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Effectiveness of low doses of yeast beta-glucan 1,3/1,6 in adults with moderate stress in fighting respiratory infections, reducing fatigue, boosting the immune system and improving digestive health

Submission date 11/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2023	**Overall study status** Completed	
Last Edited 27/01/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Beta-glucans derived from fungi and yeast are known for their immune-modulating effects. It has been asserted that yeast beta-glucan significantly improves the function of the immune system by activating macrophages, one of the primary defences of the immune system. Its benefits have been extensively studied globally among athletes, stressed women, elderly people, healthy adults and children. Upper respiratory tract infections are the most common form of infection in every age group worldwide and have a significant negative impact on productivity, healthcare spending, and the economy. Based on published studies, the application of yeast beta glucans was proven as a possible therapeutic and preventive approach in managing and preventing recurrent respiratory tract infections. Therefore, this study aims to evaluate the effectiveness of yeast beta-glucan 1,3/1,6 on fatigue, respiratory infection, immune markers and gut health among adults with moderate stress.

Who can participate?
People aged 18-59 years with moderate stress and common cold symptoms in the past 6 months

What does the study involve?
Participants are randomly allocated to take either Yeast Beta Glucan (YBG) dose 1, dose 2 or dose 3 or a placebo (a substance that has no effect, used as a control). The study duration is 12 weeks. In this study, several assessments will be conducted at the screening level, baseline, the sixth week and the twelfth week. Other assessments that will be conducted in this study include blood profile, gut microbiome analysis and diet recall. A total of 20ml of blood will be collected to conduct the complete blood count including immune and oxidative stress biomarkers. In addition, several questionnaire forms will be used to assess the occurrence of upper respiratory tract infection symptoms, mood status and fatigue. In addition, an anthropometric evaluation will be carried out to assess the nutritional status of the participants.

What are the possible benefits and risks of participating?
The benefits may not be direct. The supplement has the potential to strengthen and improve the immune system of the participants who receive this supplement. Participants may or may not experience side effects. Side effects may include changes in blood pressure, nausea, diarrhea and vomiting.

Where is the study run from?
Mead Johnson Nutrition (Malaysia)

When is the study starting and how long is it expected to run for?
January 2023 to September 2025

Who is funding the study?
Mead Johnson Nutrition (Malaysia) Educational Grant

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UKM PPI/111/8/JEP-2023-211

Study information

Scientific Title
Efficacy of low dosage yeast beta-glucan 1,3/1,6 on respiratory infection, fatigue, immune markers and gut health among adults with moderate stress

Study objectives
1. The yeast beta glucan 1,3/1,6 supplementation is effective in improving upper respiratory tract infection symptoms and its related immune responses among adults with moderate stress in Klang Valley.
2. The yeast beta glucan 1,3/1,6 supplementation is effective in improving fatigue and psychological aspects among adults with moderate stress in Klang Valley.
3. The yeast beta glucan 1,3/1,6 supplementation is effective in improving gut health among adults with moderate stress in Klang Valley.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/06/2023, Research Ethics Committee, The National University of Malaysia (Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia, Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Mukhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak 56000 Cheras, Kuala Lumpur, 56000, Malaysia; +60 (0)391455046; sepukm@ukm.edu.my), ref: UKM PPI /111/8/JEP-2023-211

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Respiratory infections, fatigue, immune system, and digestive health of adults with moderate stress

Interventions
Current interventions as of 30/01/2024:
This is a randomized, double-blind, placebo-controlled study designed to determine the efficacy of Yeast Beta Glucan 1,3/1,6 on respiratory infection, fatigue, immune markers and gut health among adults for 12 weeks.

This study requires participants to take either Yeast Beta Glucan (YBG) dose 1, YBG dose 2, YBG dose 3 or a placebo (a substance that has no therapeutic effect, used as a control). Once registered for the study, the eligible participants will undergo simple randomization to determine group allocation.

In this study, several assessments will be conducted at the screening level, baseline, the sixth week and the twelfth week. Other assessments that will be conducted in this study include blood profile, gut microbiome analysis and 3-day diet record. A total of 20 ml of blood will be collected to conduct the complete blood count including immune and oxidative stress

biomarkers. In addition, several questionnaire forms will be used to assess the occurrence of upper respiratory tract infection (URTI) symptoms, mood status and fatigue. In addition, an anthropometric evaluation will be made to assess the nutritional status of the study participant.

Previous interventions:
This is a randomized, double-blind, placebo-controlled study designed to determine the efficacy of Yeast Beta Glucan 1,3/1,6 on respiratory infection, fatigue, immune markers and gut health among adults for 3 months.

The supplement is in a 60 g sachet known as Provital Immuna Plus® is a nutritious milk that helps to support a healthy immune system. Finished products in the form of 60 mg sachet registration number 20-1-03444. The subjects will be taking either 204 mg and 100 mg of Yeast Beta
Glucan or placebo with 0 mg in the form of a 60 g sachet mixed with 160 ml of warm water until dissolved, two times daily (30 g each serving).

The placebo which will be used is a sensory-identical supplement in a sachet, composed of 60 mg maltodextrin.

Once registered for the study, the eligible participants will undergo simple randomization to determine group allocation. The study duration is 12 weeks. In this study, several assessments will be conducted at the screening level, the fourth week, the sixth week and the twelfth week. Other assessments that will be conducted in this study include blood profile, gut microbiome analysis and diet recall. A total of 20 ml of blood will be collected to conduct the complete blood count including immune and oxidative stress biomarkers. In addition, several questionnaire forms will be used to assess the occurrence of upper respiratory tract infection (URTI) symptoms, mood status and fatigue. In addition, an anthropometric evaluation will be made to assess the nutritional status of the study subjects.

Intervention Type
Supplement

Primary outcome(s)
Current primary outcome measure as of 22/01/2024:

1. Upper respiratory tract infection (URTI) episodes: occurrence, severity and duration measured using the Wisconsin Upper Respiratory Symptom Survey (WURSS)-21 at baseline, weeks 6 and 12.
2. Fatigue measured using the Profile of Mood State (POMS) at baseline and week 6 and 12.
3. Blood immune markers: cytokines interleukin: [IL] IL-6, IL 8, IL-10, TNF-interferon [IFN]-γ, inflammation - CRP measured using blood samples at baseline and week 12.
4. Biomarkers and oxidative stress: oxidative stress (MDA, LPO), inflammatory biomarkers (iNOS, Cox2) measured at baseline and week 12.
5. Quality of life measured using Short Form-36 (SF-36) at baseline and weeks 4, 6 and 12.

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Previous primary outcome measure:

1. Basic health profile (BMI, waist circumference, body fat percentage, complete blood count, fasting blood sugar, lipid profile, liver function test, renal function test) at baseline and week 12
2. Upper respiratory tract infection (URTI) episodes: occurrence, severity and duration measured using the Wisconsin Upper Respiratory Symptom Survey (WURSS)-21 at baseline and weeks 4, 6

and 12
3. Blood immune markers: cytokines interleukin: [IL] IL-6, IL 8, IL-10, TNF-interferon [IFN]-γ, inflammation - CRP measured using blood samples at baseline and week 12

Key secondary outcome(s))
Current secondary outcome measures as of 22/01/2024:

1.The gut bacterial diversity (α diversity, β diversity, comparative analysis) and predicted functional analysis will be assessed at baseline and week 12

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Previous secondary outcome measures:

1. Fatigue measured using the Profile of Mood State (POMS) at baseline and weeks 4, 6 and 12
2. Biomarkers and oxidative stress: oxidative stress (MDA, LPO), inflammatory biomarkers (iNOS, Cox2) measured at baseline and week 12
3. Quality of life measured using Short Form-36 (SF-36) at baseline and weeks 4, 6 and 12
4. Microbiome abundance and functional analysis (α diversity, β diversity, comparative analysis) at baseline and week 12

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/01/2024:
1. 18-59 years old
2. In a stressful environment
3. Scoring 14-26 (moderate stress) on the Perceived Stress Scale (PSS-10)
4. Symptoms of common colds in the past 6 months
5. Willing to comply with protocol requirements

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5. Willing to comply with protocol requirements

Participant type(s)
Healthy volunteer, Health professional, Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
59 years

Sex
All

Key exclusion criteria
1. Participant on immunosuppressant (i.e., steroids)
2. Use of immune-modifying medications or dietary supplements affecting the immune system (at least 2 weeks of washing period for inclusion)
3. Any autoimmune or health concerns
4. Uncontrolled comorbidities including diabetes, hypertension, cardiovascular disease, chronic kidney disease, chronic liver disease, active malignancy, endocrine disorder and cancer
5. Uncontrolled chronic respiratory illness including allergic rhinitis or asthma, presence of nasal ulcers/polyps
6. Body temperature >38C at study commencement
7. Pregnant/lactating female
8. On specific dietary requirements (diabetic diet/low salt diet/etc)
9. On prebiotics or probiotics supplementation (at least 2 weeks of washing period for inclusion)
10. On antibiotics washing period within 2 weeks for inclusion
11. Disabilities individuals- long-term physical, mental, intellectual and sensory impairment
12. Individuals without symptoms of common colds for the past 6 months
13. Allergy to yeast, oat, wheat, barley
14. Influenza vaccination for the past 1 year
15. Pneumococcal vaccine for the past 5 years
16. Participate in another research study

Date of first enrolment
02/02/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
H-care Wellness Center
61, Jalan Raja Muda Abdul Aziz, Chow Kit
Kuala Lumpur
Malaysia
50300

Study participating centre
Pusat Jantung & Paru-paru
Tingkat 8, Blok Klinikal
Hospital Canselor Tuanku Muhriz
Jalan Yaacob Latif, Bandar Tun Razak
Kuala Lumpur
Malaysia
56000

Study participating centre
Faculty of Medicine UKM
Level 6, Preclinical Building
Jalan Yaacob Latif, Bandar Tun Razak
Kuala Lumpur
Malaysia
56000

Sponsor information

Organisation
Mead Johnson Nutrition Malaysia

Funder(s)

Funder type
Industry

Funder Name
Mead Johnson Nutrition

Alternative Name(s)
Mead Johnson

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/01/2025	27/01/2025	Yes	No
Participant information sheet			25/07/2023	No	Yes