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Oral supplement in older adults to support physical fitness and mental well-being

Submission date
21/04/2023

Recruitment status
No longer recruiting

Registration date
21/04/2023

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
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. IminoTech Inc in the USA has produced a quality-controlled cucumber extract containing measured idoBR1 (Q-actin™) that has given good results in osteoarthritis from oral use. The aim of this study is to test if Q-actin will improve physical strength and finger dexterity when compared with placebo (and baseline) supplementation for 12 weeks. Quality of life, sleep quality, diet choices, knee and hip osteoarthritis and chemical composition of urine samples will also be measured.

Who can participate?
Healthy volunteers aged over 50 years

What does the study involve?
After pre-induction over the phone, eligible and interested participants will attend an induction session. This can be done by phone, Microsoft Teams or in person. The study is split into three experimental sessions where participants are randomly allocated 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 bedtime. Participants will need to come to the Well-being and Health Assessment Research Unit (WARU) or the remote centre for physical strength and finger dexterity measurements. The researchers will measure their quality of life and knee and hip osteoarthritis with a questionnaire, record diet choices, record sleeping habits, and collect urine samples before and after the supplementation period (at 0, 6 and 12 weeks). Participants should avoid eating cucumber, gherkins, and melon for 2 days before coming to WARU or the remote centre.

What are the possible benefits and risks of participating?
There is no financial gain for participants. This study will allow the researchers to gain important insight into the inflammatory properties of the cucumber supplement and the digestion and metabolism of the supplement in urine. This will be the first time this type of research will have been conducted and will be a valuable pilot study before the researchers can investigate further

human health benefits in the future. The supplements have been tested for any adverse effects, but if any negative effects occur, participants can leave the study.

Where is the study run from?
Well-being and Health Assessment Research Unit (WARU) and a remote centre in Trimsaran, Wales (UK)

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

Who is funding the study?
Welsh Government (UK)

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
23767

Study information

Scientific Title
Oral supplement Q-actin in older adults to support physical fitness and mental well-being

Acronym
PQQA

Study objectives
Q-actin (2 x 10 mg gummies daily) when compared with placebo (2 x 10 mg gummies daily) supplementation for 12 weeks will improve physical strength and finger dexterity (measured by hand grip strength and the Nine-Hole Peg Test (9HPT) respectively).

Additionally, generic quality of life, sleep quality, diet choices and chemical composition of urine samples will improve in the intervention arm compared with baseline and placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2022, Aberystwyth University Research Ethics Panel (Aberystwyth University, Reception, Penglais, Aberystwyth, Ceredigion, SY23 3FL, UK; +44 (0) 1970 621694; lif1@aber.ac.uk), ref: 23767

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
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.

The researchers would like to explore if the 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), knee and hip osteoarthritis (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]), and diet (diet questionnaires are tailored to your eating habits, e.g., carnivore, vegetarian, fish, vegan etc). The researchers will explore urine chemical composition using high-resolution metabolomics of home-collected urine.

After pre-induction over the phone, if the person is eligible and still interested, the researchers will first run through an induction session. This can be done by phone, Microsoft Teams or in person, whatever suits best. The study is split into three experimental sessions where the participant 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 bedtime. Randomisation will be blinded, and the participant and the researcher will not know what group they in until after the completion of the study. The participant will need to come to the centre for physical strength and finger dexterity measurements using hand grip strength and the Nine-Hole Peg Test (9HPT) respectively. Knee and hip osteoarthritis will be assessed using the WOMAC questionnaire. The researchers will measure generic quality of life with the EQ-5D questionnaire, record diet choices, record sleeping habits using the Pittsburgh Sleep Quality Index, and collect urine samples before and after the supplementation period. They would like participants to restrict from consumption of cucumber, gherkins, and melon for 2 days before coming to the centre.
Whilst undergoing the study, if necessary, the research team will be easily contacted by email, Microsoft Teams and phone.

The visits:
Tea, coffee and biscuits will be provided at each visit. Each visit will take up to 1 hour

Induction:
First, the participant will be welcomed with tea or coffee. The researchers will run through how we are working safely during coronavirus (COVID-19). Then we will introduce the participant to the urine sampling boxes, provide crib sheets and email the participant with a link to a video demonstration, if needed. The researchers will run through the logistics of study visits and the tasks that will be completed.
The researchers will also email the participant a link to the EQ-5D questionnaire, Pittsburgh Sleep Quality Index, WOMAC questionnaire and diet questionnaire, or give them a paper copy, so that they can complete these in the centre or at home (whatever is preferred).
They will arrange the participants testing day 1, 2 and 3 visit dates and times.

Testing day 1 (start):
On the participant's pre-organised day and time, the researchers will ask them to collect 2 x 4 ml first urine sample at home using home-collection urine kits. These samples will be stored in the participant's home fridge at 2-5 degrees. The participant will then come to the centre at a pre-organised timeslot with their urine samples for physical strength and finger dexterity activities. The researchers will ask them to make sure they complete their EQ-5D, Pittsburgh Sleep Quality Index, WOMAC questionnaire and diet questionnaire before they start their supplementation.

Testing day 2 (after 6 weeks):
After the 6-week supplementation period the participant completes the activities that they undertook during testing day 1.

On their pre-organised day and time, the researchers will ask them to collect 2 x 4 ml first urine sample at home using home-collection urine kits. The researchers will ask the participant to store these samples in their home fridge between 2-5 degrees. The participant will then come to the centre for their pre-organised timeslot with their urine samples for physical strength and finger dexterity activities. The researchers will ask the participant to make sure they complete their EQ-5D, Pittsburgh Sleep Quality Index, WOMAC questionnaire and diet questionnaire before or just after testing day 2.

Testing day 3 (after 12 weeks)
After the 12-week supplementation period the participant completes the activities that they undertook during testing day 1.

On their pre-organised day and time, the researchers will ask them to collect 2 x 4 ml first urine sample at home using home-collection urine kits. The researchers will ask the participant to

store these samples in their home fridge at 2-5 degrees. The participant will then come to the centre for their pre-organised timeslot with their urine samples for physical strength and finger dexterity activities. The researchers will ask the participant to make sure they complete their EQ-5D, Pittsburgh Sleep Quality Index, WOMAC questionnaire and diet questionnaire before or just after testing day 3.

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

Intervention Type
Supplement

Primary outcome(s)
Physical strength measured using hand grip strength at 0, 6, and 12 weeks

Key secondary outcome(s))
1. Finger dexterity measured using Nine-Hole Peg Test (9HPT) at 0, 6, and 12 weeks
2. Generic quality of life measured using EQ-5D questionnaire at 0, 6, and 12 weeks
3. Diet choices measured using the Prime Diet Quality Score (PDQS) at 0, 6, and 12 weeks
4. Sleeping habits measured using the Pittsburgh Sleep Quality Index at 0, 6, and 12 weeks
5. Non-targeted metabolomics of urine samples at 0, 6 and 12 weeks

Added 24/04/2023:
6. Knee and hip osteoarthritis assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire at 0, 6, and 12 weeks

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged over 50 years
2. Consent
3. Commit to urine sampling
4. Able to commit to attending WARU or the remote centre for measurements of physical strength, finger dexterity, quality of life, diet choices, and sleep
5. Able to restrict from consumption of cucumber, gherkins, and melon for 2 days before coming to WARU or the remote centre

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 to coronavirus or live with someone at a higher risk of a severe illness from COVID-19 (aged over 70 years, 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, being 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 medication

Date of first enrolment
12/12/2022

Date of final enrolment
22/04/2023

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
Phytoquest Ltd

Organisation
Gateway Health Alliances, Inc

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?
Results article		12/05/2025	27/05/2025	Yes	No

Participant information sheet	21/04/2023	No	Yes