

Participant Information and Consent Form:

HBIT: Habit-Based Weight Loss Intervention Trial



Researchers:

Hello, I'm Dr. Gina Cleo, the Chief Investigator on this study. I am a Habit Researcher and Dietitian and my mission is to help people lose weight and keep it off. The research team includes: Professor Paul Glasziou, Associate Professor Rae Thomas, Associate Professor Mark Jones and research assistant, Miss Hannah Larsen.

Why is the study being conducted?

Have you ever lost weight, only to regain it again? If so, you're not alone; the majority of people regain the weight they worked hard to lose. The good news is, recent research shows that changing our everyday *habits* is a novel and effective way to achieve weight loss and weight loss maintenance. We are conducting this study to assess whether a coach-led or self-directed program is more effective for weight loss and weight loss maintenance.

What do I need to do?

As part of this study, you will be invited to complete a 12-month habit-change, weight management program, designed to help you develop new healthy habits. You will be randomly allocated to one of the three interventions described below.

Intervention A. Sum Sanos™ is a 12-month, coach-supported program. A Health Coach will meet with you monthly for 1 hour face-to-face (or video call if face-to-face is not practical) and follow-up with you weekly for 10-minutes via telephone. Each month, you will be presented with a new module to discuss with your Coach. Module topics include: goal setting, forming new habits, breaking old habits, mindful eating and setback strategies, to name a few.

Intervention B. Seven Savvy Habits Booklet (7SH-B), is a program which aims to increase habitual performance of 7 proven weight management strategies, such as: drinking water before your meals, keeping active for 30 minutes a day and increasing your protein intake, to name a few. The habits are presented to you in the form of a booklet, and a tracking diary is provided for self-monitoring of the habits. You are required to try to perform as many of the 7 habits as you can, everyday for 12-months. You will receive multiple follow-up phone calls by a member of the research team to help support you on the program; these

phone calls will be monthly for the first 3 months and every 3 months after that (at 6, 9 and 12 months).

Intervention C. Seven Savvy Habits App (7SH-A), presents the same 7 proven weight management strategies as the 7SH-B, but the habits are presented via a smartphone application, instead of a booklet. The tracking diary for self-monitoring of the habits is embedded within the app. The intervention and follow-up phone calls are the same as above.

Data collection

Before you start the assigned intervention, we will collect measurements including: height, weight, waist circumference, blood pressure, and questionnaire data related to your health related quality of life, habit strength, self-regulation of eating behaviour and general wellbeing. We care about your long-term outcomes, so these measurements will also be collected after 3, 6, and 12 months from study commencement (see Table 1). We would also like to contact you for longer-term (open-ended) follow-ups; this may be a quick telephone call, a request to measure your weight and waist circumference and/or to complete an online questionnaire.

We are interested in your general experience on the intervention, so there may be a short, 30-minute telephone interview after the intervention.

Table 1 Data collection timeline

	Baseline	3 months	6 months	12 months	Open-ended
Informed consent	x				
Demographic information	x				
Height	x				
Weight	x	x	x	x	x
Waist circumference	x	x	x	x	x
Blood pressure	x	x	x	x	x
Temperament (24 Q's)	x		x	x	x
Questionnaires - Habit-strength (32 Q's) - Self-regulation of eating (5 Q's) - Effortful Control (19 Q's) - Health related quality of life (12 Q's) - Fruit and vegetable intake (2 Q's) - Exercise behaviours (1 Q)	x	x	x	x	x
Telephone interview				x	

Time commitment

Sum Sanos: We anticipate the total time required from you during your participation in this study to be no more than **21 hours** over the 12 month period – this includes the pre-intervention introductory meeting (30 minutes), 3 measurement time points (1.5 hours), monthly meetings with your Coach (12 hours), weekly 10-minute phone calls (6.5 hours) and post-intervention interview (30 minutes).

Seven Savvy Habits: We anticipate the total time required from you during your participation in this study to be no more than **12 hours** over the 12 month period – this includes the pre-intervention introductory meeting (30 minutes), 3 measurement time points (1.5 hours), self-monitoring of the habits (8.5 hours), 5 x 10 minute follow-up phone calls (50 minutes) and post-intervention interview (30 minutes).

If there are any follow-ups beyond 12-months, we will only require enough time to gather study data (generally 15-20 minutes) per year.

How will participants be selected?

We will be enrolling ~150 participants from the Gold Coast area. Participants must be aged between 18 and 65 years and have a Body Mass Index (BMI) of 27.0kg/m² or above.

How will this research be used?

The data collected during this study will assist us in evaluating the differences between coach-led and self-directed habit-based interventions for weight loss. Your participation in this study will help us to further understand the impact habits have on short and long-term health outcomes and will enhance work towards developing successful weight loss interventions.

The potential benefits for you include: losing weight, improving level of wellness, forming new healthy habits, changing old unwanted habits and general lifestyle improvements.

What are the risks?

The research study is considered 'low risk' and is conducted in a way that is beneficent and minimizes any risks or harms. The interventions used in this study are not associated with any known harms. The questionnaires used have been validated and commonly used in research; they do not contain sensitive information and are not known to cause emotional or psychological discomfort. However, if you experience distress from participation in this research, please contact a Queensland community support officer on 13 HEALTH (13 43 25 84) for professional guidance and advice.

Am I free to withdraw?

Yes. Participation in this study is completely voluntary and you may withdraw at any time without risking any negative consequences. If you choose to withdraw your participation in this study, the information you have provided will be immediately destroyed and your privacy protected.

What if I want to know more information about the study?

For additional information about the project, contact the research team, habits@bond.edu.au; +61 7 5595 1588.

What if I want to make a complaint?

Should you have any complaints concerning the manner in which this research is being conducted please make contact with: Bond University Human Research Ethics Committee, c/o Bond University Office of Research Services. Bond University, Gold Coast, 4229. Tel: +61 7 5595 4194 Email: buhrec@bond.edu.au

How do I express consent?

By completing and returning the consent form below you have consented to participation in the research project: *'Habit-based weight loss intervention trial'*.

How will my confidentiality be protected?

All data collected in this study will be treated with complete **confidentiality** and not made accessible to any person outside the researcher team working on this project. You will remain anonymous in any output of results or outcomes. Anonymous/non-identifiable data may be deposited in an open or mediated access repository and made available for future use in accordance with the Privacy Act.

Data will be stored in a secured location at Bond University for a period of five years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee.

Consent

By signing below, I confirm that I have read and understood the information package, and in particular I have noted that:

- I understand that providing my contact details to the researchers is entirely voluntary;
- I understand that I will be contacted by the researchers following the voluntary provision of my contact details;
- I understand that my participation in this research is entirely voluntary and that I am free to withdraw from this research at any time, without comment or penalty;
- I have had any questions answered to my satisfaction and understand that if I have any additional questions I can contact the research team;
- I have been informed that the confidentiality of the information I will provide will be safeguarded, my opinions will be treated as personal information, and my privacy respected;
- I understand that I can contact the Manager, Research Ethics, Office of Research Services, Building 1C, Level 4, Bond University (phone +61 7 5595 4194 or buhrec@bond.edu.au) if I have any concerns about the ethical conduct of the project; and
- I agree to participate in this study.

Name:

Signature:

Date: