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Date: 20 April 2023

ORAL SUPPLEMENT IN OLDER ADULTS TO SUPPORT PHYSICAL FITNESS AND MENTAL WELL-BEING PARTICIPANT INFORMATION SHEET

Dear _____

You are being invited to participate in one of our research studies being conducted by the Well-being and Health Assessment Research Unit (WARU) at Aberystwyth University, funded by Welsh Government through a Covid Recovery Challenge Fund led by Future Foods. 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?

At WARU, Aberystwyth University we are following the guidance set out by the Government on May 11th, 2020 and updated on the 22nd June 2021, 'Working safely during coronavirus (COVID-19)'. 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 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?

Cucumbers have been anecdotally claimed to have anti-inflammatory activity for a long time, but the active principle was not identified. idoBR1 is an iminosugar amino acid isolated from fruits of certain cucumbers, *Cucumis sativus* (Cucurbitaceae), which has been shown to have anti-inflammatory activity.

We would like to explore if consumption of cucumber extract Q-actin when compared with placebo can have an impact on physical strength (measured by hand grip strength), finger dexterity (measured by Nine-Hole Peg Test (9HPT)) as well as quality of life (EQ-5D questionnaire), sleep quality (Pittsburgh Sleep Quality Index), and diet (diet questionnaires are tailored to your eating

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habits, e.g., carnivore, vegetarian pescetarian, vegan etc). We will explore urine chemical composition use high resolution metabolomics do this by looking at the chemical composition of home-collected urine.

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, Teams or in person, whatever suits you best. The study is split into three experimental sessions where you will be randomised to one of two supplements, Q-actin (2 x 10 mg gummies daily) or placebo (2 x 10 mg gummies daily) supplementation for 12 weeks. The vegan gummies will need to be consumed in the evening, before bed-time. Randomisation will be blinded, and you and the researcher will not know what group you're in until after the completion of the study. You will need to come to WARU or the remote centre for physical strength and finger dexterity measurements using hand grip strength and the Nine-Hole Peg Test (9HPT) respectively. We will measure generic quality of life with the EQ-5D questionnaire, record diet choices (Prime Diet Quality Score (PDQS)), record sleeping habits using the Pittsburgh Sleep Quality Index, and collect urine samples before and after the supplementation period (see flowchart). We would like you to restrict from consumption of cucumber, gherkins, and melon for two days before coming to WARU or the remote centre.

Whilst undergoing the study, if necessary, we will be easily contacted by email, Teams and phone.

The WARU or the remote centre visits (see flowchart)

Tea, coffee and biscuits will be provided at each visit. **Each visit will take up to an hour**

Induction

First, you'll be welcomed with tea or coffee. We will run through how we are working safely during coronavirus (COVID-19). Then we will introduce you to the urine sampling boxes, provide crib sheets and email you a link to a video demonstration, if needed. We will run through the logistics of study visits and the tasks that will be completed.

We will also email you a link to the EQ-5D questionnaire, Pittsburgh Sleep Quality Index, and diet questionnaire, or give you a paper copy, so that you can complete these in WARU, the remote centre or at home (whatever is preferred).

We will arrange your testing day 1, 2 and 3 visit dates and times.

Testing day 1 (start)

On your pre-organised day and time, please collect 2 x 4ml first urine sample at home using our urine kits. Store these samples in your home fridge between 2-5 degrees. Then please come to WARU or the remote centre for your pre-organised timeslot with your urine samples for physical strength and finger dexterity activities. Please make sure you complete your EQ-5D, Pittsburgh Sleep Quality Index, and diet questionnaire before you start your supplementation.

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Testing day 2 (after 6 weeks)

After the 6-week supplementation period we would like you to complete the activities that you undertook during testing day 1.

On your pre-organised day and time, please collect 2 x 4ml first urine sample at home using our urine kits. Store these samples in your home fridge between 2-5 degrees. Then please come to WARU or the remote centre for your pre-organised timeslot with your urine samples for physical strength and finger dexterity activities. Please make sure you complete your EQ-5D, Pittsburgh Sleep Quality index, and diet questionnaire before or just after testing day 2.

Testing day 3 (after 12 weeks)

After the 12-week supplementation period we would like you to complete the activities that you undertook during testing day 1 and 2.

On your pre-organised day and time, please collect 2 x 4ml first urine sample at home using our urine kits. Store these samples in your home fridge between 2-5 degrees. Then please come to WARU or the remote centre for your pre-organised timeslot with your urine samples for physical strength and finger dexterity activities. Please make sure you complete your EQ-5D, Pittsburgh Sleep Quality Index, and diet questionnaire before or just after testing day 3.

There will also be an optional feedback questionnaire at the end.

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 inflammatory properties of the cucumber supplement and the digestion and metabolism of the supplement within urine. 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 further human health benefits in the future.

Are there potential side effects?

The supplements have been tested for any adverse effects, however if any negative effects occur, please refrain from continuing in the study.

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

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, however only up to the point of data analysis (immediately after the 12 week period). If you chose to leave the study, this will not affect your involvement in future research studies managed by 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?

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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. 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. Only those researchers involved will be able to look at the information you provide. Specific details, which identify you, will only be available to the researchers. After the end of the study, any information relating to you will be made pseudonymous (coded without your name associated). 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.

Will my GP be informed?

No.

What will happen to the samples collected?

The urine samples that are collected will be examined at analytical laboratories in Aberystwyth University and AberInnovation. All samples will be stored securely and pseudonymously (coded). We will perform tests in urine to investigate the metabolism and excretion kinetics of the supplements. After the study has finished, the samples will be stored in our laboratory freezers in accordance with government regulations. Your name and details will no longer be associated with the samples. We will keep some samples 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.

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 category data, and can be contacted at infocompliance@aber.ac.uk. Your personal data will be stored securely and processed for metabolomic 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

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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 WARU team (waru@aber.ac.uk) or phone 01970622299 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.

Many thanks,
WARU Team

Flowchart of the experimental sequence

