Study Protocol: HBIT

Title: Coach-led vs self-directed habit-based interventions for weight loss in adults with overweight and obesity: a randomised controlled trial

Short title: Habit-**b**ased **i**ntervention **t**rial (HBIT)

Trial registration: This trial will be registered through the Australian New Zealand Clinical Trials Registry (ANZCTR) and will have an allocated Australian Clinical Trial Registry Number (ACTRN). The Universal Trial Number is: U1111-1231-0198

Funding: Financial support will be co-contributed by (a) an Australian Commonwealth Government Innovation Connections Grant along with (b) Life in Balance Seminars Pty Ltd. Each will fund $50,000 towards the project to be used within a 12-month period. Budget total $100,000 for 12 months. The Centre for Research in Evidence-Based Practice, Bond University, has agreed to provide a research management committee and Biostatistician for the trial duration in kind.

Roles and responsibilities:
- Dr. Gina Cleo[1], Chief Investigator: study design, data collection management, interpretation of data, writing of the report, submit report for publication.
- Professor Paul Glasziou[1], Co-Investigator: coordinating the research committee, study design, overseeing the trial.
- Associate Professor Rae Thomas[1], Co-Investigator: member of the research committee, study design, interpretation of data, overseeing the trial.
- Associate Professor Mark Jones[1], Co-Investigator: member of the research committee, study design, data analysis and interpretation of data.
- Miss Hannah Larsen[1], Research Assistant: study manager, quality assurance, intervention implementation, writing reports.
- Ms Sally Priest[1], Research Assistant: data collection.

Investigator affiliation:

1. Institute for Evidence-Based Healthcare, Bond University.

Introduction

Background: The weight loss – weight regain cycle can defeat many. The majority of individuals with overweight or obesity, who lose weight will regain the weight within just a few months. With 30% of the global population categorised as overweight or obese and the prevalence increasing each year, addressing the determinants for weight loss and weight loss maintenance is essential.

Recent studies demonstrate that habit-based weight loss interventions are a novel and effective strategy to help reduce excess weight long-term (research up to 2 years). Average weight losses in adults with overweight and obesity using habit-based interventions appear to be of clinical benefit and are statistically significant when compared with control groups. However, habit-based research is scarce and further studies are required to better understand the role of habits in weight management.

Sum Sanos, is a 12-month, one-on-one coach-led, habit-based weight loss program. Health coaches meet face-to-face with participants (or video call if face-to-face is not feasible) on a monthly basis and follow-up with them via telephone on a weekly basis. The frequency of these follow-ups is aimed to establish accountability, support and maintain engagement in the program. The methodologies that form the foundation of Sum Sanos are based on evidence of key weight-loss facilitators (i.e., habit-change, self-compassion, mindful eating, setback strategies, etc.).

Seven Savvy Habits (7SH), is a one-off self-guided booklet or smartphone application which the participants will engage in for 12-months. 7SH is focused on making simple diet and exercise behaviours habitual. The intervention focuses explicitly on the recommendations of habit-formation theory; therefore, advice on repetition and context stability are provided. Research assistants in each centre provide participants with the 7SH booklet together with a simple logbook for self-monitoring of target behaviours, or the 7SH smartphone application. Previous research of a similar intervention has shown effectiveness for long-term weight loss maintenance (24-months post-intervention) and offers a low-intensity alternative to 'usual care'.

Overall research question: Is a coach-led, or self-directed habit-based intervention more effective for weight loss and weight loss maintenance: a randomised clinical trial

Research questions

1. *Primary outcome:* What is the effectiveness of a coach-led (Sum Sanos) compared with two self-directed (7SH booklet and app) habit-based interventions on 12-month weight loss outcomes in adults with overweight or obesity?
2. *Secondary outcomes:* What are the effects of Sum Sanos and 7SH on weight loss maintenance post 12-months (open-ended time frame)?
3. What are the effects of Sum Sanos on fruit and vegetable intake, physical activity levels, blood pressure, waist circumference, health-related quality of life, habit-strength, and self-regulation of eating behaviour at 3, 6, 12 and 24 months, and how do these compare with the 7SH interventions?
4. Is there a relationship between individual temperament and BMI, weight change, habit-strength, health-related quality of life and self-regulation of eating behaviour?
5. What is the relationship between the number of coach-appointments and weight loss?

Objective: The objective of this trial is to assess the effectiveness of a coach-led (Sum Sanos) compared with two self-directed (7SH booklet and app) habit-based interventions on 12-month weight loss outcomes in adults with overweight or obesity.

Hypothesis: We hypothesise that Sum Sanos will be superior for weight loss outcomes compared with 7SH booklet and 7SH app.

Study arms: Sum Sanos vs Seven Savvy Habits Booklet vs Seven Savvy Habits App

Study design: Open-ended, multi-site, 3-armed randomised controlled trial. This is a superiority trial.

Methods: participants, interventions and outcomes

Study setting: This trial will be conducted in the community on the Gold Coast, Australia. Data collection will take place at a Bond University.

Eligibility Criteria: Eligible participants will be aged between 18 and 65 years, have a BMI ≥27.0kg/m^2, own a smartphone, able to consent for themselves and able to attend all required appointments during the intervention period. Participants will be recruited regardless of obesity-related comorbidities (e.g., cardiovascular disease and diabetes). Exclusion criteria includes participants who are pregnant, significantly ill, participating in other weight management programs, expecting to have bariatric surgery in the next 24-months, or taking medications affecting appetite, metabolism or weight.

Interventions: There are three intervention groups in this trial.

A. Sum Sanos™ (https://www.sumsanos.com/) is a 12-month, one-on-one, Coach-supported program. Participants meet with a Sum Sanos™ Health Coach monthly (either in a public place or the coaches' office), for 1 hour face-to-face or video call and receive a weekly 10-minute follow-up phone call. Each month, the participant will be presented with a new module to discuss with their Coach. Module topics include: goal setting, forming new habits, breaking old habits, mindful eating and setback strategies, to name a few.

B. Seven Savvy Habits Booklet (7SH-B) is a program which aims to increase habitual performance of 7 proven weight management strategies, such as: reducing non-hungry eating, drinking water before meals and being active for at least 30 minutes a day, to name a few. The habits are presented in the form of a booklet, and a tracking diary is provided for self-monitoring of the habits. Participant are required to try and perform as many of the 7 habits as they can, everyday for 12 months. To support participants on the program and reduce attrition, they will receive follow-up phone calls by a member of the research team (monthly for the first 3 months then once every 3 months till the end of the intervention period).

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. Participant are required to try and perform as many of the 7 habits as they can, everyday for 12 months. To support participants on the program and reduce attrition, they will receive follow-up phone calls by a member of the research team (monthly for the first 3 months then once every 3 months till the end of the intervention period).

Adherence: Participants in the three intervention groups will be provided with a tracking diary for self-monitoring. Sum Sanos participants will present the diary to their coaches at their monthly meeting. They will also have weekly contact with their coach which shows increased adherence through support and accountability.

7SH participants will return their tracking diary to the research assistant during the data collection appointment at 3, 6 and 12-months. Participants will receive a follow-up phone call monthly for the first 3 months, as this is the average time it takes to acquire a new habit. They will then receive a phone call once every 3 months till the end of the intervention period.

Outcome measures:
Primary: (measured at 12-months from intervention commencement)
- Weight change (kg, %) - between group differences

Secondary: (measured at 3, 6, 12 and 24-months from intervention commencement)
- Weight change (kg, %)
- Body Mass Index (BMI)
- Waist circumference (cm)
- Blood pressure
- Health related quality of life, using SF12
- Habit strength
- Self-Regulation of Eating Behaviour
- Fruit and vegetable intake
- Hours of physical activity performed per week
- Temperament
- Number of coach sessions attended (Sum Sanos)
- Number of habits achieved on average per week (7SH-B and 7SH-A)

Other:
Longer time frames for collecting secondary outcome measures (3, 4, 5 years) are dependent on funding.

Participant timeline: See Table 1

$-t_1$: Eligibility screening over the phone. Study information pack and consent form sent to participant via email. Participant makes appointment time to meet with research assistant.

t_0: Baseline appointment with research assistant. Provide written informed consent and baseline measurements.

t_1: During the baseline appointment, the participant is randomly allocated to an intervention by a member of the research team and informed of their intervention allocation. 7SH participants are given instructions on how to use the booklet or app. Sum Sanos participants are contacted within 24 hours by their assigned Health Coach. Commence intervention.

t_2: 3-month data collection.

t_3: 6-month data collection.

t_4: 12-month data collection. Participants cease intervention. Qualitative interviews.

t_5: 24-month follow-up data collection.

Table 1. Participant timeline

		STUDY PERIOD						
		Enrolment	**Allocation**	**Post-allocation**				**Follow-up**
	TIMEPOINT	***$-t_1$*** ***Screening***	***t_0*** ***Baseline***	***t_1*** ***Commence intervention***	***t_2*** ***3 months***	***t_3*** ***6 months***	***t_4*** ***12 months***	***t_5*** ***24-months***
ENROLMENT	Eligibility screen	x						
	Informed consent		x					
	Allocation		x					
INTERVENTION	Sum Sanos™			←	—	—	→	
	Seven Savvy Habits Booklet			←	—	—	→	
	Seven Savvy Habits App			←	—	—	→	
DATA	Data collection/outcome measurements		x		x	x	x	x
	Qualitative interviews						x	

Sample size: We aim to observe a difference between Sum Sanos and 7SH intervention groups at 12-months from baseline. Sample size calculations were based on mean weight loss and standard deviation from previous trials using a similar intervention to 7SH. Our power calculation suggests 35 participants are required in each of the 3 arms to achieve a 90% power and 5% significance criterion to detect a 4kg (SD 5.03) difference between Sum Sanos and 7SH intervention groups at 12 months. To account for 30% attrition, we will recruit 138 participants.

Recruitment: The research investigators will recruit participants through local public relations, including newspaper, television and radio advertisement and through social media. Our study timeline has allowed 3 months to recruit the required sample size. The recruitment progress will be monitored on a weekly basis. If the number of enrolled participants is not reaching key milestones, additional public relation outputs will be instigated.

Methods: assignment of interventions

Allocation: Computer generation randomisation will occur after baseline assessment to allocate participants to either Sum Sanos, 7SH-B or 7SH-A (allocation ratio 1:1:1). After a 1-week run-in period, participants will be informed of their study group allocation via telephone by the primary investigator. We will use minimization stratified on, BMI categories (overweight, obese class I, II, III), age (18-30, 31-43, 44-56, 57-65 years); and gender.

Implementation: Individuals interested in participating in the trial will email through their expression of interest using the contact details specified in the media advertisements. The primary investigator will speak with each individual over the phone to conduct initial screening against the eligibility criteria. If eligible, individuals will meet with the research assistant at the relevant university, to provide written consent and baseline measurements. Ineligible individuals will be recommended to see their local health care provider for weight management support.

One week after recruitment to the trial, the primary investigator will randomise participants into one of the three study arms using the clinical trial management software package, MASCoT (https://mascot.org.au). Participants will be informed of their allocation via telephone call from the primary investigator.

Participants randomised to Sum Sanos, will be distributed to Life in Balance Pty Ltd (the parent company of Sum Sanos), to assign each participant with a health coach and commence the intervention. Participants randomised to the 7SH-B and 7SH-A groups, will be managed through the central research centre at Bond University.

Blinding: Outcome assessors (research assistants) and data analysts will be blinded to group allocation. Trial participants and the primary investigator will not be blinded to group allocation.

Methods: data collection, management and analysis

Data collection: An experienced research assistant blinded to treatment allocation will be trained by the primary investigator to collect data. The data collection timeline is presented in Table 2.

Table 2. Data collection timeline

	Baseline	3 months	6 months	12 months	24 months	Open-ended
Informed consent	x					
Demographic information	x					
Height	x					
Weight	x	x	x	x	x	x
Waist circumference	x	x	x	x	x	x
Blood pressure	x	x	x	x	x	x
Temperament (24 Q's)	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	x
Qualitative telephone interview				x		

Anthropometry:

Height will be measured in centimetres using a stadiometer with integrated level. As per NHMRC standard protocol for measuring height [1]; participants will be instructed to stand with feet together and flat on the ground (no footwear), with heels, shoulder blades and buttocks touching the wall. Participants will also be asked to look straight ahead; measurement will be taken as the participant takes a deep breath in and stretch to their fullest height.

Weight will be measured to the nearest 0.1kg using calibrated digital weight scales. As per the NHMRC clinical practice guidelines for the management of overweight and obesity [1], participants will be asked to remove any outer garments, take off their shoes and empty pockets. Participants will be instructed to stand centred on the scale with weight evenly on both feet.

Body Mass Index will be calculated using body weight in kilograms (kg), divided by height in metres squared $(m)^2$.

Waist circumference (cm) will be measured using a soft tape over light clothing. Measurements will be taken twice and the average of the two recorded. As per NHMRC standard protocol [1], participants will be asked to remove heavy outer garments, loosen any belts and empty pockets. Participants will stand with their feet close together (about 12-15cm) with their weight equally distributed and breathing normally. Waist is defined as the point midway between the iliac crest and lower rib (approximately in line with the umbilicus). Measurement will be taken in centimetres at the end of normal expiration.

Clinical:

Systolic and diastolic blood pressure will be measured using a calibrated digital inflatable cuff on the upper arm. Whilst seated, participants will be asked to raise their arm to heart level, and rest it on a table, desk or chair. After one to three minutes, the reading will be checked again for accuracy; the average of the two readings will be recorded.

Self-reported questionnaires*:*

All questionnaires will be distributed to participants via a secure Qualtrics web link. They will complete the questionnaires during their data collection meetings with the research assistant, in a private room at the university or healthcare clinic. Research assistants will inform participants that they may complete the questionnaires at home if they would prefer.

Habit strength: Two questionnaires will be used to measure habit strength.

1. The self-reported, 27-item Creature of Habit Scale (COHS) includes two subscales which incorporate the general concept of habits, namely *routine* behaviour and *automatic* response [2]. The COHS measures individual's propensity for habit in daily life and demonstrates good validity and reliability [2]. Participants rate themselves for each question using a 5-point Likert scale (1. Strongly Disagree, 2. Mildly Disagree, 3. Undecided, 4. Mildly Agree, 5. Strongly Agree), where a higher score reflects a greater expression of habitual behaviours.

2. The strength of habit instigation (deciding to do an action), will be measured using the instigation-specific item of Self-Reported Behavioural Automaticity Index (SRBAI); ('Deciding to do behaviour X is something I do automatically'). The habitual behaviours measured in this research include:

- Deciding to eat 5 serves of vegetables a day is something I do automatically
- Deciding to eat 2 serves of fruit a day is something I do automatically
- Deciding to eat mindfully (avoiding distraction and eating slowly) is something I do automatically
- Deciding to exercise consistently is something I do automatically
- Deciding to be more active (everyday movement) is something I do automatically

Participants rate themselves for each question using a 5-point Likert scale (1. Strongly Disagree, 2. Disagree, 3. Neutral, 4. Agree, 5. Strongly Agree), where a higher score reflects a greater habit strength for the listed behaviours. The SRBAI item is a reliable measure of habit instigation ($a \geq .90$) [3].

Self-regulation of eating: Eating self-regulatory capacity can help individuals to cope with the obesogenic environment and achieve, as well as maintain, a healthy weight and diet. Self-Regulation of Eating Behaviour (SREBQ) is a 5-item scale used to measure eating self-regulatory capacity. The SREBQ has strong construct validity, showing a positive correlation with general measures of self-regulation. It is also positively correlated with motivation and behavioural automaticity, and negatively correlated with food responsiveness and emotional over-eating ($p < 0.001$). Overall the SREBQ is a reliable and valid measure for assessment of eating self-regulatory capacity in adult populations [4] (questionnaire attached).

Temperament (Effortful Control): The 19-item Effortful Control Scale - short form (EC) is a subscale from the Adult Temperament questionnaire (ATQ) [5] which assesses an individual's capacity to exert control over their behaviour and emotions as they interact with their environment. Previous studies show, lower levels of effortful control may increase risk of hedonically motivated disinhibited eating behavior (the drive to eat to obtain pleasure in the absence of an energy deficit) [6]. The relationship between effortful control and habit change is not yet understood as little to no research has been conducted on this topic.

Health-related quality of life: The Short Form-12 (SF-12) is the most commonly used and most valid and reliable health measure for assessing health-related quality of life [7]. The 12 questions include: 2 questions concerning physical functioning; 2 questions on role limitations because of physical health problems; 1 question on bodily pain; 1 question on general health perceptions; 1 question on vitality (energy/fatigue); 1 question on social functioning; 2 questions on role limitations because of emotional problems; and 2 questions on general mental health (psychological distress and psychological well-being) [8].

Fruit and vegetable intake: Following Australian dietary guidelines, fruit and vegetable intakes were measured as a count of serves, from 0 to 3+ for fruit and 0 to 5+ for vegetables [9]. Participants are simply asked, "How many serves of fruit/vegetables, do you eat on a typical day?" [10].

Exercise: Following a similar scale to fruit and vegetable intake, physical activity will be recorded as hours of exercise performed per week (1-item); "How many hours of exercise do you do in a typical week?".

Coach sessions attended: The number of coach sessions attended (Sum Sanos) will be recorded by the health coaches and reported back to the primary investigator at 3, 6, and 12-months.

Habits achieved: The number of habits achieved (7SH-B and 7SH-A) will be recorded by the participant and reported back to the primary investigator at 3, 6, and 12-months)

Post-intervention qualitative interview: Using a maximum variation design, a selected group of participants will be invited to take part in a post-intervention interview. Semi-structured qualitative interviews will be conducted to explore participants' general experience on the interventions. Interviews will be audio-recorded with participants' consent, transcribed and thematically analysed. The interviews will be modelled based on a previous study conducted by the primary investigator [11].

Baseline only:

Demographic information: General demographic and medical history will be collected at baseline using the participant registration form (attached).

Temperament (BIS/BAS): Previous research reports there are two general motivational systems of temperament which underly behavior and affect: a behavioural inhibition system (BIS) and a behavioural activation system (BAS) [12]. A behavioral inhibition (or avoidance) system (BIS) is said to regulate aversive motives, in which the goal is to move away from something unpleasant. A behavioral activation system (BAS) is believed to regulate appetitive motives, in which the goal is to move toward something desired. The understanding of these systems through the BIS/BAS 24-item scale, may help to predict hedonic responses to palatable food [6]. Furthermore, there is a scarce amount of research in how these motivational systems affect habit-development and weight.

Completion of assessment: To promote completion of the data assessments, participants will have the chance to enter into a draw to win one of three $100 shopping vouchers (relevant to their country) at each assessment point. However, they will be informed about the prize draw after commencement of the intervention to ensure only participants who are motivated to lose weight and improve their health are

recruited to the study. The primary investigator will also impliment strategies to mitigate loss of data including, sending the participants birthday messages and appointment reminders.

Data management: Data will be entered, coded and managed using the software package, MASCoT. Data will then be stored, accessed, archived or destroyed in accordance to Bond University's Research Data Management and Sharing Policy (Policy number: TLR 5.12). The policy states, data will be retained for a minimum of 5 years from the date of publication. Digital data retrieved from sites outside Bond University, will be managed and stored on the Bond University network drives which are routinely backed up, and the University's digital research repository. Such precautions include password access and 'locking' data files.

Datasets (including open, controlled, access or closed digital data and records of all primary materials) of completed reports will be archived by Bond University's Library Services in appropriate facilities and will be recorded in a durable and appropriately referenced form for ease of identification and retrieval. Confidential research data and records will be stored securely.

Statistical methods: Analysis of covariance (ANCOVA) will be used for analysis of pre-post continuous measures collected during the study. For the primary outcome of change in weight at 12 months we will use linear regression to compare change in weight from baseline to 12 months with adjustment for baseline weight. We will use a type 3 analysis of effects to test the null hypothesis of no difference between the 3 treatment groups. If there is evidence of a difference ($P<0.05$), further pairwise comparisons between groups will be undertaken. Similar analyses will be undertaken for other continuous pre-post outcomes. Treatment effects will be reported as mean differences with 95% confidence intervals.

We plan to finalise and publish a detailed statistical analysis plan (SAP) prior to completion of data collection and before any statistical analysis is undertaken.

Additional analyses: In addition to the primary analysis outlined above we will conduct an adjusted analysis of the primary outcome to assess the impact of any potential baseline imbalances between treatment groups that may have occurred by chance. Variables to be included as covariates for this analysis include treatment site (included as indicator variables), gender and age. BMI will not be included as it is highly correlated with baseline weight which is already included in the ANCOVA regression model.

Handling missing data: We will conduct intention-to-treat analysis. To account for missing primary outcome data, we will implement multiple imputation. In an additional analysis of the primary outcome we will use a per-protocol strategy to compare treatment groups after excluding participants who did not follow the study protocol.

Methods: Monitoring

Harms: Although we do not anticipate harms in this trial, participants are provided with the contact details of the primary investigator prior to recruitment and encouraged to make contact if they experience any harms, discomforts or adverse events. Participants may also discuss harms with the research assistant during data collection appointments. They may also speak with the primary investigator (7SH groups) or health coach (Sum Sanos) during the follow-up calls. An open-ended discussion on consequential events will be discussed during the 12-month interviews.

Ethics and dissemination

Research ethics approval: Ethics approval will be sought from the Bond University Human Research Ethics Committee in Australia.

Consent: Eligible participants will be emailed the Participant Information and Consent forms straight after the initial eligibility phone call. Participants will then make a baseline appointment with a research assistant who will obtain written consent from the participants.

Confidentiality: The primary investigator will deidentify participants on eligibility using the coding feature in the software package, MASCoT. Only the study manager will have the authority to reidentify participants.

Data management will comply with the Australian Standard on personal privacy protection and will act in accordance with the National Privacy Principles of the Privacy Act.

Bond University's Research Data Management and Sharing Policy ensures that research data and records are maintained securely to prevent unauthorised access, destruction, alteration or removal, accidental or intended damage or destruction.

The University's Human Research Ethics Policy ensures all researchers implement good research data management practice in accordance with legal, statutory and ethical requirements. The researchers on this project have an obligation to respect the confidentiality of information we receive in the conduct of the research. We will only use data in accordance with the agreements with the participants as outlined in the informed consent form, which take into consideration the terms of Bond University's Human Research Ethics Committee. Any notes, reports or publications will only contain anonymous data.

Declarations of interests: Dr Gina Cleo is the co-creator of Sum Sanos and developed the Seven Savvy Habits intervention and assisted in the design of the associated booklet and app. To limit any potential bias, blinded research assistants not involved in the study design, group allocation or data analysis will conduct the data collection and a blinded biostatistician will conduct the data analysis.

In addition, a research management committee independent of Life in Balance Pty Ltd (the parent company of Sum Sanos), will meet regularly (monthly until completion of recruitment, then every 3 months)

throughout the trial to discuss the research protocol and design. Dr Cleo may attend the committee meetings as a non-voting member. A chairman will be appointed to facilitate the committee meetings.

Access to data: In accordance with the funding body agreement, the details and outcomes of this research will be made available to the Commonwealth for use as an Innovation Connections Project case study and for other purposes relating to the Commonwealth's evaluation of the program.

Bond University owns the Intellectual Property Rights in any reports or other Material it is required to provide the Commonwealth under the funding Agreement. Bond University will have ongoing custody of data and research outputs.

Sharing the information from this research with other researchers, secondary use of information for related research, publishing the data for unrelated research and non-research purposes is not planned, however is not restricted.

Non-identifiable/anonymised data or information may be deposited in an open or mediated access repository, such as the Australian Institute for Health and Welfare, where it will be handled and released for future use, in accordance with the law and their governance obligations. This includes meeting government requirements to release information under the Information Publication Scheme (https://www.aihw.gov.au/about-us/freedom-of- information/information-publication-scheme-ips).

The expectations of use of this data must be in accordance with the Office of the Australian Information Commissioner, which encourages all entities to take a holistic approach to ensuring that their data use is reasonable and appropriate, compliant with the Privacy Act and considers ethical and social responsibilities

Dissemination policy: The outcomes of this project will be disseminated to the participants and the public via published reports and journal publications. All data will be de-identified.

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