Loughborough University

Effects of Probiotic Supplementation in Alcohol Use Disorder: A Randomised, Placebo-Controlled Pilot Trial

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Study on the gut-brain-axis

Investigators Details:
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I would like to invite you to take part in my study. Before you decide whether to participate, I would like you to understand why the research is being done and what it would involve for you.

What is the purpose of the study?

As part of my postgraduate research, I am undertaking an intervention study to examine the possible effects of probiotics on behaviour and health. This study aims to gain more knowledge on the gut-brain-axis.

Who is doing this research and why?

This is a Doctoral Research project supervised Dr Thom Wilcockson and Professor Eef Hogervorst. This study is funded through an AKT grant which is a publicly funded initiative from Innovate UK, and Cultech Ltd will be providing all supplements. However, all research is conducted by Loughborough University, which holds all study rights.

Are there any inclusion or exclusion criteria?

Exclusion criteria are the following:

- Participants being under 18 years of age
- Current supplementation of probiotics or prebiotics within the past 4 weeks
- Antibiotic use within the past 4 weeks
- Major psychiatric conditions diagnosed e.g., bipolar disorder, schizophrenia
- Current pregnancy or breastfeeding
- Having had a heavy drinking episode (≥8 units) in the last 12 hours OR a breath alcohol reading above 35 µg/100 ml

Inclusion criteria are the following:

- A self-reported history of heavy drinking
- At least one heavy drinking episode (≥8 units) in the last 28 days

What will I be asked to do?

You will randomly be assorted to one of 2 participant groups: probiotics or placebos. You will not know which group you have been assorted to until the end of the study, nor will I. You will receive a bottle containing one of the two possible capsules, and you will ingest one capsule every day with food and a full glass of water for 4 weeks. It is important that you do not have a hot drink 30 minutes before or after ingesting the capsule. I will give you a contact number which you can message if you have any questions at any stage of the 4-week study.

I will collect data from you at 2 timepoints: at the beginning of the study and at the end, which will be after 4 weeks. Data collection involves you completing online questionnaires, providing a stool and saliva sample, and performing cognitive tasks.

Before taking part, you might be asked to provide a quick non-invasive breath sample using a breathalyser. At the first data collection timepoint, I will collect your cognitive data in-person, which should take around 20 minutes. The stool sample and online questionnaires can be completed in your own time within 48 hours of the study visit, and together these will take around 20 minutes. The stool sample kit will contain clear instructions, and you will be asked to message the provided contact number once the stool sample has been provided. If you are located at Turning Point or Exaireo at the time of the data collection, I will come there to collect the stool sample, and if you are not registered at either centre, we can arrange a pick-up of the sample

wherever is best for you within 24 hours of the sample provision. Upon picking up the stool sample, I will also ask you to provide a saliva sample.

After the 4-week intervention, I will collect the same data from you again.

Will I be asked to attend any sessions and where will these be?
If you are registered at Turning Point or Exaireo, I will come there to collect your data and provide you with all necessary materials for the study. If you are not registered at Turning Point or Exaireo at any of the 2 data collection timepoints, we can arrange the sessions wherever is best for you.

Once I take part, can I change my mind?
After you have read this information and asked any questions you may have, I will ask you to sign a consent form stating that you are happy to participate. However, if at any time, before, during or after the sessions you wish to withdraw from the study, please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for this. However, once the results of the study are published, it may not be possible to withdraw your individual data from the research.

How long will it take?
The total time demand will be 4 weeks. Breakdown of the study is as follows:

- **First round of data collection: total duration 40 minutes**. The cognitive data will be collected in-person and take around 20 minutes. The stool sample and online questionnaires will be completed in your own time within 48 hours of the study visit. The online questionnaires will take around 15 minutes for completion, and the stool sample 5 minutes.
- **Taking 1 placebo capsule daily for 4 weeks- takes 30 seconds daily**
- **Second round of data collection: total duration 40 minutes.** The cognitive data will be collected in-person and take around 20 minutes. The stool sample and online questionnaires will be completed in your own time within 48 hours of the study visit. The online questionnaires will take around 15 minutes for completion, and the stool sample 5 minutes.

Are there any disadvantages or risks in participating?
A possible risk of taking part in this research is a potential realisation of an alcohol, eating, or mental health problem, as this questionnaire will be assessing drinking & eating behaviours and mental health symptoms. Another potential risk is experiencing mild gastrointestinal symptoms, as this is a possible side effect when starting to ingest probiotics.

What are the possible benefits of participating?
You will receive a £20 Amazon Voucher for compensation of your time. You will also have the opportunity of ingesting probiotics at no cost, and you will contribute to research on the gut-brain-axis.

Data Protection Privacy Notice
Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

What personal information will be collected from me and how will it be used?
The personal data being collected from you will be your gender, age, health information, email address, name, and biological data in the form of stool samples. All personal data will be anonymised at the first point of contact. Your name is collected for consent. Your email address will be used to send you the questionnaire at the beginning and end of the study but will be anonymised by being matched with a unique participant ID. A stool sample will be collected from you at the baseline and follow-up timepoints of the study, to examine any possible physiological markers brought about by the probiotic intervention.

Details of storage of bodily samples.
Stool samples will be stored and analysed at Loughborough University and will be retained for this study no longer than 1st October 2027.

What is the legal basis for processing my personal information?
Personal data will be processed on the public task basis. For further details on the data protection legislation see: https://ico.org.uk/for-the-public/.
Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as "sensitive data". The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

How long will my personal information and anonymised data be retained?
Your personal information and anonymised data will be stored until 1st October 2027.

Will my taking part in this study be kept confidential?
Because I will be issuing participant IDs, I might be able to identify participants responses. However, no identifiable personal information will be included in any of the project submissions or shared beyond the investigators. All data will be fully anonymised, with participant IDs replacing names and any other identifying details removed. Anonymised data will be securely shared with Cultech Ltd and the Innovate UK project team following the study, during a scheduled follow-up meeting. No individual will be identifiable in any report, presentation, or publication.

How will the anonymised data/results collected from me be used?
Your anonymised data will be used in postgraduate research, which will likely be published. All information will be securely stored on the University IT systems (OneDrive).

I have some more questions; who should I contact?
Kim Gehrke k.m.gehrke2@lboro.ac.uk

If you require any further information regarding the General Data Protection Regulations, please see: https://www.lboro.ac.uk/privacy/research-privacy/.

All procedures have been approved by the Loughborough University Ethics Approvals (Human Participants) Sub-Committee.

What if I am not happy with how the research was conducted?
If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Review Sub-Committee, Research & Innovation Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: researchpolicy@lboro.ac.uk
The University also has policies relating to Research Misconduct and Whistle Blowing which are available at https://www.lboro.ac.uk/internal/research-ethics-integrity/research-integrity/.