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Effects of a mushroom blend on gastrointestinal symptoms and the microbiome

Submission date
06/06/2025

Recruitment status
No longer recruiting

Registration date
10/06/2025

Overall study status
Completed

Last Edited
20/01/2026

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Building upon the foundational understanding of gut microbiota's role in health, current research aims to understand the potential effects of edible mushrooms on GI microbiota health. These mushrooms have been recognized for their therapeutic properties in traditional Asian medicine and have surged in popularity in Western supplements. This specific study is investigating the effects of a mushroom blend on gastrointestinal symptoms, quality of life of the individual, and gastrointestinal microbiota make-up following a 6-week period of consuming the study product or placebo.

Who can participate?
Healthy volunteers between the ages of 30 and 60 years with occasional gastrointestinal (GI) discomfort (less than three times per week over the last 6 weeks)

What does the study involve?
The study involves four in-person laboratory visits, each about an hour long, over 6 weeks. Participants will be randomly placed in the study product or placebo group, consume the study product or placebo once daily for 6 weeks, and fill out daily online questionnaires. At study visits 2, 3, and 4 they will fill out questionnaires. At study visits 2 and 4 they will give a small amount of blood and bring in a stool sample.

What are the possible benefits and risks of participating?
Taking part in this study may or may not benefit participants personally. However, this research may help researchers better understand the effect of these supplement combinations on GI distress. Possible risks for these study products are mild GI distress, such as stomach upset, nausea, and diarrhea. Additionally, there are very low possibilities of dry mouth, changes in blood pressure, and excessive bleeding. Reishi can potentially lower blood pressure in individuals with severely high blood pressure. Reishi has been shown to exhibit anti-platelet properties, which can contribute to cardiovascular benefits, but can also lead to a potential risk of excessive bleeding if already on blood-thinning medications, such as when you have a small cut, this may bleed more than normal.

Where is the study run from?
University of South Carolina (USA)

When is the study starting and how long is it expected to run for?
February 2025 to December 2025

Who is funding the study?
M2 Ingredients (USA)

Who is the main contact?
Shawn M. Arent, sportsci@mailbox.sc.edu

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT07027462

Protocol serial number
Pro00144162

Study information

Scientific Title
A randomized, double-blind, parallel-group, placebo-controlled clinical trial of a mushroom blend to evaluate its impacts on gastrointestinal and overall quality of life and microbiome makeup in healthy adults

Acronym
GI Health

Study objectives
1. The mushroom blend will lead to beneficial changes in gastrointestinal microbiota as compared to placebo.
2. The mushroom blend product will improve the quality of life as measured by the Gastrointestinal Symptom Rating Scale and the Patient Assessment of Constipation Quality of Life.
3. The mushroom blend will improve overall mood states as measured by the profile of mood states questionnaire.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/05/2025, University of South Carolina Institutional Review Board (1600 Hampton Street, Suite 414D, Columbia, 29208, United States of America; +1 (0)803 777 6670; LisaJ@mailbox.sc.edu), ref: Pro00144162

Study design
Randomized double-blind parallel-group placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life

Health condition(s) or problem(s) studied
Gastrointestinal health

Interventions
This is a 6-week, double-blind, randomized controlled trial. Randomization will be carried out in Excel using the RANDO function. Participants will be stratified by sex and block randomization will be applied to ensure balanced groups across both sexes.Those randomized into the placebo group will receive acacia gum. Those randomized into the study product will consume 1.8 g of cordyceps, 99 mg reishi, and 99 mg of lion’s mane. Participants will consume the study product

or placebo once daily for 6 weeks and fill out daily online questionnaires. At study visits 2, 3, and 4 they will fill out questionnaires. At study visits 2 and 4 they will give a small amount of blood and bring in a stool sample.

Intervention Type
Supplement

Primary outcome(s)
Gastrointestinal microbiome measured using 16S rRNA gene sequencing, PCR, and deep shot sequencing at baseline (day 0) and day 42

Key secondary outcome(s))
1. Gastrointestinal symptoms measured by the Gastrointestinal Symptoms Rating Scale (GSRS) at baseline (day 0), day 21, and day 42
2. Constipation measured by the Patient Assessment of Constipation – Quality of Life (PAC–QOL) at baseline (day 0), day 21, and day 42
3. Quality of life measured by the Profile of Mood States (POMS) questionnaire at baseline (day 0), day 21, and day 42
4. Metabolites measured using blood samples at baseline (day 0) and day 42

Completion date
23/12/2025

Eligibility

Key inclusion criteria
1. Healthy males and females aged 30 to 60 years of age (inclusive)
2. Subject has provided written and dated informed consent
3. Individual indicates they experience occasional GI discomfort, and have never been diagnosed with any gastrointestinal disorder, yet have occasional complaints of bowel irregularity, bloating or discomfort (after meals or beverages)
4. Subject may express that they experience occasional after-snack or a meal, intestinal gas-related symptoms including abdominal discomfort, cramps, distended feeling/bloating, and or flatulence as part of the study entry criteria. Occasional GI distress will be defined as <3 times per week over the prior 6 weeks, with each episode resolving within 24 hours and not requiring medical intervention
5. Body Mass Index (BMI) 19 to 34.9 kg/m2 (normal weight to class I obesity)
6. Subject is a non-smoker
7. Subject agrees not to use any new vitamin, mineral, or other dietary supplement product until after study completion
8. Subject agrees to provide a stool sample for microbiota analysis per the study protocol
9. Subject is willing and able to comply with the protocol and the scheduled study visits
10. Subject will be asked about dietary supplementation use within the past 6 months. If the subject began taking a supplement within the past month, they will be asked to discontinue supplement use followed by a 2-week washout prior to participation. In all other cases, supplement use will be asked to be maintained throughout the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Subject has any of the following medical conditions:
1.1. Gastrointestinal disease or any GI diagnosed disorder (i.e., dyspepsia, functional dyspepsia, gastrointestinal reflux, etc)
1.2. Active heart disease
1.3. Uncontrolled high blood pressure (≥140/90 mmHg)
1.4. Renal or hepatic impairment/disease
1.5. Type I or II diabetes
1.6. Bipolar disorder
1.7. Parkinson's disease
1.8. Unstable thyroid disease
1.9. Immune disorder (such as HIV/AIDS)
1.10. Any medical condition deemed exclusionary by the Principal Investigator (PI)
2. Subject has a history of cancer (except localized skin cancer without metastases) within 5 years prior to screening
3. Subject is currently taking any blood thinners
4. Subject has a medical condition that is known to impact the gastrointestinal system and functions
5. Subject is currently taking or has within the prior 120 days any prescription antibiotics, or supplemental probiotic or prebiotics (30-day washout is acceptable)
6. Subject is currently taking supplemental (OTC medicine or dietary supplements) of any laxative or bowel function stimulant (i.e., Ri-Mucil, Metamucil [psyllium], Colace, Milk of Magnesia, MiraLAX, FiberCon [polycarophil], DulcoLax, etc)
7. Subject is on an unstable dose of medication (defined as fewer than 90 days at the same dose)
8. Subject is taking a prescription medication deemed exclusionary by the Principal Investigator (PI)
9. Subject has an allergy to any ingredients in the Study Product
10. Subject has a history of drug or alcohol abuse in the past 12 months
11. Subject has a history of a psychiatric illness or mental health disorder (including for drug or alcohol treatment) that required hospitalization in the prior 12 months
12. Subject has any condition or health history abnormality that in the expert opinion of the PI, participation in the study would compromise the safety of the subject or the quality of the study data
13. The subject is participating in or has participated in another clinical research study within 30

days prior to the Screening visit.
14. Subject is consuming any of the study products already
15. Subject is diagnosed with a stress disorder

Date of first enrolment
11/06/2025

Date of final enrolment
08/10/2025

Locations

Countries of recruitment
United States of America

Study participating centre
University of South Carolina
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Columbia
United States of America
29208

Sponsor information

Organisation
Substantiation Sciences, LLC

Funder(s)

Funder type
Industry

Funder Name
M2 Ingredients

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes