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Gut microbiome and blood markers after habitual herbal tea consumption (SRTT)

Submission date
27/04/2023

Recruitment status
No longer recruiting

Registration date
02/05/2023

Overall study status
Completed

Last Edited
26/11/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a dual centre research study being conducted by the Future Foods/SMART recovery Team in the Well-being and Health Assessment Research Unit (WARU) at Aberystwyth University and Trimsaran Community Health Centre. This project has been funded by the Welsh Government under a Covid Challenge Recovery fund led by Aberystwyth University.

TeTrimTeas intends is 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 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.

Who can participate?
Healthy adult participants (>18 years)

What does the study involve?
The recruited cohort will be randomised into one of three intervention teas (green tea control, senna herbal mix and rhubarb root herbal mix). This will be double blinded so neither the participant nor the researcher will know what group they have been allocated into. Information can be disclosed at the end of the study. Participants will come to WARU or Trimsaran Community Health Centre for induction and study visits.

'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 the researchers interpret any results after consumption of the test/control food. We would ask them 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 they find that it is necessary to take any such medication during the trial.

Experimental session- 21 days
Morning: Participants will come to WARU or Trimsaran Community Health Centre for their pre-organised timeslot to allow researchers to collect a fasted capillary (fingerpick) blood samples and stool sample. They may consume their breakfast after their visit. They will also collect their tea bags. Researchers will also take participants weight and height andcollect diet data (PDQS) and stool scores (Bristol Stool scale).

Over 21 days: we would ask the participants to consume a cup of tea after their last meal/snack of the day (post 6pm) daily, for 21 days. We would ask them not to consume anything after the tea. In a cup/mug we would ask them to place a 2.5-g tea bag and add 190 ml of hot water (80-100°C) and stir clockwise 10 consecutive times to allow for optimal infusion and then allow to brew for 5 minutes, before removal.

After the experimental period:
Before their final visit (or at their final visit): we would like you to fill in another food questionnaire and a stool scale.

Morning of their final visit. We would ask the participant to come to WARU or Trimsaran Community Health Centre for their pre-organised timeslot to allow us to collect a fasted capillary (fingerpick) blood samples and stool sample. We will also take their weight and height. They may consume their breakfast after their visit. Afterwards, they can go back to their 'normal' eating pattern.

What are the benefits and risks of participating?
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.

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.

Where is the study run from?
Well-being and Health Assessment Research Unit (WARU) at Aberystwyth University and Trimsaran Community Health Centre (UK)

When is the study starting and how long is it expected to run for?
October 2022 to December 2023

Who is funding the study?
This project has been funded by the Welsh Government under a Covid Challenge Recovery fund led by Aberystwyth University (UK)

Who is the main contact?
Amanda J Lloyd, abl@aber.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
23306

Study information

Scientific Title
Gut microbiome, and plasma lipids after habitual herbal tea consumption in a healthy human cohort

Acronym
SRTT

Study objectives
Rhubarb root tea is better than green and senna tea in the impact on gut microbiome and plasma lipids

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2022, Research Ethics Panel, Aberystwyth University (Aberystwyth University, Reception, Penglais, Aberystwyth, Ceredigion, SY23 3FL, UK; +44 (0) 1970 621694; lif1@aber.ac.uk), ref: 23767

Study design

Interventional randomized parallel trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Overweight individuals, high BMI

Interventions
The recruited cohort will be randomised into one of three intervention teas (green tea control, senna herbal mix and rhubarb root herbal mix) using an online tool and matched for gender, age and location (site). We will 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, in particular the short chain fatty acids. They will also assess lipid composition in capillary bloods and the microbiome of stools. Diet data, stool consistency and anthropometric measurements will be collected pre and post intervention.

Detailed Description:
TeTrimTeas has created herbal green tea blends, improving on existing Chinese formulation, and would like to test it as 'health tea'. The recruited cohort will be randomised into one of three intervention teas (green tea control, senna herbal mix and rhubarb root herbal mix). This will be double blinded so neither the participant nor the researcher will know what group they have been allocated into. Information can be disclosed at the end of the study. Participants will come to WARU or Trimsaran Community Health Centre for induction and study visits.
The experimental sequence
'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 the researchers interpret any results after consumption of the test/control food. We would ask them 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 they find that it is necessary to take any such medication during the trial.

Experimental session- 21 days
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Morning of their final visit. We would ask the participant to come to WARU or Trimsaran Community Health Centre for their pre-organised timeslot to allow us to collect a fasted capillary (fingerpick) blood samples and stool sample. We will also take their weight and height. They may consume their breakfast after their visit. Afterwards, they can go back to their 'normal' eating pattern.

Intervention Type
Supplement

Primary outcome(s)
Change in total cholesterol, HDL, LDL, triglycerides, non-HDL, cholesterol/HDL ratio after the intervention teas (between teas and between pre/post) measured in capillary bloods

Key secondary outcome(s))
1. Change in gut microbiome between arms and between pre and post intervention measured using 16S rRNA Amplicon Sequencing in stools
2. Change in diet score between arms and between pre and post intervention measured using the Prime Diet Quality Score (PDQS) questionnaire
3. Change in stool score (using the Bristol stool score) between arms and between pre and post intervention
4. Change in weight/BMI/waist: hip between arms and between pre and post intervention
5. Change in concentration of short chain fatty acids between arms and between pre and post intervention measured using GC-FID

Completion date
10/12/2023

Eligibility

Key inclusion criteria
1. Consenting adults >18 years
2. Commit to fasting capillary blood collection
3. Commit to stool sampling collection
4. Able to refrain from taking any over-the-counter medication or herbal supplements during the diet monitoring and experimental periods.
5. Able to prepare and consume the tea during the experimental days, after the last meal/snack of the day and not to consume anything afterwards
6. Fill in diet diaries, FFQ and stool ranking
7. Able to inform the researcher if any antibiotics or heavy alcohol is consumed over the intervention period

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
53

Key exclusion criteria
1. Showing (or anyone within the household) any COVID-19 symptoms (see COVID-19 basic health screen)*
2. Higher risk or vulnerable from coronavirus or live with someone at a higher risk of a severe illness from COVID-19 (over 70, undergoing cancer treatment, high risk of getting infections).
3. Had a letter from the NHS advising you to shield (isolate)
4. Had been at risk of exposure to COVID-19 such as travel, contact with someone with COVID-19, been exposed to the virus, or has been asked to self-isolate by the track and trace system.
5. Serious health conditions that require daily long-term medications (including immunosuppressants)
6. A history or current diabetes, lung issues, gut inflammation (Crohns, IBD), digestive disorders
7. Diagnosed with a serious health condition within the last 12 months
8. Pregnant
9. Play sports at a high level (more than 7h/week or 1h/day)
10. Smoking
11. consume high dose of alcohol > 21 unit per week for men and > 14 units per week for women
12. Food allergy /food intolerance/ eating disorder or are on a specially prescribed diet

*If the potential participant has had COVID-19 previously (and are fully recovered and not within isolation) then they are eligible to join the study

Date of first enrolment
11/06/2023

Date of final enrolment
11/07/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Well-being and Health Assessment Research Unit (WARU)
Carwyn James Building

Penglais Campus
Aberystwyth
United Kingdom
SY23 3FD

Study participating centre
Trimsaran Leisure Centre
Heol Llanelli
Trimsaran
United Kingdom
SA17 4AA

Sponsor information

Organisation
Welsh Government

ROR
https://ror.org/000wh6t45

Organisation
TeTrimTeas Cyf

Funder(s)

Funder type
Government

Funder Name
Llywodraeth Cymru

Alternative Name(s)
Welsh Government, The Welsh Government

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request (Amanda Lloyd, abl@aber.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		27/04/2023	28/04/2023	No	Yes