

Future Foods Team

Well-being and health Assessment Research Unit (WARU),
Carwyn James Building,
Aberystwyth University,
Penglais,
Aberystwyth,
Ceredigion.
SY23 3FD

Date: 27 April 2023

Gut microbiome and blood markers after habitual herbal tea consumption PARTICIPANT INFORMATION SHEET

Dear _____

You are being invited to participate in a dual centre research study being conducted by the **Future Foods Team** in the Well-being and Health Assessment Research Unit (WARU) at Aberystwyth University or Trimsaran Community Health Centre. **This project has been partly funded by the Welsh Government under a Covid Challenge Recovery fund led by Aberystwyth University.** Before you decide to participate, please read the information below about the project, and what will be involved. Take the time to read this information carefully and if you wish, discuss it with friends, relatives or your GP. Please ask us if you are unclear on any information and take time to decide whether you want to take part. It is your decision.

Will I be safe taking part in a research project whilst there are COVID-19 restrictions in place?

We are following the guidance set out by the Government, 'Working safely during coronavirus (COVID-19)'. We are adhering to the guidance for running research facilities. We have adapted bespoke working practices for COVID-19, that all researchers would be obliged to follow.

We will provide you with as much coaching as you need, so that you feel confident when taking part in the study.

Why have I been offered entry into this study?

You have been offered entry into this study as you have been recruited by Mari Arthur from TeTrimTeas, or you have expressed interest in the activities at WARU and may be interested in participating in one of our studies. Additionally, we believe you may fit the eligibility criteria we are looking for.

Why is this study being performed?

TeTrimTeas intends to establish a long-term cooperative with local growers and producers who will become partners in the business, with profit share to local growers and producers. The overall aim of the company is to produce quality, science-based botanical/herbal teas to improve health and wellbeing, growing as many of the ingredients locally and organically, to reduce food-to-fork miles within the decarbonisation and sustainability agendas in Wales.

TeTrimTeas have created herbal green tea blends with honey, improving on existing Chinese formulation, and would like to test it as 'health tea'. The recruited cohort will be randomised into

GDPR: For the data the Welsh Government/WEFO requires, Welsh Government is the data controller and Aberystwyth University (WARU) is the data processor. For any other data, including sensitive personal data, the data controller and the data processor is Aberystwyth University (WARU).

one of three intervention teas. They would like to explore if consumption of the teas for 21 days has an impact on digestion and potentially help control weight gain. We will use high resolution metabolomics to investigate the chemical composition of capillary blood samples. We will also assess lipid composition in capillary bloods and the microbiome of stools. Results would advance product development and data would be used in grant applications into the health benefits of the herbal teas.

What exactly would I have to do as a participant?

After pre-induction over the phone, if you are eligible and still interested, we will firstly run through an induction session. This can be done by phone or Teams (whatever suits you best). The study is randomised so you will be allocated into one of three groups. This will be double blinded so neither you nor the researcher will know what group you have been allocated into. Information can be disclosed at the end of the study if you desire. You will need to come to WARU or Trimsaran Community Health Centre for a capillary blood sample collected from the finger using a lancet. You will need to collect a stool sample using kits and toilet facilities provided.

Induction

We will firstly run through how we are working safely during coronavirus (COVID-19). Then we will introduce you to all the study materials you will experience during the experimental session.

Materials will include:

- Tea bags for the 21 days
- Stool collection kit and Bristol stool scale
- Blood collection kit
- Prime Diet Quality Score (PDQS) questionnaire

We will run through the logistics of WARU or Trimsaran Community Health Centre visits and organise dates.

The experimental sequence (see flowchart):

‘Diet-monitoring’ period (two days before the study)

Prior to the experimental session it is important that all participants undergo a period where foods are recorded. This will help us interpret any results after consumption of the test/control food. We would ask you to refrain from taking any over-the-counter medication (such as ibuprofen, paracetamol, aspirin, cough/ cold remedies) or herbal supplements, and to let us know if you find that it is necessary to take any such medication during the trial.

Experimental session- 21 days

Morning: Please come to WARU or Trimsaran Community Health Centre for your pre-organised timeslot to allow us to collect a fasted capillary (fingerpick) blood samples and stool sample (which may be brought with you). You may consume your breakfast after your visit. You will also collect your tea bags. We will also take your weight and height. We will ask you to record your stool using the Bristol stool scale and record your diet using the PDQS questionnaire.

Over 21 days: we would like you to consume a cup of tea after your last meal/snack of the day (post 6pm) daily, for 21 days. We would like you not to consume anything after the tea. In a

GDPR: For the data the Welsh Government/WEFO requires, Welsh Government is the data controller and Aberystwyth University (WARU) is the data processor. For any other data, including sensitive personal data, the data controller and the data processor is Aberystwyth University (WARU).

cup/mug we would like you to place a 2.5g tea bag and add 190ml of hot water (80-100°C) and stir clockwise 10 consecutive times to allow for optimal infusion and then allow to brew for 3 minutes, before removal.

Whilst undergoing the experimental sessions, if necessary, we will be easily contacted by email, Teams or phone.

After the experimental period:

Morning of your final visit. Please come to WARU or Trimsaran Community Health Centre for your pre-organised timeslot to allow us to collect a fasted capillary (fingerpick) blood samples and stool sample (this may be brought in with you). We will also take your weight and height. We will ask you to record your stool using the Bristol stool scale and record your diet using the PDQS questionnaire. You may consume your breakfast after your visit. Afterwards, you can go back to your 'normal' eating pattern.

Post study

We would like you to fill in an additional PDQS questionnaire at least 21 days after your experimental period, and provide your weight.

What will I gain?

There is no financial gain for you if you decide to join this study. You will allow us to gain important insight into the action of a health tea using a combination of techniques including metabolomics, gut microbiome analysis and lipid analysis. This will be the first time this type of research will have been conducted and will be a valuable pilot study before we can investigate any human health benefits in the future. We will provide you with tea for the experimental days.

Are there potential side effects?

For the capillary blood samples, some people may feel nervous and on rare occasions dizziness may occur. Alongside green tea and honey, the intervention teas may contain honeysuckle flower, Cassia seed, lotus leaf, five-leaf ginseng, hawthorn fruit, senna leaf and rhubarb root. The herbal teas contain low amount of caffeine and, if large quantities of the herbal teas are consumed in one go, a laxative effect may occur.

What if I am ineligible or no longer want to be a part of the study?

If you choose, your details can be retained in the system to be contacted for future studies in the event you are deemed ineligible for this current study. You have an option to opt out of this at any time.

Whilst we would be sorry to see you leave the study, participation is entirely voluntary, and you are free to withdraw at any stage without explanation. All data collected over the investigation can be withdrawn, but only up to the point of reporting. If you chose to leave the study, this will not affect your involvement in future research studies managed by the WARU.

What if I feel unwell during the study, or if I or a member of my family/household develop COVID-19 related symptoms? What if something else goes wrong during the study?

GDPR: For the data the Welsh Government/WEFO requires, Welsh Government is the data controller and Aberystwyth University (WARU) is the data processor. For any other data, including sensitive personal data, the data controller and the data processor is Aberystwyth University (WARU).

If you, or a member of your family/household become unwell during the study, please alert a member of the research team immediately using the contact information at the end of this document. We will be available the experimental days. Participation in the study should be suspended immediately until further discussion with the research team has taken place. If you become unwell at any point and need medical assistance, please contact 111 and seek advice from the NHS health sector or your doctor's surgery. We have a duty of care towards you and can help monitor your health remotely over 14 days and will help in any way we can.

Please alert a member of the research team immediately using the contact information at the end of this document.

Will the information and data be confidential?

Yes. You will be provided with a pseudonymous code without your name associated, what only the WARU gatekeeper can link to your name. Only those researchers directly involved will be able to look at the pseudonymous information you provide. Specific details, which identify you, will only be available to the WARU gatekeeper. Neither the Funding body nor TeTrimTeas will have access to personal data. You will not be identifiable in any publication that may arise from this research.

Please note that in exceptional circumstances confidentiality may have to be breached in cases where persons are considered to be at risk or if required by law.

What will happen to the samples collected?

The blood samples that are collected will be examined at analytical laboratories in Aberystwyth University and AberInnovation. Stool samples will be analysed in Swansea. All samples will be stored securely and pseudonymously. After the study has finished, blood samples will be stored in laboratory freezers in accordance with government regulations and stool samples will be discarded. Your name and details will no longer be associated with the samples. We will keep some samples and data securely for up to 5 years so that if new techniques or biomarkers are discovered in line with this study, we can do further testing without having to collect new samples from other volunteers.

Will my GP be informed?

No. If you have any concerns then you may chat to your GP or ring 111 after participating in the study, as we are unable to discuss or disclose the results.

Who has reviewed the project?

This project has been reviewed and approved by the Research Ethics Panel, Aberystwyth University (ethics@aber.ac.uk). As the research team, we are required to conduct the research in accordance guidelines set out.

Does the project conform to GDPR guidelines?

This research is being conducted in accordance with the GDPR guidelines. The AU Data Protection Manager provides oversight of AU activities involving the processing of UK GDPR and special

GDPR: For the data the Welsh Government/WEFO requires, Welsh Government is the data controller and Aberystwyth University (WARU) is the data processor. For any other data, including sensitive personal data, the data controller and the data processor is Aberystwyth University (WARU).

category data, and can be contacted at infocompliance@aber.ac.uk. Your personal data will be stored securely and processed for analysis. The legal basis that would be used to process your personal data will be ‘a task in the public interest’. If you are concerned about how your personal data is being processed, please contact AU in the first instance at infocompliance@aber.ac.uk. If you remain dissatisfied, you may wish to contact the Information Commissioner’s Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>.

What do I do next?

Either contact the Future Foods team (waru@aber.ac.uk or mobile 07813 562381) to confirm you wish to proceed, and we will contact you shortly. If you have any further questions after reading this document, please do not hesitate to contact us. We hope you agree to participate and look forward to hearing from you very soon.

Flowchart of the experimental sequence

