INFORMATION SHEET (VALIDATION)

Research Title:

A randomized, double-blind, and placebo-controlled study to investigate the Efficacy of Low Dosage Yeast Beta Glucan 1,3/1,6 on Respiratory Infection, Fatigue, Immune Markers and Gut Health Among Moderate Stress Adults.

Introduction:

You are invited to participate in a research study. Before participating in this study, it is important that you take time to read and understand the information in this information sheet.

Purpose of Study:

The aim of this study is to investigate the Efficacy of Low Dosage Yeast Beta Glucan 1,3/1,6 on Respiratory Infection, Fatigue, Immune Markers and Gut Health Among Moderate Stress Adults.

What will the study involve?

This study requires you to take either Provital Immuna Plus of Yeast Beta Glucan(YBG) dose 1, Provital Immuna Plus of Yeast Beta Glucan (YBG) dose 2, Provital Immuna Plus of Yeast Beta Glucan(YBG) dose 3 or 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. 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 20ml 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.

Risks:

The benefits you will receive if you participate in this study may not be direct. The Provital Immuna Plus of Yeast Beta Glucan(YBG) supplementation given has the potential to

strengthen and improve the immune system of the study subjects who received this supplementation.

Benefits:

You may or may not experience side effects. Side effects may include changes in blood pressure, nausea, diarrhea and vomiting. If this happens, you should notify the researcher immediately of any side effects experienced by you by calling the phone number listed below. Rest assured that you will be treated or referred appropriately.

Do you have to take part?

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet. Should you decide to participate, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for a variety of reason. In this event, you will not be penalized or lose your rights as a patient.

Data & Confidentiality:

The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential. All remaining specimens taken will be discarded in accordance with proper disposal procedures.

Payment and compensation:

You do not have to pay to participate in this. This study will be conducted with a sponsorship from Mead Johnson Nutrition Malaysia. If you develop complications related to the study, then you will be compensated accordingly by the sponsor, Mead Johnson Nutrition or Universiti Kebangsaan Malaysia (UKM).

Who can I ask about the study?

If you have any questions, you can direct them to the research team. You can also contact the following researcher for clarifications.

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