Participant Information Sheet

Title:
Investigate the weight management effect of Probiotic Super Green Powder (a dietary supplement containing white kidney bean extract, blood orange extract, dietary fibre, and probiotics) in healthy overweight participants

Chief Investigator/Senior Supervisor: Professor Harsharn Gill

Associate Investigator(s)/Associate Supervisor(s): Dr Jessica Danaher
Dr Lisa Newman

What does my participation involve?

Introduction

You are invited to take part in this research project, which is called "Investigate the weight management effect of Probiotic Super Green Powder (a dietary supplement containing white kidney bean extract, blood orange extract, dietary fibre, and probiotics) in healthy overweight participants".

You have been invited because you have shown interest in learning more about and/or participating in this research project.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

Being overweight affects more than 1 billion adults worldwide and it is reaching epidemic proportions in Australia. Snacking is commonly associated with an excessive intake of high-fat and high-sugar foods, and is considered to be a predisposing factor to obesity. Even being mildly to moderately overweight (body mass index [BMI], 25-28 kg/m^2) increases the risk of complications such as type 2 diabetes, hypertension and kidney disease. Although participating in calorie reduced weight loss programs and correcting inappropriate eating habits (i.e. by increasing fibre and protein content) are often sufficient in people who are moderately overweight; maintaining adequate nutrition habits over time is often difficult and thus leads to weight regain.

Probiotic Super Green Powder™ is a new commercially available nutritional supplement that contains white kidney bean, blood orange and green tea extracts in addition to probiotics (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum). These active ingredients have been reported to have body weight reduction effects when looked at individually in scientific investigations. Based on these investigations, it has been hypothesized that a supplement containing a cocktail of these ingredients would influence weight reduction and snacking behaviours.

The primary purpose of this study is to assess the potential benefit of using Probiotic Super Green Powder™ to sustain the commitment of overweight people trying to control their body weight over an 8-week period. The specific aims of the study will determine the effects of an 8-week supplementation period from either a Probiotic Super Green Powder™ supplement or a placebo and subsequent 4-week follow up on:

- Food cravings, food preference, snacking behaviours and mood status
- Body mass, body composition and waist circumference
- Gut microbiota
- Serum concentrations of lipid levels (including triglycerides and cholesterol) and glucose
- Serum concentrations of inflammation and hormonal regulators of appetite (including C-reactive protein, ghrelin and insulin)

What does participation in this research involve?

Experimental testing will be performed at the RMIT Bundoora Campus Clinical Suites (Building 203). Procedures involved in the project are as follows:

Eighty (80) overweight males and females between the ages of 18 - 55 years will be recruited to participate in this study. Overweight is defined by having a body mass index (BMI) above 25 kg/m^2.

You will be excluded from participating within this project for the following reasons: if you do not meet the BMI criteria defining “overweight”, presence of psychiatric disorders, pathologic eating disorders, chronic diseases related to the metabolism of energy and nutrients (i.e. hyperthyroidism, diagnosed diabetes mellitus), unable or unwilling to give informed consent, weight unstable in the previous 3 months (evident by a loss or gain of more than 10% of total body weight), pregnant, post-menopausal, taking contraindicated mediation (i.e. antibiotics, psychotropic drugs or appetite suppressants) or the use of any dietary supplement that might interfere with the results of the study.

You will be initially interviewed on the phone or in person to determine suitability to participate in this study. You will then be invited to attend a familiarisation session, where you will be familiarised with the study purpose, design, and the risks and benefits associated with your participation in this study. Prior to reporting to the RMIT Clinical Suites for this session, you will be asked to fast overnight. You will be asked to provide written consent based on RMIT approved Human Research Ethics documents, and complete personal history and medical history questionnaires. Completing these questionnaires will take approximately 5–10 minutes. You will then have your height and body weight measured. These will be used to verify that you are eligible to take part in the study based on the inclusion and exclusion criteria mentioned above. You will then be asked to ingest the supplement (Probiotic Super Green Powder™) and sit for approximately 30 minutes to ensure that there are no adverse reactions from the active ingredients.

After this, you will be invited to attend your initial testing session. Prior to reporting to the RMIT Clinical Suites for this session, you will be asked to fast overnight. The testing session will take approximately one hour. You will complete questionnaires about your food cravings and eating behaviour using a Food Craving Inventory and Food Frequency Questionnaire. You will also complete a questionnaire regarding your mood status via the Profile of Mood States (POMS) questionnaire.

You will have your blood pressure measured using a blood pressure cuff, body composition measured using bioelectrical impedance analysis, and waist circumference measured using a tape measure. The bioelectrical impedance analysis will involve a very low level of electrical current that will pass through your body. The analyser is commercially available and has been used in the health care/fitness industry as a means to assess body composition for over 20 years. After this, a needle will be inserted into an antecubital vein (in your arm) using standard/sterile procedures and a blood sample will be taken. You will also be provided with a stool sample kit and be asked to provide a sample in the days following the initial clinical session.

Following the initial clinical session, you will randomly be placed into the supplement or placebo group and matched according to your body mass index, body composition and snacking frequency. Over a period of 8-weeks, you will orally ingest one sachet (16g) of the supplement or placebo three times a day (sprinkled over breakfast/lunch/dinner or dissolved in water before each meal). You will be asked to not alter your diet or exercise habits throughout the duration of the study. You will also be asked to keep a four-day food and physical activity diary prior to the subsequent testing session.

An individual involved in the study (Professor Harsharn Gill, Dr Jessica Danaher, Dr Lisa Newman or a Research Fellow) will contact you by phone every week to ensure that procedures are being followed and to see if there are any problems/issues. After 8-weeks of supplementation you will be asked to cease taking the supplement and return to the RMIT Clinical Suites to complete the same battery of tests as the initial clinical session.

Following the 8-weeks of supplementation and clinical testing, you will be asked to maintain a similar diet and exercise regime for another 4-weeks and then return to the RMIT Clinical Suites for follow-up testing. This will also follow the same battery of tests as completed during the initial clinical session.

After the follow-up session, you will be offered nutritional counselling from an Accredited Practicing Dietitian (Dr Jessica Danaher) on general healthy eating principles. If in the placebo group, you will be given the opportunity to undertake the intervention (Probiotic Super Green Powder™) if it is found to be effective.

There are no costs associated with participating in this study, nor will you be paid. However, you will be offered compensation in the form of a gift card for time committed to the project. At the end of each of the three clinical sessions you will receive a gift card to the value of $25 (total of $75).

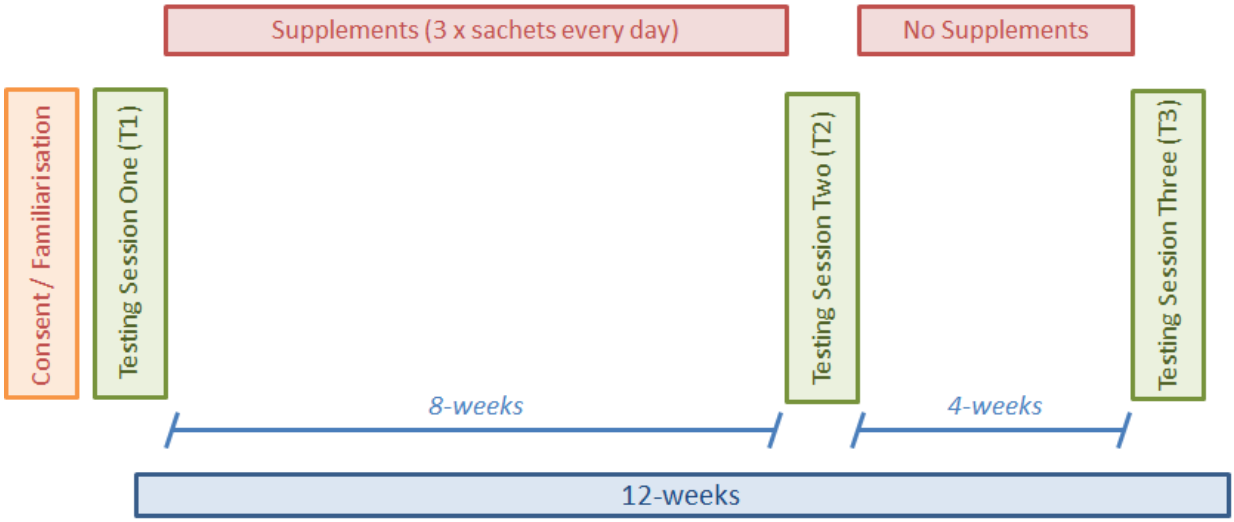

Figure 1: A schematic overview of the 12-week research project. The consent / familiarisation and testing sessions will take approximately one hour each. T1-T3 will involve questionnaires, body composition testing, blood pressure testing, and blood and stool sample collection.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers or with RMIT University.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, you may gain a better understanding about your health. You may receive information regarding your individual results if desired, however it is recommended that you seek an interpretation of this data from your own medical professional.

You may also gain personal satisfaction for your contribution to scientific knowledge and evidence based nutritional practice. The information generated from this project is intended to assess the potential benefit of using Probiotic Super Green Powder™ to sustain commitment of overweight people trying to control their weight.

What are the risks and disadvantages of taking part?

There are a few potential risks of participating in this study.

Blood Sampling: There is a small risk of minor bruising or infection associated with blood sampling. To minimise risk of bruising and infection, blood samples will be performed by a qualified venepuncturist. The area will be swabbed with disinfectant prior to the insertion of the needle to reduce the risk of infection. Compression will be applied to the area following the withdrawal of the needle to reduce risk of bleeding and haematoma. After use, the needle and syringe will be disposed of properly and safely to eliminate further risk of infection.

In the case of an adverse reaction, infection or bruising associated with blood sampling; you would be asked to contact one of the listed investigators and advised to see your own medical professional for assessment at our expense. Occasionally people faint while having blood taken. During the blood test, there will be a staff member who is currently qualified in dealing with the risk associated with the test (i.e. CPR trained and level 2 first aid). As an extra precaution, we have oxygen treatment available.

Psychological distress: You may feel some stress, anxiety and/or embarrassment during the course of the project. This may be due to procedures involved in blood and faecal sampling, body composition analysis, and /or dietary analysis. All actions will be undertaken to reduce the risk of psychological distress. You will be guided through each procedural step (in a verbal and/or written form) as they are being performed. If you become uncomfortable during these procedures, you may stop immediately. If you become upset or distressed as a result of your participation in the research project, members of the research team will be able to discuss appropriate support for you.

An independent counselling service will be offered to you if you wish to seek counselling as a result of your involvement in the study through RMIT University's counselling services (Ph: 9925 5000).

Online surveys: This project will use an external site to collect and analyse data collected in a survey format. The site we are using is Newcastle Innovation (Australian Eating Survey). If you agree to participate in this project, the responses you provide will be stored on the University of Newcastle host server. Once we have completed our data collection and analysis, we will import the data to the RMIT University server, where it will be stored securely for 15 years (a requirement for all clinical studies). The data on the host server will then be deleted and expunged.

Nutritional supplement: In the unlikely event of any ill effects for the nutritional supplement, please inform the researchers as soon as possible. If medical intervention is required, we will write an explanatory note describing the study and any treatment will be provided at our expense.

What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team. Please note that there are no implications if you do decide to withdraw from continued participation. You also have the right to have any unprocessed data withdrawn and destroyed, providing it can be reliably identified.

What happens when the research project ends?

The overall main findings and results from the research project will be available to you if you indicate on the RMIT Consent Form that you would like to receive this information. Results will be supplied in the form of an email summary of the main findings of the project and be provided once the project has concluded. You can opt in or out of receiving a summary of the main findings at any time.

How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information from you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. This information will be coded and re-identifiable. Personal identifying information will be kept separately to your data and can be used to identify you such as in the case of an adverse event. Professor Harsharn Gill will be responsible for the security of all confidential information.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Researchers will ensure that confidentiality is maintained by not presenting your individual data. Instead we will merge your data with that of other participants when presenting the results of the research project.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information that you provide can be disclosed only if (1) it is protecting you or others from harm, (2) if specifically allowed by law, (3) you provide the researchers with written permission.

Any information obtained for this research project that can identify you will be treated as confidential and securely stored. All hardcopy data will be kept in a locked cabinet file at RMIT University. All electronic data will be kept in password locked protected files on the RMIT University server. Professor Harsharn Gill will be responsible for the security of this data. Your data will be accessible to researchers from the School of Science at RMIT University; Professor Harsharn Gill, Dr Jessica Danaher and Dr Lisa Newman. As this is a clinical trial, all data will be retained for 15 years following publication and then all hardcopy will be destroyed by shredding. All electronic data files will also be destroyed at this time.

Who is organising and funding the research?

This research project is being conducted by Professor Harsharn Gill, Dr Jessica Danaher and Dr Lisa Newman from the School of Science at RMIT University. This research is funded by Victorian Department of Economic Development, Jobs, Transport and Resources (50%) and the manufacturer Bio-E Australia Pty Ltd (50%).

A Research Agreement contract has been finalised by RMIT Legal Services, in conjunction with the manufacturer Bio-E Australia Pty Ltd, who will also be providing the substance for investigation (Probiotic Super Green Powder™). The researchers declare that they have no conflict of interest.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been approved by the RMIT University HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact:

If you want any further information concerning this project, you can contact the researchers:

Chief Investigator / Primary Contact Person

Name	Professor Harsharn Gill
Position	Professor Food and Health
Telephone (Office)	Office: (03) 9925 2600
Email	harsharn.gill@rmit.edu.au

Co-Investigator

Name	Dr Jessica Danaher
Position	Lecturer / Early Career Development Fellow in Nutrition
Telephone (Office)	Office: (03) 9925 6117
Email	jessica.danaher@rmit.edu.au

Co-Investigator

Name	Dr Lisa Newman
Position	Lecturer / Early Career Development Fellow Nutrition
Telephone (Office)	Office: (03) 9925 6113
Email	lisa.newman@rmit.edu.au

Co-Investigator

Complaints:

Should you have any concerns or questions about this research project, which you do not wish to discuss with the researchers listed in this document, then you may contact:

Reviewing HREC name	RMIT University
HREC Secretary	Peter Burke
Telephone	03 9925 2251
Email	human.ethics@rmit.edu.au
Mailing address	Research Ethics Co-ordinator Research Integrity Governance and Systems RMIT University, GPO Box 2476, MELBOURNE VIC 3001

Consent Form

Title:

Investigate the weight management effect of Probiotic Super Green Powder (a dietary supplement containing white kidney bean extract, blood orange extract, dietary fibre, and probiotics) in healthy overweight subjects

Chief Investigator/Senior Supervisor: Professor Harsharn Gill

Associate Investigator(s)/Associate Supervisor(s): Dr Jessica Danaher and Dr Lisa Newman

Acknowledgement by Participant

☐ I have read and understood the Participant Information Sheet.

☐ I understand the purposes, procedures and risks of the research described in the project.

☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received.

☐ I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my relationship with RMIT.

☐ I understand that I will be given a signed copy of this document to keep.

☐ I would like to receive information on the main findings of this research project once the research project has concluded.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.