collected from the questionnaires with no personal or identifiable information, will be transferred to a third party in the United States (outside of the EEA) for analysis, and may be used to support other research in the future and may be shared anonymously with other researchers.

The sponsor of this study is the Quadram Institute Bioscience (QIB). We will be using information from you to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. QIB will keep your identifiable information for 15 years after the study has finished. Archived identifiable data will not be used to contact you after the end of the study. At 15 years, all information about you will be destroyed. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. *Archived identifiable data will not be used to contact you after the study has ended.* You can find out more about how we use your information by contacting the **NBI Data Protection Adviser:** (dpa@nbi.ac.uk) or **QIB Human studies coordinator** (Dr Antonietta Hayhoe, antonietta.hayhoe@quadram.ac.uk).

Individuals at QIB who will have access to information that identifies you will be those who need to contact you due to unblinding procedures or those who are auditing the data collection process. The people who analyse the information will not be able to identify you and will not have access to any pf your personally identifiable information such as your name or contact details. Data will be managed by the study team in compliance with EU General Data Protection Regulation (GPDR) and the UK Data Protection Act (DPA; 2018). All research is subject to inspection and audit. Although your records may be accessed for this purpose, any personal information remains confidential. Please note, QI has CCTV cameras in use for security purposes.

What will happen to the results of the research study?

Your participation in our study is of great value and without your participation our research would not be possible. However, unfortunately we are unable provide individual results to anyone. The data resulting from the study may be published in scientific journals or presented at meetings. The data presented is anonymously. Your name will not appear anywhere in any of the results presented, shared, or published. At the end of the study we will provide general findings of the study.

Who is organising and funding this

This study is funded through government research organisation (Biotechnology and Biological Sciences Research Council (BBSRC) Institute Strategic Programme Food Innovation and Health Award).

Who has reviewed this study?

As with all human studies conducted under the governance of QIB, this research project has been reviewed by the QIB Human Research Governance Committee (HRGC), as well as an external Local Research Ethics Committee (REC). These are groups of independent people who review research to protect your safety, rights, well-being, and dignity. The study protocol will be formally registered on a publicly available database (Clinicaltrials.gov). It is good practice for all research projects to be registered in a publicly-accessible database since this supports research transparency. After reading this information sheet, if you are interested in taking part in the study, please contact the study team using the information provided in the contact us section. Alternatively, you can complete the response form below using the pre-paid envelope enclosed.

Taking part in the research is entirely voluntary. You are free to withdraw from the study at any time without giving a reason.

The BETA Study

Broccoli Effect on Glycated Haemoglobin (HbA1c)

I am interested in taking part and/or finding out more information about this study, please complete the personal details below or via the QI study webpage**:** **www.quadram.ac.uk/BETAstudy**.

Name:.....

Address: .....

.....

.....

Daytime telephone:.....

Evening telephone:.....

Mobile:.....

I am happy for a message to be left via my daytime/evening/mobile number:

YES / NO
*please circle as applicable

Preferred number/time to call:.....

E-mail address:.....

Please return this form in the **FREEPOST** envelope provided to:

Dr Jennifer Ahn-Jarvis
Quadram Institute Bioscience
FREEPOST XXX
Norwich Research Park
Norwich
NR4 7UQ

Expressing an interest does not commit you to taking part in the study.