UNIVERSITI SAINS MALAYSIA

Human Research Ethics Committee USM

JEPeM-USM

RESEARCH INFORMATION

You are invited to take part voluntarily in a research study to determine the effect of weight loss by COMBINE-BROWN weight loss program and evaluation study during follow-up.

Research Title:

Effect Of Combination Of Behavioural Intervention And Nutrition Education With Brown Rice (Combine-Brown) Weight Loss Program On Body Composition, And Antioxidant Level In Overweight And Obese Adults.

Researcher's name: Ong Mei Gee, Associate Prof. Dr Rohana Abdul Jalil, Prof. Dr Wan Rosli Wan Ishak, Associate Prof. Dr Che Badariah Ab. Aziz (No. MMC: 29445), Dr Noor Aman Hamid (No. MMC: 63187), Prof. Walter Willet, Prof. Frank Hu, Dr Vasanti Malik, Ms Wan Suriati Wan Nik (USM), Ms Nik Fadzlina Hamid (USM)

INTRODUCTION

Obesity or being overweight is a major health problem nowadays. It is due to chronic diseases such as heart disease, diabetes, and high blood pressure and has adverse effects on the quality of life, thus a study of a weight loss program should be conducted among people who have obesity problems.

Brown rice is whole grain and consists of several vitamins, minerals, unsaturated fats, antioxidants, and phytochemicals. White rice, which is refined grain, is formed by removing the husk, bran and germ layers in the milling and polishing process. As a result, it causes a total

loss of nutrients such as vitamin B, manganese, phosphorus, iron, dietary fibre, and essential fatty acid (Babu et al., 2009).

Before you agree to participate in this program, you must read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts and precautions of this study. It also describes the alternative procedures that are available to you and your right to withdraw from the intervention at any time. If you agree to participate in this study, you will receive a copy of this form to keep for your records.

Your participation in this study is expected to last up to 26 weeks, 12 weeks for the weight loss program and another 12 weeks for evaluation study by follow-up. 132 subjects are expected to participate in this study.

PURPOSE OF THE STUDY

This study aims to:

1. To determine the nutrition composition and glycaemic index of brown rice and white rice varieties.
2. To determine the weight change after participating in 12 weeks of weight loss program.
3. To determine the difference in body composition and body composition after participating in 12 weeks of weight loss program.
4. To determine the difference in lipid profile after participating in 12 weeks of weight loss program.
5. To determine the difference in antioxidant levels after participating in 12 weeks of weight loss program.
6. To assess the changes in the quality of the scores after participating in 12 weeks of weight loss program.
7. To determine the weight change and body composition during follow-up for the evaluation study.

QUALIFICATION TO PARTICIPATE

The doctor in charge of this study or members of the study has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about your health status. You should not participate in this study if you do not meet all qualifications.

Some of the requirements to participate in this study include:

i. Age between 18 and 60 years
ii. Body mass index is overweight or obese according to WHO (2016)
iii. Confirmed fit and healthy to participate in weight loss program although you are being diagnosed as having other chronic diseases.
iv. Able to walk without aiding instrument.
v. Do not take part in any other weight loss program or research
vi. Willing to consume brown rice for three months for one meal daily.
vii. Consume white rice as a staple diet

You **cannot** participate in this study if:
i . Age less than 18 years, and more than 60 years
ii . Having a body mass index of less than 25.0 kg / m^2
iii . Pregnant and plan to become pregnant during the study period
iv . Using a pacemaker or disabled
v. Consume brown rice, parboiled rice or any rice that claimed to decrease blood sugar level as a staple diet

If you participate in this study, you must agree to adhere to a weight loss regimen as directed by study personnel.

STUDY PROCEDURES

If you agree to participate in this study, we will perform a physical test including a blood test. You are also required to provide information about your medical history, and any illness, drugs or supplements that you are taking. You will be given instructions on how to modify your daily

diet and will be introduced to an exercise regimen. Participants will be randomised into intervention groups based on their willingness to take part in the desired weight-loss regimen.

After enrolling in the program, a briefing will take place on the first visit to explain the purpose and flow of the program. Consent forms will be distributed and enquiry about the program will be explained by the administrators and staff of the program. The participants will be given two weeks of probation period before they confirm their participation to fully take part in this program. After reaching an adequate number of participants to enrol in this program, the pre-intervention baseline data will be collected, which include sociodemographic information, dietary intake, anthropometric measurements (weight, height, body mass index), body composition (percentage of body fat and weight and body fat), and blood profile (glucose, lipid profile, oxidative stress and antioxidant).

The regimen should be followed repeatedly for 12 weeks and at week 12, identify any significant changes that occur before and after the program. When the program has ended, you are expected to continue the weight loss regimen learned in the program on your own to maintain your weight without facilitators. Study evaluation at follow-up will be conducted at week 26 to evaluate the efficiency of the program and changes in body weight after the program.

RISKS

The study has few risks. You may experience some discomfort during blood is taken. BODYSTAT 1500 will be used to measure your body fat levels. It uses electric current flowing through the body, but the electric current is very low and has very minimal risk. During aerobic exercise, you might have a risk of knee pain due to the pressure of your body weight. If any important new information is found during the study that might change your consent to continue in the study, you will be notified as soon as possible.

REPORTING HEALTH EXPERIENCES.

If you have any injury, bad effect, or any other unusual health experience during this study, make sure that you immediately inform the researcher. You will be referred to doctors who are involved in this study. You can call at anytime, day or night, to report such health experiences.

PARTICIPATION IN THE STUDY

Your participation in this study is entirely voluntary. You may refuse to take part in the study or you may stop participating in the study at any time, without a penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the doctor or staff without your consent.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

The weight loss regimen and study procedures will be provided to you without any cost. You will receive information about the status of your body weight, total fat and blood profile in your body. Information from this study will provide information about diet, lifestyle changes and a form of exercise that can improve public health and quality of life, and the information from this study may be used for future research.

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law or the ethics committee. Data obtained from this study that does not identify you individually will be published for knowledge purposes. Your original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities to verify intervention procedures and/or data. Your medical information may be held and processed on a computer. By signing this consent form, you authorize the record review, information storage and data transfer described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign on the signature page **[ATTACHMENT S or ATTACHMENT P]**

ATTACHMENT S

Subject Information and Consent Form

(Signature Page)

Research Title:	**Effect of Combination of Behavioural Intervention and Nutrition Education with Brown Rice (COMBINE-BROWN) Weight Loss Program on Body Composition, and Antioxidant Level in Overweight and Obese Adults**
Researcher's Name:	**Ong Mei Gee, Associate Prof. Dr. Rohana Abdul Jalil, Prof. Wan Rosli Wan Ishak, Associate Prof. Dr Che Badariah Ab. Aziz (No. MMC: 29445), Dr. Noor Aman A. Hamid (No. MMC: 63187), Prof Walter Willet, Prof Frank Hu, Dr Vasanti Malik, Ms Wan Suriati Wan Nik (USM), Ms Nik Fadzlina Hamid (USM)**

To become a part of this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Subject Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time. I have received a copy of this Patient Information and Consent Form to keep for myself.

Subject's Name (Print or type)	**Subject's Initials**
Subject's I.C No. (New)	**Subject's I.C** No. (Old)
Signature of Subject or Legal Representative	**Date** (dd/MM/yy) (Add time if applicable)
Name of Individual Conducting Consent Discussion (Print or Type)	
Signature of Individual Conducting Consent Discussion	**Date** (dd/MM/yy)
Name & Signature of Witness	**Date** (dd/MM/yy)

Note: i) All subjects who are involved in this study will not be covered by insurance.

ATTACHMENT P

Subject's Material Publication Consent Form

Signature Page

Research Title:	**Effect of Combination of Behavioural Intervention and Nutrition Education with Brown Rice (COMBINE-BROWN) Weight Loss Program on Body Composition and Antioxidant Level in Overweight and Obese Adults**
Researcher's Name:	**Ong Mei Gee, Associate Prof. Dr. Rohana Abdul Jalil, Prof. Wan Rosli Wan Ishak, Associate Prof. Dr Che Badariah Ab. Aziz (No. MMC: 29445), Dr. Noor Aman A. Hamid (No. MMC: 63187), Prof Walter Willet, Prof Frank Hu, Dr Vasanti Malik, Ms Wan Suriati Wan Nik (USM), Ms Nik Fadzlina Hamid (USM)**

To become a part of this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.

- All the published materials will be shared among medical practitioners, scientists and journalists worldwide.
- The materials will also be used in local publications, and book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used for advertising purposes or as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Subject's Name (Print or type)	**Subject's Initials** or **Number**

Subject's I.C No.	Subject's Signature	**Date** (dd/MM/yy)

Name and Signature of Individual Conducting Consent Discussion	**Date** (dd/MM/yy)

Note: i) All subjects who are involved in this study will not be covered by insurance.