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Exploring the effects of a natural seaweed supplement on digestion, health, and well-being

Submission date	**Recruitment status**	[X] Prospectively registered
02/04/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/04/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/06/2025	Digestive System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

More than 50% of individuals over the age of 45 years are living with diet-related noncommunicable health conditions, placing a significant burden on NHS resources. Addressing this growing public health challenge requires the development of foods with enhanced nutritional value. Functional ingredients that support health and well-being are essential not only for improving individual health outcomes but also for promoting a healthier planet.

In this context, BioMara and Aberystwyth University (AU) are collaborating to evaluate the health benefits of fucoidan, a seaweed-derived bioactive polysaccharide, in human clinical trials. Fucoidan has demonstrated a wide range of biological activities, including anticancer, antioxidant, immunoregulatory, antiviral, and anti-inflammatory properties.

While lab and animal studies have shown fucoidan's potential to reduce colitis, evidence from human trials remains limited. To date, only two studies have investigated its effects in humans: one examining fucoidan combined with wheat for its impact on gastritis, and another assessing its potential in managing chronic colitis.

This study aims to conduct a randomised, placebo-controlled, parallel-group human trial to assess the potential effects of spray-dried fucoidan on gastrointestinal (GI) symptoms, general health, well-being, and dietary patterns in young adults. The study will rely on self-reported data to evaluate these outcomes.

Who can participate?

Healthy volunteers aged 18-35 years

What does the study involve?

Volunteers will consume either spray-dried fucoidan (250 mg in vegan clear capsules) or placebo (microcrystalline cellulose) control daily for 28 days. This will be a remote trial where no samples are collected. Self-report questionnaires on gastrointestinal (GI) symptoms, health and well-being, and diet will be completed at the start and end of the study.

What are the possible benefits and risks of participating?

There will be a £20 voucher for completing this study. This study will allow researchers to gain important insight into fucoidan to improve health and well-being in healthy volunteers, which may be applied to other groups such as those suffering from gastrointestinal issues.

Fucoidan has already been tested for any adverse effects in a human cohort, however, if any negative effects occur, the participants are asked to refrain from continuing in the study. Any participant with molluscs and crustacean allergens should not take part in the study.
Some of the questionnaires will require the participant to answer questions relating to their physical health, well-being and diet. They will not receive feedback on their questionnaire scores because they are NOT intended for diagnostic or clinical purposes. However, if they have any concerns regarding the scoring criteria or about their health in general upon completing these questionnaires, then we recommend that they speak to their GP. If they have any questions regarding any of the questionnaires and how they are used, then they are to contact WARU at waru@aber.ac.uk. If they would like to speak to someone generally about their well-being and mental health, or if they have any other well-being health concerns, then we recommend that they use one of the support services listed at the end of the Participant Information document.
This study will provide valuable insights into the potential of fucoidan as a functional food ingredient for improving gut health and overall well-being. The findings will contribute to the growing body of evidence supporting the role of bioactive compounds in addressing diet-related health conditions and informing future larger-scale clinical trials.

Where is the study run from?
The study is remote and is run from the Well-being and health Assessment Research Unit (WARU) (UK)

When is the study starting and how long is it expected to run for?
September 2024 to August 2025

Who is funding the study?
Innovate UK

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Amanda Jane Lloyd

Contact details
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Additional identifiers

Protocol serial number
29082Ha

Study information

Scientific Title
Fucoidan supplement on health and well-being

Study objectives
Daily supplementation with 250 mg of spray-dried fucoidan for 28 days will lead to significant improvements in gastrointestinal (GI) symptoms, general health, mental well-being, and dietary patterns in healthy young adults, compared to a placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/03/2025, Aberystwyth University Research Ethics Panel (Research, Business & Innovation Visualisation Centre, Penglais, Aberystwyth, SY23 3BF, United Kingdom; +44 (0)1970 622385; ethics@aber.ac.uk), ref: 29082Ha

Primary study design
Interventional

Study design
Randomized placebo-controlled parallel-group trial

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Gut health and overall well-being

Interventions
Volunteers (F/M balanced, young adults aged 18-35 years, n = 15/treatment group) will consume either spray dried fucoidan (250 mg in vegan clear capsules)or placebo (microcrystalline cellulose) control daily in the morning for 28 days.

Method of randomisation: number generated online, factored by gender and age

Intervention Type
Supplement

Primary outcome(s)
1. Gastrointestinal health measured using Digestion-Associated Quality of Life Questionnaire (DQLQ) and Bristol Stool Scale/Bristol Stool Chart from baseline to 28 days post-intervention
2. General health and well-being measured using Short Form Health Survey (SF-12), General Health Questionnaire (GHQ-12), EQ-5D items (Health Survey for England) from baseline to 28 days post-intervention
3. Mental well-being measured using Warwick-Edinburgh Mental Well-being Scale (WEMWBS) from baseline to 28 days post-intervention

Key secondary outcome(s)

1. Feasibility of fucoidan supplementation measured using participant compliance (daily intake tracking) and completion rates of online questionnaires and diet diaries across 28 days of intervention
2. Dietary patterns and food intake measured using online diet diaries via Intake24 from baseline to 28 days post-intervention
3. Variability in response to fucoidan measured using inter-individual variation in questionnaire outcomes (GI symptoms, mental well-being, general health) from baseline to 28 days post-intervention

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Consenting adults aged 18 -35 years
2. Able to provide written informed consent PRIOR to performing any study procedures
3. Are able to commit to consuming daily supplements
4. Willing to complete a series of online questionnaires

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
All

Key exclusion criteria
1. Serious health conditions that require daily long-term medications
2. Allergens: any participant with molluscs and crustacean allergens
3. Those taking anticoagulant and blood sugar-lowering medications
4. A history of or current diabetes or gut inflammation (Crohn's, IBD)
5. Subjects with a medical condition or disease that is life-threatening
6. Consume a high dose of alcohol >21 units per week for men and >14 units per week for women
7. Food allergy/food intolerance/ eating disorder or are on a specially prescribed diet
8. Pregnant or breastfeeding
9. Subjects who smoke cigarettes or use other products containing nicotine
10. Subjects who are already regularly taking fucoidan or supplements related to fucoidan within 30 days of screening

Date of first enrolment
09/04/2025

Date of final enrolment
13/06/2025

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Well-being and health Assessment Research Unit (WARU)
Carwyn James Building
Aberystwyth University
Penglais
Aberystwyth
United Kingdom
SY23 3FD

Sponsor information

Organisation
Aberystwyth University

ROR
https://ror.org/015m2p889

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Pseudonymous data will be made available upon request from Amanda Lloyd (abl@aber.ac.uk).
The type of data that will be shared: Pseudonymised data
Dates of availability: Upon publication
Whether consent from participants was required and obtained: Yes

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		02/04/2025	03/04/2025	No	No