

# Effects of Probiotic Supplementation on Cognitive Lapses and Gastrointestinal Symptoms in a Non-Clinical Population: A Randomised, Placebo-Controlled Trial

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## **Background and Rationale**

Emerging research highlights the significant role of gut inflammation and dysbiosis in a range of health outcomes. This study aims to explore how probiotic supplementation can improve cognitive function, mental health, and gastrointestinal symptoms in a non-clinical population.

## **Study Objectives**

- **Primary Aims:** To assess the impact of probiotics on cognitive lapses and gastrointestinal symptoms
- **Secondary Aims:** To assess the impact of probiotics on drinking behaviour, alcohol cravings, and mental health
- **Exploratory Aim:** To evaluate whether probiotics affect disordered eating behaviours

## **Study Design**

- A triple-blind, randomised, placebo-controlled trial
- The study will be conducted over an 8-week period with baseline and post intervention data collection points

## **Participants**

~80 healthy adults in the Loughborough community. Participants will be randomly put into the intervention or the placebo group. Exclusion criteria are:

- Participants under 18 years of age
- Current use of probiotics or prebiotics (in supplements or foods) within the past 4 weeks
- Antibiotic use within the past 4 weeks
- Chronic gastrointestinal disorders (e.g. Irritable Bowel Syndrome, Crohn's disease, etc)
- Major psychiatric conditions diagnosed (e.g., bipolar disorder, schizophrenia, etc)
- Current pregnancy or breastfeeding

## **Data Collection**

Participants will be asked to complete lifestyle and demographic questions, as well as the following online questionnaires, at baseline and at the 8-week completion mark:

- **Cognitive Failures Questionnaire 2.0 (CFQ 2.0)** – Measures everyday cognitive lapses
- **Gastrointestinal Symptom Rating Scale (GSRS)**: Assesses gastrointestinal symptoms
- **Penn Alcohol Craving Scale (PACS)** – Measures an individual's craving to drink alcohol
- **Loughborough Alcohol Drinking Questionnaire (LoAD-Q)** – Assesses drinking behaviours
- **Eating Disorder Examination Questionnaire (EDE-QS)** – Measures disordered eating behaviours
- **Depression Anxiety Stress Scales (DASS-12)** – Measures depression, anxiety and stress

## **Hypotheses**

1. Probiotics will improve cognition (lower CFQ 2.0 scores)
2. Probiotics will reduce gastrointestinal symptoms (lower GSRS scores)
3. Probiotics will reduce alcohol cravings (lower PACS scores)
4. Probiotics will improve mental health symptoms (lower DASS-12 scores)
5. Probiotics will improve drinking behaviours (lower LoAD-Q scores)
6. Probiotics will mediate eating behaviours (lower EDE-QS scores)

## **Innovative Aspects**

This study brings several novel contributions to the existing literature:

- **Gut-brain axis:** Investigates gut microbiota's role in a range of health-related outcomes
- **A non-clinical sample:** Limited probiotic research has been conducted on non-clinical individuals seeking preventative or holistic health improvements.
- **Exploration of drinking and eating behaviours:** Exploring whether the gut mediates these.

### Conclusion

This study will investigate the impact of probiotics on self-reported mental health, cognition, and gastrointestinal symptoms in non-clinical adults. Probiotics might offer cost-effective interventions to improve symptomology before disorders become fully clinical, potentially paving the way for novel early intervention strategies.

The study would also provide pilot data for the next study, in which we will carry out a probiotic intervention on Alcohol Use Disorder patients. We will investigate the impact of probiotics on biological and cognitive markers in more detail through lab-based measures like cognitive tasks and blood samples.