Quadram Institute Science Health Food Innovation

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THE HARVEST STUDY

Hydroponic Fortification and Dietary App Effect on Vitamin B12 and Iron (Fe) Status

UKRI Biotechnology and Biological Sciences Research Council

Co-funded by the European Union

NHS Norfolk and Norwich University Hospitals NHS Foundation Trust

Hydroponic Fortification and Dietary App Effect on Vitamin B12 and Iron (Fe) Status

You are invited to participate in a research study led 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 it. 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 doctors. This information is yours to keep. Thank you for your time in reading this information.

The Study Team:

Dr. Paul Kroon

Chief Investigator

Dr. Olla Al-Jaibaji

Principal Investigator

Dr. Jennifer Ahn-Jarvis

Study Co-Investigator

The Study Facility:

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

Quadram Institute Clinical Research Facility
Science Health Food Innovation

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

Study Mobile: 07385 969508

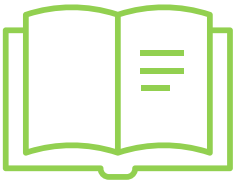
QI Study Webpage: https://quadram.ac.uk/harvest-study/

Email: HARVEST@quadram.ac.uk

What is the purpose of this study?

Vegans and vegetarians are more likely than omnivores to not be consuming sufficient iron and vitamin B_{12}, which are both very important nutrients. This is because plants do not produce vitamin B_{12} and the iron in plant foods is less bioavailable than that in meat and animal products. As a result, vegans and vegetarians are more likely to become insufficient or even deficient in these nutrients and may develop anaemia over time. This is especially true for vegan women of childbearing age. Women of childbearing age are more prone to iron deficiency anaemia because the iron stores become depleted during menstruation, and the demand for iron during pregnancy and breastfeeding becomes much greater.

People who are diagnosed with low iron are normally asked by their GP to consume iron supplements. People who are diagnosed with low B_{12} status may take B_{12} supplements or receive regular B_{12} injections as a treatment. The Harvest Study is investigating an alternative to supplements/injections, which is using a dietary app to deliver iron-rich recipes and a hydroponic unit 'kitchen garden' to deliver vegetables biofortified with vitamin B_{12}. We will measure iron and vitamin B_{12} levels in your blood to determine if these dietary tools are effective in improving your iron and vitamin B_{12} status over the duration of the study.



Overview of the HARVEST study

The Harvest study is investigating the impact of bespoke recipes consumed daily using a dietary app on blood iron levels. Additionally, the study is investigating how eating salad greens grown in a hydroponic unit (picture) and biofortified with Vitamin B_{12} will affect blood Vitamin B_{12} levels in women of childbearing age who follow a vegan or vegetarian lifestyle.

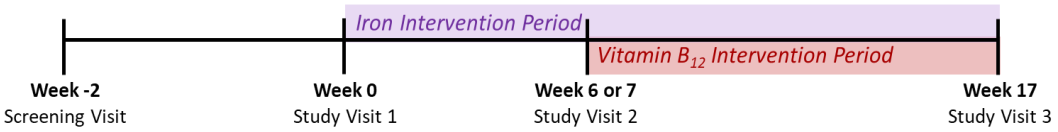
During this 17-week study, you will be asked to eat two recipes (breakfast, lunch, or dinner) from the dietary app every day. Also, you will be asked to grow salad greens (i.e. rocket, parsley, mizuna) using a hydroponic indoor kitchen garden system, pictured on the right. Hydroponic plants are grown in nutrient-rich water instead of soil. After 6 or 7 weeks, you will be asked to harvest and eat the salad greens daily.

At the three study visits, we will collect:

- Blood
- Multiple questionnaires
- Salad greens clippings of plants grown in your hydroponic unit

You will be provided with specific instructions for the dietary app and hydroponic unit to ensure your success as well as supplies to grow your plants. Participants who do not want a hydroponic garden or grow salad greens but want to participate in using the dietary app are still welcome to participate. The study team can be contacted throughout the study if problems or questions arise with the dietary app or hydroponic gardens. Further details of the blood collection, questionnaires, and other study activities are included in this booklet.

women
Over 18 years
Vegan or Vegetarian



	Screening Visit	Study Visit 1	Study Visit 2	Study Visit 3
Informed Consent	X			
Medical Questionnaire	X			
Body Measurements	X	X		X
Serum Ferritin	X	X	X	X
*Screening markers**	X			X
*Iron Status Biomarkers***		X	X	X
*Vitamin B_{12} Status Biomarkers****		X	X	X
Food Frequency & Fatigue Questionnaires		X		X
User Feedback Questionnaires		X	X	X
Dietary App Questionnaires				X

**Screening markers:* full Blood Count, high sensitivity c-reactive protein

**Iron Biomarkers: serum transferrin, iron, high sensitivity c-reactive protein, alpha 1 acid glycoprotein

***Vitamin B_{12} Biomarkers: vitamin B_{12}, holotranscobalamin, total plasma homocysteine

Figure 1. Overview of The Harvest Study

You are eligible to take part if you:

- ✓ Are you a woman over 18 years with a regular menstruation cycle?
- ✓ Are you a vegan, vegetarian, or follower of another diet that does not include the consumption of meat for at least 1 year?
- ✓ Have a Body Mass Index (BMI) between 18.5 – 40 kg/m^2.
- ✓ Live within 40 miles of the Norwich Research Park (NR4 7UQ).
- ✓ Have access to a smartphone or online platform as well as access to the internet**.**
- ✓ Are willing to eat two recipes a day recommended by the app we provide**.**
- ✓ Regularly take iron and/or vitamin B_{12} supplements and agree to maintain the same doses 3 month prior and for the entire duration of the study.

You will not be able to take part if:

- ✗ Your screening test indicated you are not suitable to take part in this study.
- ✗ You have an irregular menstruation cycle <21 and >40-day interval.
- ✗ You have allergies to spinach, rocket, or mizuna (mustard green).
- ✗ You are diagnosed or undergoing treatment for anaemia.
- ✗ You are currently pregnant or breastfeeding.
- ✗ You have high alcohol consumption (more than 2 pints a day).
- ✗ You are a current smoker or have only ceased in the last 6 months.
- ✗ You are on, or about to start, a diet programme such as the 5:2 programme.
- ✗ You have an eating disorder.
- ✗ You are unable to give written or verbal informed consent.
- ✗ You are unwilling to give GP contact details.
- ✗ You have difficulties in adequately understanding written or verbal information in English.
- ✗ You participated in another dietary intervention study or were given blood in another research study in the last 3 months.
- ✗ You are related to or living with any member of the study team or part of the management/supervisory structure of the Chief Investigator.
- ✗ You have symptoms of COVID-19, have been asked to self-isolate, or have been diagnosed with COVID-19 in the last 14 days.

About The HARVEST Study

A total of 3 visits to the QI CRF will be required during the study. The visits will be scheduled according to your preferred time of the day.

Pre-Study Talk (No Visit)

Participants who express interest will be contacted by the study team and study details will be discussed.

Screening Visit (at QI CRF) — Week -2

Consent will be reviewed and signed. Medical questionnaire, physical examination (including height, weight, waist, and hip measurements), and blood collection will be completed.

Baseline Visit 1 (at QI CRF) — Week 0

Medical questionnaire will be reviewed. Medical declaration agreement will be signed. Physical examination, blood collection, and lifestyle questionnaires will be collected. Dietary app will be installed and a 'kitchen garden' system will be provided.

Study Visit 2 (at QI CRF) — Week 6/7

Blood collection, pregnancy test and follow-up questionnaires will be completed, and the progress of the kitchen garden and the use of the dietary app will be reported.

Study End Visit 3 (at QI CRF) — Week 17

Blood collection, lifestyle, and follow-up questionnaires will be completed, and the progress of the kitchen garden and the use of the dietary app will be reported.

What will happen if I take part?

PRE-STUDY TALK: Once we have received your expression of interest to participate in the Harvest study, a study team member will contact you at a convenient time to discuss the details of the study. This study talk will last 20 – 30 minutes. You have at least 24 hours to decide whether you would like to participate in this study. During this time, you can contact the study team with any questions or concerns that may arise. If you decide to participate in the study, we will then arrange for a screening visit. *When we schedule your screening visit, we will ask about your menstrual cycle since all visits need to be performed during a week when you are not menstruating.*

SCREENING VISIT: The screening visit will be used to determine if you are eligible to participate in this study. This visit will last between 60 – 90 minutes at the QI CRF. At this visit, we will ask you to complete an informed consent before we can proceed with any of the screening activities. The CRF nursing staff will complete a medical questionnaire with you, so please remember to bring details of any medications you are taking. A simple physical exam will involve collecting your height, weight, BMI, waist and hip circumference as well as blood pressure and pulse (heart rate). At the end of the visit, we will collect 15 mL (approx. 3 teaspoons) of blood from a vein in your arm.

***If you are considered eligible**, the study team will invite you to schedule your Baseline visit at QI CRF. Please note, that if you do not commence the study within 1 month of your screening visit, you will have to be re-screened should you wish to take part.*

BASELINE VISIT (visit 1): The baseline visit is to measure your iron and Vitamin B_{12} status at the start of the study. This visit will last between 90 – 120 minutes at the QI CRF. We will first make sure that there are no changes to your medication or health since the screening visit. We will request you to sign a medical declaration agreement containing your

agreement to inform the study managers about any alterations to your health status or in the event of pregnancy. We will collect 65 mL (approx. 13 teaspoons) of blood to measure several different iron and vitamin B_{12} biomarkers. Using a tablet, you will be asked to complete three questionnaires regarding your dietary pattern, fatigue level, and your general opinions on using a hydroponic unit. At the end of this visit, we will help you install your dietary app onto your mobile phone or iPad or provide you with a link to use on your desktop, we will provide you with your personalised login details that are anonymised. The dietary app provides bespoke recipes that you will make at home. Also, during this visit, you will be given a kitchen garden kit, seeds, nutrient media, and vitamin B_{12} to biofortify the plants as well as instruction manuals. *Please note, that all questionnaires will be analysed without any of your personal details.*

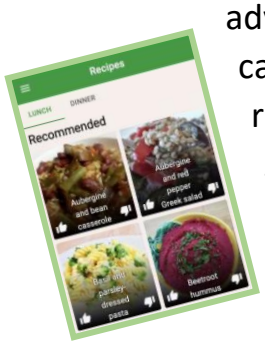
MIDPOINT VISIT (visit 2): At week 6 or 7 (depending on your menstrual cycle), you will have your midpoint visit. This visit will be held at the QI CRF and last between 30 – 60 minutes. During this visit, you will be asked to show us a picture of the hydroponic unit and the salad greens you have grown so that we can document your progress. We will collect 15 mL of blood. We will request you provide us with a urine sample for the purpose of conducting a pregnancy test. We will also ask you to complete user feedback and fatigue questionnaires at the end of this visit.

END-OF-THE-STUDY VISIT (visit 3): This visit marks the completion of the intervention period. This visit will be between 90 – 120 minutes at the QI CRF to evaluate your interaction with the tools provided. 65 mL of blood will be collected. We will ask you to complete three types of questionnaires regarding dietary pattern, fatigue level, and user feedback provided on a tablet and 2 questionnaires through the app.

The HARVEST Study Tools

This study includes the use of a ***dietary app*** that recommends recipes and personalised dietary advice, a ***kitchen garden*** to grow and harvest leafy plants and ***study questionnaires*** to assess your wellbeing and interaction with the tools.

DIETARY APP: We will help you install your dietary app onto your mobile phone or iPad or provide you with a link to use on your desktop, we will provide you with your personalised login details that are anonymised so that your personal information is kept confidential from the dietary app third party. The app will recommend a range of recipes that you can use for breakfast, lunch, or dinner and it will provide dietary advice (i.e. broccoli is a superfood, its good for health, can help lower cholesterol, good for eye health, etc.). The recipes you will be given are tailored to contain specific nutrients such as iron. You will be asked to **eat 2 recipes a day** for 17 weeks. The dietary app is specifically designed to track how much iron you have consumed from the recipes you have selected so it is important to document your selection as you prepare your recipe. Documenting your recipe selection and how much you have eaten is an important part of this study.



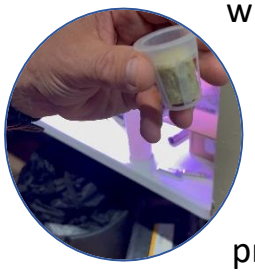
iDOO KITCHEN GARDEN: You will be given an indoor gardening kit (image below) (18.5 x 31.4 x 63.2 cm; 4.26 kg) that comes with 4 water tanks to grow 20 plants at once. The height of the LED Grow Light (32.6-Watt) can be adjusted to help salad greens absorb energy and promote growth. The hydroponic delivery of nutrients combined with LED lights (simulating the sunlight) promotes the efficient growth of plants. This method of growing plants is faster than soil and

the vegetables are fresher than store-bought. A range of seeds to grow leafy plants such as spinach, rocket, and Mizuna (Japanese mustard greens) will be provided. We will provide detailed instructions, a quick reference card, and a user manual to ensure success for those with no gardening experience at all. You will use the unit during the 17 weeks of this study to grow plants but once you have completed the study, the unit is yours to keep, or you can return it to us.

During the study, you will be supplied with seeds, nutrient solution, and vitamin B_{12} to biofortify the plants grown. The vitamin B_{12} will be pre-portioned into tubes. The nutrient solution is a mixture of mineral salts used to prepare the nutrient solution. Both the nutrient solution and vitamin B_{12} should be used solely for the preparation of the nutrient media. Please keep these chemicals stored in a safe place, away from children or pets. If you accidentally lose seeds or nutrients, please contact the study team immediately to provide more supplies. Further instructions for the kitchen gardens will be provided.

Growing plants (salad greens) using the hydroponic kitchen garden

After your baseline visit, you will receive your hydroponic kitchen garden. You will be asked to assemble the garden at home. Please make sure to select an area where there is no direct sunlight and could become wet 13 to 14 weeks of the study.



How long will it take to grow the plants?

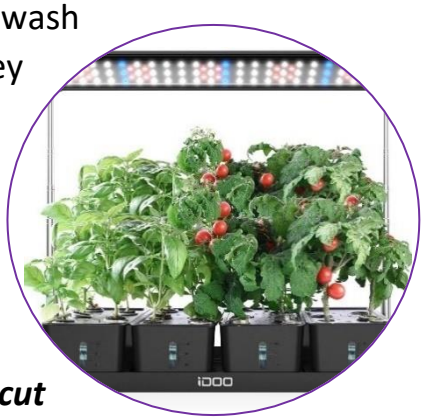
You will be asked to assemble your garden and read through the provided instruction sheets. You will be instructed to seed the iDOO unit. Depending on the plant type i.e. spinach, mizuna, rocket, germination time (seedling formation time) will vary. In general, in a week, you will be asked to add the provided nutrient solution, and then after 2 weeks, you will add the provided B_{12} into the solution and keep topping up for 3-4 weeks. After your 6-7 week visit, you will be asked to harvest and eat the plants. You will be asked to continue eating the plants every day until the end of the study. On the off chance that you have eaten all your plants, we ask that you re-seed and grow more plants so that there are enough plants for you to eat every day.

What is the nutrient solution (Handling and Use)?

The nutrient solution (media) is a mixture of minerals and nutrients that are essential for the growth of healthy plants in your hydroponic unit. Two bottles, labelled A and B, contain dried nutrient grannules which you will dissolve using tap water. It is important that these solutions be prepared away from food preparation areas such as the kitchen sink. It is important to understand that bottle A contains traces of boric acid which may cause irritation if comes into contact with your skin so please remember to handle them with care when preparing the nutrient solution and to promptly clean any spillages during the nutrient solution preparation. Additional information regarding preparation and handling of the nutrient solution will be provided during the study visits.

What do I need to do with plants while I take part in this study?

Once salad greens have matured (after your midpoint visit at 6 to 7 weeks), you can harvest them by snipping the leaves with scissors. Please wash the greens before you eat the plants you have grown. They can be eaten as is, added to your recipes or the recipes provided in the dietary app. We ask that you eat at least 10 grams of salad greens (¼ cup for parsley or ½ cup for rocket, mizuna, or a mix of all three) every day.



Prior to your study visit 2 and 3 – we will request you to cut 3 -4 grams of each plant type, along with (3 mL) samples of the nutrient solution from each water tank into separate vials. This collection aims to quantify the biofortification of vitamin B_{12} within the plants under hydroponic conditions, the goal is to assess the uptake and accumulation of vitamin B_{12} in the plant tissues as a result of the hydroponic nutrient solution, contributing to our understanding of the potential nutritional enhancement offered by this cultivation method.

STUDY QUESTIONNAIRES: Many factors can affect the way one absorbs nutrients and how they metabolize them. Therefore, study questionnaires will collect your dietary data, energy level, and your satisfaction with these dietary tools. The following is a list of the questionnaires collected for this study:

Please note, that all questionnaires are anonymised so the data collected will be analysed without any of your personal or contact details.

1. **A food frequency questionnaire** (**FFQ**) collects information about foods that make up your habitual diet (30 – 40 mins duration).
2. **VAS Fatigue questionnaire (VFQ)** collects information about your energy levels (10 – 15 min).
3. **The user feedback questionnaire (UFQ)** collects your feedback on the study tools including the kitchen garden and dietary app (10 – 15 mins).
4. **Questionnaire of User Interface Satisfaction (QUIS)** assesses your satisfaction and impression of the app (10 – 15 mins).
5. **ResQue questionnaire** assesses your interaction and use of the app (10 – 15 mins).

Reimbursement for expenses

Your participation in this intervention study is voluntary. However, we do appreciate your time and we understand the inconvenience of participating in the study will create some expenses. For this reason, you will receive an inconvenience payment of £100 and you can keep the unit and all un-used seeds, nutrient solution and accessories. If you do not wish to keep the unit then please return it to QIB on your last visit. 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. Samples or data collected up to the point of withdrawal will be kept and used in the study if possible. Travel expenses to and from the CRF are reimbursed at the current QIB mileage rate for private cars upon presentation of a receipt. Please note that payments are liable to tax, and you are personally liable for your tax assessment. QIB and NBI employees will be taxed via the payroll.

What happens to my blood samples?

The blood samples you provide during the study visits will be analysed at the Norfolk and Norwich University Hospital (NNUH), and QIB. The results will be logged on the hospital electronic system where your GP can access them. The remaining blood samples will be kept stored at QIB until analysis and discarded when this study is completed. The stored samples will not carry any personal information and assigned a unique code.

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 HARVEST study team. For your safety and the success of the study, please contact us as soon as possible if your health changes even if they seem to be trivial.

07385 969508

HARVEST@quadram.ac.uk

Quadram Institute Bioscience Norwich Research Park, Norwich, Norfolk, NR4 7UQ

Frequently Asked Questions

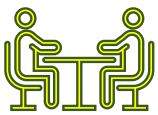
What COVID-19 precautions and safety measures will be implemented?

You will be given the option to decline your appointment if you are worried about the associated increased risk of COVID19 infection.

- You will be contacted within 7 days of any scheduled appointments at QI CRF and asked if you have any COVID19 symptoms (a high temperature, a new continuous cough, a loss or change to your sense of smell or taste), if yes, we will reschedule your appointment.

- 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.
- Appointments will be scheduled to reduce contact with other participants and members of staff.

At the appointment:



- ✓ Before each appointment, we will disinfect the common surfaces of the appointment room (chair, desk, etc).
- ✓ We will schedule appointments in a way so you will not have to wait at the QI CRF reception for more than 10 minutes.
- ✓ Please wear your protective equipment (PPE). If you have not brought your PPE, we can provide them. Research staff will wear PPE following NNUH guidelines.
- ✓ Research staff and NNUH staff will adhere to the current government and NHS guidelines wherever possible. However, during physical measurements and blood collection, this may not be possible. Staff conducting this aspect of the study will do so as safely as possible.

What happens if I fail the screening?

We will send you a copy of your test results and the reason you have been excluded from the study. You will be invited for another screening (re-screening) 4 weeks later. Similarly, if you do not commence the study within 4 weeks of your screening, you will have to be re-screened should you wish to take part.

What's the cost of running the kitchen garden?

The unit power is 34 watts (LED lights). So, assuming the lights are set to be on/off every 16 hours, we can calculate the energy costs. From the 1st of October 2022, a unit (KWh) of electricity in Eastern England will cost 50.4 pence. 16 hours x 34 watts = 544 watts = 0.544 KWh. This will cost 0.408 x 50.4 pence per day = 27.4 pence per day. You will have the lights on for 15 weeks, which is 105 days, so the total cost estimate comes to 27.4 pence x 105 days = £28.77 (£7.2 per month).

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 a reason. Once you have informed a member of the HARVEST 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 if possible. 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 will not affect your participation in future studies.

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

Benefits: You will be able to grow and access fresh plants to supplement your cooking and try different types of recipes suggested by the app.

Risks: Minimal risks associated with blood collection. The hydroponic unit will need to be placed safely away from kids and pets. Children should be supervised to ensure they do not play with the appliance. The power output voltage is 12V, which is normal for a kettle or a toaster so do not alter or change the adapter in any way. Always insure the electrical parts are not submerged in water to prevent the risk of electrical shock. QIB will not be liable for any missue of the appliance. Please read the hydroponic safety instruction carefully before use.

Side Effects: There can be slight discomfort associated with taking blood from a vein. You may develop a small bruise at the site where the blood was sampled but

that should fade over a few days. However, if the site becomes increasingly more painful or red, please notify the study team as soon as possible.

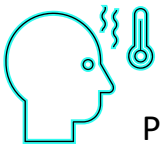
What if new information becomes available or the study changes?

If there are changes to the study or new information becomes available, we will contact the study participants. If these changes are significant, you may be asked to sign another consent form.

What if a problem arises while I am at home?

While you are on the study and you have any concerns or complaints about the study, you can speak to the principal investigator, Olla Al-Jaibaji, 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 at 01603255030 or email antonietta.hayhoe@quadram.ac.uk.

What do I do if I'm unwell while I'm in the study?



You should seek medical advice from your GP or go to A&E if you require medical attention. If you can contact the study team, please do so. 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 consider claims suffered as a result of participating in the trial, except for 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.

Why do I need to take a pregnancy test?

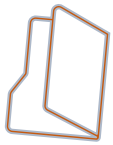
We conduct pregnancy tests as a precautionary measure in our dietary intervention study to ensure your safety and the integrity of the research. Pregnancy can have an impact on how your body responds to dietary changes, which could affect the outcomes we are studying. Identifying pregnancy early allows us to ensure your well-being and maintain the accuracy of our findings. Your health and the success of the study are our top priorities, and this step helps us achieve both goals. If you are found to be pregnant during the course of the study, we would need to respectfully withdraw you from the research. This is because pregnancy can introduce variables that may impact the accuracy of our findings, and ensuring the safety and well-being of both the mother and the potential baby is of utmost importance. We greatly value your participation, and if such a situation arises, we will fully support you in this decision and provide any necessary information you might need. Your understanding and cooperation are greatly appreciated.

Will my GP be informed?

Yes, it is routine practice for us to inform your GP that you are participating in a study at QIB. When you sign the consent form for taking part in the study, this is one of the things you are agreeing to.

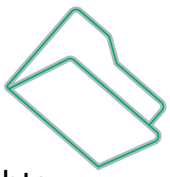
How will my data be protected and kept confidential?

Following 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 a computer that is password protected and personal information that is essential for the study will be collected. To safeguard your identity, at the screening visit you will be assigned a 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 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 the NNUH Pathology department to QIB for analysis. The data collected from the questionnaires will have no personal or identifiable information, 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. In 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 the QIB Human studies coordinator (Dr. Antonietta Hayhoe, antonietta.hayhoe@quadram.ac.uk).



Individuals at QIB who have access to information that identifies you will be those who need to contact you due to emergency 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 of 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, that QI has CCTV cameras in use for security purposes.

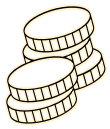
The study will be conducted alongside a sister trial in Belgium, data collected through the app will be analysed by the team in Belgium whereas the primary analysis will be done in QIB. All data shared will be pseudo-anonymised, i.e. we (as the data controller) could trace it back to a specific individual, but our third parties would not. Any accounts used on third-party websites or apps will be pre-registered by the study team using non-identifiable data.

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 to provide

individual results to anyone. The data resulting from the study may be published in scientific journals or presented at meetings. The data will be presented 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. With your consent, pseudo-anonymised data from the app will be collected, stored, and analysed by our partners in Belgium and shared with the QIB study team.

Who is organising and funding this study?



This study is funded by the European Institute of Innovation and Technology for Food (EIT Food). And the Biotechnology and Biological Sciences Research Council (BBSRC).

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 Research Ethics Committee (REC). Comprising 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.

Recontact for future research studies at QIB

With your consent, we will ask you if you would like to be contacted for future research studies conducted at the Quadram Institute. We will keep your name and contact details in the QIB database, which is accessible only by the database manager, which means your details will be kept confidential and only used to contact you in case you are eligible for future studies.

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

Hydroponic Fortification and Dietary App Effect on Vitamin B_{12} and Iron (Fe) Status

I am interested in taking part and/or finding out more information about this study (please complete the personal details below).

Name: ……
Address: ……
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……
……
Telephone: ……
Mobile: ……

I am happy for a message to be left via my 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. Olla Al-Jaibaji
Quadram Institute Bioscience
FREEPOST NC252
Norwich Research Park
Norwich
NR4 7UQ

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