HEALS (Healthy Eating And Living Study): A Randomized Controlled Trial Participant Information Sheet

1. Study Title:

Effect of an 8-week free pre-prepared meals and prescribed exercise on weight loss in obese and overweight individuals: Healthy Eating And Living Study (HEALS) Randomized Controlled Trial. **T**

This trial is funded by an external organization. It is a registered trial by the Australian New Zealand Clinical Trials Registry: U1111-1206-4798.

2. Investigators: Professor Remco Polman (PI- Principal Investigator) and Dr Erika Borkoles (CI- Co-investigator).

3. Introduction:-

You have been asked to take part in the HEALS (Healthy Eating And Living Study) randomized controlled trial (RCT). This trial is registered with the Australian New Zealand Clinical Trial Registry (U1111-1206-4798). RCT means that study participants will be divided (at random) into two equal groups. One group will be provided with 3 pre-prepared meals per day and snacks over an 8 week period. The second group will be provided with dietary guidelines as developed by the Australian Government (www.eatforhealth.gov.au) but will prepare their own food. Both groups will take part in an identical prescribed exercise programme. You will not be able to choose which group you are assigned to.

You are receiving this "Welcome to the HEALS trial" pack because you have volunteered and met the initial inclusion criteria for the study. However, your eligibility will be further assessed at week zero (W0) after completing an adult pre-exercise screening questionnaire designed by the governing body of the exercise physiologists ESSA (Exercise & Sport Science Australia), and you will only be included in the study if you received a 'low-risk' classification in this screening tool.

In your "Welcome to the HEALS trial" pack there is a Participant Information Sheet (PIS), a Participant Consent Form (PCF), a Participant Confirmation of Eligibility Criteria Form, a Questionnaire Pack containing a short demographics section (e.g., age, occupation), the ESSA (Exercise & Sport Science Australia) Adult Pre-Exercise Screening questionnaire, a mental health (DASS – Depression, Anxiety, & Stress Scale) and quality of life (SF-12) questionnaires and an instruction letter stating how to enroll and arrange the test day for W0 of the trial.

The PIS and the PCF tells you everything you need to know about the research project. It explains the purpose of the research, procedures and risks involved. It also describes information about you that will be obtained, how that information will be used and with whom it will be shared. 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, friend or your local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the Consent Form.

By signing it you are telling us that you;

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to use of your personal and health information as described

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

To be eligible for the trial you will be required within one week of receipt of the "Welcome to the HEALS trial" pack to return all completed and signed documentation to the research team either electronically to (heals@qut.edu.au) or by post to:

Prof Remco Polman (Principal Investigator)
Head of School Exercise & Nutrition Sciences
Queensland University of Technology
O-A411, Kelvin Grove Campus
Brisbane, QLD, 4059, Australia

Those participants whose forms and GP clearance if aged 40+ had been satisfactorily completed, including all documents signed will then be invited to come to the Physiology Laboratory of the Queensland University of Technology (QUT) at the Institute of Health and Biomedical Innovation (IHBI), 60 Musk Avenue, Kelvin Grove Campus, Brisbane, QLD, 4059, Australia.

4. Purpose of the Study:

You are invited to participate in a research study, which has a primary aim of comparing short-term (8 weeks) effects of both commercially pre-prepared meals and prescribed exercise on weight loss (e.g. body weight and body composition) in comparison to prescribed exercise and standard Australian dietary advice in previously untrained men and women with overweight and obesity. Additional aims are to describe the effects on biological factors (e.g. lipids, cardiopulmonary fitness).

5. Study Procedures:

5.1 Treatment Schedule & 5.2 Length of Treatment Time Including Length of Each Visit

Table 1: Treatment Schedule. Please tick any or as many as you want to discuss with the research team via email (heals@qut.edu.au) or telephone Dr Erika Borkoles (+61 (0)7 31384547) **or at W0 testing day.**

Tick	Week	Time (min)	Activities	Risk
☐	W0	25	Pre-laboratory tests – Questionnaire Pack completion	Low
			Laboratory tests at QUT/IHBI	
☐	W0 1 hr in total	15	DEXA – Body composition measurements	Low
☐		5	Blood Pressure Readings	Low
☐		5	Blood Sample	Low
☐		20 max	Assessment of aerobic fitness using an exercise bicycle	Medium
☐		5	Height & weight measurements	Low
			Start of Trial	
☐	W1-W8	Total of 3 hours per week	Exercise & Weekly log of activity Strength training 2 x weekly HIIT (High Intensity Interval Training) 2 x weekly Brisk walking & Active play 2 x weekly Rest 1 x weekly 5 minute weekly exercise log	Low
☐	W1-W8		Healthy Eating Depending on arm of trial EITHER following the Australian Dietary Recommendations self-prepared meal plan OR receiving pre-prepared meal packages & snacks.	Low
	W3 & W6	20 min	24 hour dietary recall Only for participants in the Exercise and Standard dietary advice arm of the study.	Low
☐	W1-W9	2-4 min	Weekly video/audio diary This should recorded by any smartphone, ipad, and/or computer software and submit this to the research team's email address (heals@qut.edu.au). You will receive a prompting text message each week as a reminder to complete the diary.	Low
☐	W9	As per W0	All tests to be repeated as per W0 protocols – Laboratory and Questionnaire packs.	Low
☐	W9	30 min	In addition to the pre- and post- trial tests 10 participants in each arm of the study will be asked to volunteer for a short 30 minutes semi-structured interview about their experiences in the trial. All people who withdrew will also be contacted to be interviewed about their experiences in the trial.	Low

5.3 Procedures:

During the laboratory testing sessions you will be asked to wear comfortable exercise attire (e.g. shorts/leggings, exercise shirt/top and pair of trainers as a footwear). You will also be asked to fast and abstain from any sugary water, coffee and tea at least 8 hours before their pre-interventions tests are scheduled. However, you are allowed to drink water throughout the fasting. Changing facilities, including shower and restrooms are available in the testing precinct. The times of testing will be scheduled from 6 am to 10 am on weekdays at a convenient time for you.

On W0, on the day of the testing a member of the research team will meet on arrival at the Reception area of the IHBI, QUT (60 Musk Avenue, Kelvin Grove, Brisbane, QLD, 4059, Australia) to explain the study again. At this session you will be again given an opportunity to asks questions regarding the tests/trial and any other aspects of the trial. You then will be asked to sign an 8 weeks free membership contract with the University fitness provider HealthStream, where all of the exercise sessions will take place. This membership will allow you to have a free and unlimited access to the HealthStream gym facilities at Kelvin Grove and Gardens Point. However, you will be asked to strictly adhere to the prescribed HEALS exercise program as set out in the manual for the 8 week duration of the study.

After satisfactory pre-intervention results confirming eligibility criteria you will then be given a sealed envelope stating the arms of study (Exercise & Standard Dietary Advice or Exercise & Pre-prepared meals) you will be participating in. You will be also given an electronic copy on an USB of all the relevant manuals for your arm of the study, which you can refer to at your convenience. You will be also prompted by the HEALS trial research team at the end of each week from W1-W8 inclusive for completing a simple weekly exercise log, as per the Prescribed Exercise Manual instructions.

If you want to join the trial with your partner, you then will be given the option to exercise together or separately. The 8 weeks HEALS trial then will commence, until all 35 individuals in each condition will be recruited (70 individuals in total will be recruited for this study).

In the both arms of the study you will be required to adhere to an 8 week prescribed exercise program 4 x a week for 8 weeks. In the first two weeks, all 4x2 sessions will be led by a personal trainer. In the following six weeks, only one of these four sessions will be with the trainer to check your progress and quality of exercise techniques. There is a flexibility around the sessions, but in general you will required to complete 2 strength training sessions a week and two HIIT sessions, with one rest day and be advised to take an active recovery/rest of 30 minutes walk daily on the remaining two days of the week as per the HEALS exercise manual.

You will also be asked to complete a weekly video/audio diary recorded by any smartphone, ipad, and/or computer software and submit this to the project Dropbox file as per the research team's instructions. You will receive a weekly text prompt from the research team to remind

you to conduct the reflective recordings. The videos/audios are required to be between 2-4 minutes long, telling your story of barriers, facilitators to adherence, fidelity, acceptability, and adaptability to the HEALS trial for that week. For example, anything that helped or hindered you to follow the HEALS trial manual/protocol. It will be up-to you to choose whether you will include images of yourself or not in these recordings.

In the Exercise & Pre-prepared meals arm of the trial participants will be given 3 prepared meals for free and snacks through a local caterer who will either deliver the meals and snacks to their home or to a collection point previously agreed by the participants near their homes.

In the Exercise & Standard Dietary arm of the trial participants will be asked to prepare their meals according the guidelines provided by the Australian Government, National Health and Medical Research Council, Department of Health and Ageing (www.eatforhealth.gov.au).

The HEALS trial will commence as soon as you are ready to start. The HEAL trial will run from W0 (pre-intervention testing) to W9 (post-intervention testing), with 8 weeks of program in between as per Table 1. on Page 3 of this document. All post-tests will be exactly the same and the pre-test and will follow the exact same protocols.

However, all people who withdrew will be followed up throughout the study with an exit interview, which will last no longer than 30 minutes. Ten participants in each conditions after the completion of the HEALS trial will also be asked to participate in a post study semi-structured interview to reflect back on their experiences in the trial. All interviews will be transcribed verbatim.

All participants can request their test results in a form of a report from the HEALS trial. Altogether the fitness tests, the gym membership, and the exercise program will be provided for free for all recruited participants. Participants in the pre-prepared meals arm will also be provided with meals.

At the end of the trial you will also be asked whether you would be willing to be contacted in the future about the study, and if yes, to consent to use your contact details to contact you in the future.

6. Pregnancy during course of the study:

The effects of this clinical trial on the unborn child are not known. Because of this, it is important that research project participants are not pregnant or breast feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breastfeeding. If you do become pregnant whilst participating in the research project, you should advise the research team immediately, as you must not continue in the research if you become pregnant.

7. Risk and Discomforts

Currently there is no evidence that low carbohydrate diets have negative health consequences. In a review by Makris et al. (2011) a ketogenic diet showed no negative effects on lipids, body composition or mineral density over a 2 year period. A study by Castaldo et al. (2016) shows that a short term ketogenic diet followed by an almost carbohydrate free oral nutrition may effectively reduce body weight, waist circumference, blood pressure, and insulin resistance in clinically health obese adults. You will be monitored for adverse effects weekly and be referred to a registered dietitian if you report any adverse effects during the duration of the trial. Some of the short-term side effects include headache, constipation, fatigue, diarrhea, insomnia, bad breath, and backache. The duration of such symptoms are highly individual and can be for a few days to a couple of weeks.

8. Ionising Radiation

This research study involves exposure to ionising radiation. These procedures (two DEXA scans to assess body composition) are additional to those you would have received if you were not in the study. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this is about 0.005 mSV. The effective dose is less than 2 mSV. At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible.

9. Possible Benefits:

The potential benefits of the study include improved body composition (weight loss, reduced fat mass), enhanced fitness and improved blood profile. These are all important to reduce susceptibility for chronic conditions like diabetes and heart disease. Ultimately the trail would like to promote a healthy lifestyle in terms or regular exercise participation and healthy eating. Your involvement in the study may be of no direct benefit to you.

10. Alternatives to participation: N/A

11. Tissue Samples:-

In the HEALS trial blood samples are OBLIGATORY. This means that analyses on samples are necessary for the conduct of this research; refusal to provide them is a sufficient condition for exclusion from the trial. The ultimate destruction date for your data will be 15 years after their collection date.

12. Data retention: -

All data and information arising from the HEALS trial will be kept for a minimum of 15 years.

13. Voluntary Participation/Right to Refuse or Withdraw:

There is no obligation for you to be involved in this study. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future trials conducted at QUT.

14. Confidentiality:

Your records relating to this study and any other information received will be kept strictly confidential. However staff participating in this research, the sponsor and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published. However, results may be suppressed for commercial reasons as the sponsor of the project retains the rights to the data.

Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the Principal Investigator, Professor Remco Polman.

15. Costs

The cost of travel to collect the meal packages and to the exercise venue will be met by you. There will be no reimbursement of petrol costs, parking costs or the use of taxi vouchers.

16. Illness or Injury

If, as a result of being in this study, you become ill or are injured, please immediately contact your GP and inform the HEALS trial research team. It is expected that the GP will then give you all necessary information and treatment and will also inform the research team.

17. Compensation for Injury

If, as a result of your participation in this study, you become ill or are injured, immediately advise the Principal Investigator, Professor Remco Polman of this clinical trial. It is advised that you ask your GP to evaluate your condition and discuss treatment with your GP. Any questions about compensation must initially be directed to the Principal Investigator, who will advise QUT's insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this clinical trial protocol that you seek independent legal advice.

18. Termination of the Study

This research project may be stopped for a variety of reasons. These may include the following:

Unacceptable reactions to pre-prepared meals and not need further investigation and decisions made in the commercial interests of the sponsor.

19. Investigators Benefits

The researchers conducting this study do not receive any remuneration beyond their normal University salaries. They will not allow a conflict of interest to compromise their position or this research study.

20. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs.

21. Results of Project

Because of the commercial sensitivity of the findings the final decision to publish the results of the study will be with the company commissioning this project. However, the research team is keen to publish the finding in peer reviewed journals and present findings at academic and professional conference. In addition, participants will be able to receive the results of their testing if requested.

22. Consent

Your study doctor is required to provide you with all information regarding the nature and purpose of the research study, risks/benefits and the possibility of alternative treatment and you should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

23. Advice and Information

If you have any further questions regarding this study, please do not hesitate to contact

Dr(s) Erika Borkoles by phone +61 (0)7 31384547.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (HREC: 2017-12-937) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.