



## Effects of mushroom extract on individuals with inflammatory bowel disorder

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We invite you to take part in a research study to help us understand the beneficial effects of mushroom extract for inflammatory bowel disorder.

### Purpose of the study:

There are more than 2,000 species of edible mushrooms. They contain a wide range of health-promoting compounds, one of which are polysaccharides. These are not able to be digested by your gut but are prebiotics (food source) for beneficial gut bacterial such as *Bifidobacteria* and Lactobacilli. Your gut microbiota play a vital role in gut health and changes in its population (dysbiosis) are associated with, and may also contribute to, a range of gut disorders.



White mushroom

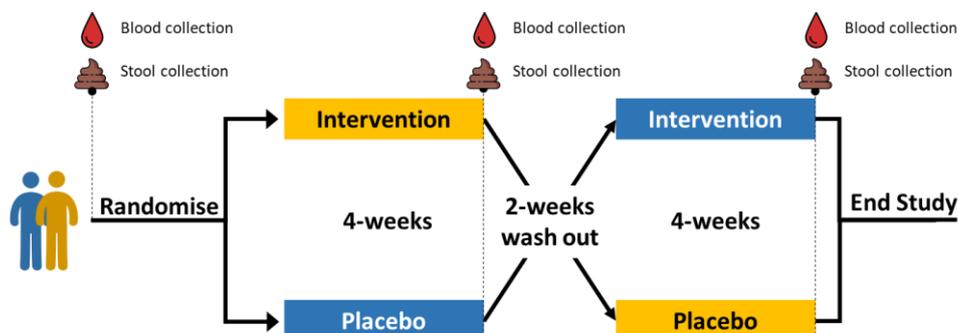
Mushroom extract provide an excellent source of polysaccharides. This study looks at if a diet supplemented with white mushroom extract can improve bowel motion and help restore healthy gut microbiome. This study is sponsored by ViGA Global, the producers of the mushroom extract.



Frozen mushroom extract

### How can you be involved?

You will be asked to take part in a randomised cross-over study. This means you will undertake two 4-week trials of the mushroom extract or a placebo. The order is randomised, both you and the investigator will not know of the order until the end of this study.



Before starting, you will be asked to provide a stool sample (using self-collection kit) and blood sample (at Campbelltown Private Hospital) as the baseline. For the 4-week trial, you will be asked to consume half servings of the extract or placebo in the first 3 days (for your gut to get use to the polysaccharides) then a full serving every day. During this period, you will fill out a weekly symptom questionnaire and

keep a bowel diary (this will be provided to you). At the end of the first 4-week trial you will provide a blood and stool sample. There will be a 2-week “wash-out” period where you return to your normal diet before starting the second 4-week trial.

The total study will involve 3 face-to-face meetings (initial, after trial #1, after trial #2). You will be provided with a \$100 gift voucher at the end of trial #1 and #2 for you time and travel costs (totalling \$200). You will be emailed a copy of the study report at the conclusion of this study, summarising the effects of mushroom extracts on IBD symptoms and microbiota.

#### Are there any risks?

Mushroom extract are safe to eat, similar studies in individuals with gut disorders showed no adverse effects. The increase in polysaccharide consumption may cause extra bloating, flatulence, or diarrhoea in some individuals. The half-serving for the first 3-days should minimise these symptoms but if you experience abdominal pain or constant diarrhoea after 24hrs, stop consumption immediately and seek medical advice.

Please let us know if you have had allergies or adverse reactions to mushrooms.

#### Why are we doing this?

IBS a common gut disorder that requires long-term management. Non-starch polysaccharides, such as these found in mushrooms, may provide a food-source natural produce to help induce remission of symptoms by restoring health gut microbiota. Changing the gut microbiome using natural prebiotics provide a promising therapeutic approach to sustainable treatment of dysbiosis and management of IBD symptoms. Your data will be non-identifiable and combined with other participant’s data. Your data will only be used for this study and may be presented (as a statistic) in an academic publication.

Participation is entirely voluntary. You can withdraw from this study at any time, and we will not include your data in our study. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the investigators.

Dr Vincent Ho is a clinical gastroenterologist and a member of this research team. He can discuss this study with you and answer any questions you may have. To find out more, please feel free to contact:

**Chief investigator:** Dr Jerry Zhou and Dr Vincent Ho

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If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au) and quote this ethic project number **[project number]**.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is **[enter approval number once the project has been approved]**.