Title: Evaluating a small change approach to preventing long term weight gain in overweight and obese adults - study rationale, design, and methods

Authors: Robert Ross ^{a, b}, James O. Hill^c, Amy Latimer^a, Andrew G. Day^d

Institutional Affiliations:

^a School of Kinesiology and Health Studies, Queen's University, Kingston, Ontario

^b Department of Medicine, Division of Endocrinology and Metabolism, Queen's University, Kingston, Ontario

^c Anschutz Health and Wellness Center, University of Colorado, Aurora, Colorado.

^d Department of Public Health Sciences, Queen's University, Kingston, Ontario, Canada

Corresponding author:

Robert Ross, PhD, R. Kin, FACSM, FAHA

School of Kinesiology and Health Studies

28 Division Street

Queen's University

Kingston, Ontario, Canada, K7L 3N6

E-mail: rossr@queensu.ca

Phone: (613) 533-6583

Fax: (613) 533-2580

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Abstract

Despite the rapid rise in obesity worldwide, few strategies have been effective in treating this epidemic. An emerging strategy is to focus on preventing excessive weight gain rather than weight reduction. The proposed intervention, *small change approach* (SCA), is an innovative weight gain prevention strategy in which individuals monitor their usual nutrition and physical activity patterns and then make modest but sustainable alterations through behavioural intervention techniques (self-regulation, goal setting) enough to reduce overall energy balance by 100 to 200 kcal per day (e.g., reduce caloric intake by 100 kcal per day and/or increase daily step count by ~2000 steps (~100 kcal) per day). The primary aim of the trial is to determine whether small changes in energy expenditure and/or energy intake prevent weight gain in overweight and obese men and women long-term. The pre-specified primary and secondary assessments are at 2 and 3 years post randomization respectively. The primary outcome is change in body weight. Secondary outcomes include body composition variables (adipose tissue distribution and lean mass distribution) and cardiorespiratory fitness (VO_{2peak}).

We randomized 320 primarily White (n=305) overweight and obese men and women to one of 2 conditions: 1) Usual care (UC), 2) Small change approach (SCA). Participant involvement in the study is 3 years; 2 year intervention with a 1 year follow-up. Our study findings will indicate whether there is value in clinicians adopting a SCA to lifestyle counselling for their patients who are overweight and obese.

Key Words: weight gain prevention, overweight, obesity, diet, physical activity.

Introduction

The prevalence of obesity worldwide has doubled since 1980. Approximately 40% of the adult population is now overweight and obese ¹. Obesity is associated with a wide range of health outcomes including type-2 diabetes, cardiovascular disease, certain cancers, and psychiatric disorders such as depression ².

Despite the urgent need to address the obesity problem, few strategies have been successful on a wide scale basis. We ³ and others ⁴ have repeatedly demonstrated in randomized controlled trials that most adults are not able to sustain major changes in behaviour that are required to maintain weight loss long term. Therefore, a more reasonable and achievable goal may be to focus on weight gain prevention. As initially described by Hill et al ⁵, the biological compensatory mechanisms defending body weight appear to respond much more strongly to negative energy balance than to the prevention of positive energy balance. In other words, the energy balance system is biased toward preserving existing body weight but does not appear to strongly defend against body weight not yet acquired. Thus, preventing further weight gain in the population may be more feasible. Hill et al ⁶ and others ⁷ have estimated that a reduction of about 100-150 kcal/day would be required to prevent positive energy balance in 90% of the adult population. In fact, two separate pilot studies have shown that a small change approach (increase daily steps by 2000 and/or decrease energy intake by 100 kcal) prevented weight gain in a small group of adults and children over 13 weeks ^{8,9,11}.

In the present intervention, we evaluate the long-term effectiveness of the *small change approach* (SCA) in a rigorous design within a large randomized clinical trial. Participants attend both group- and individual-based counselling sessions over the course of the 24-month period; these sessions guide participants in making small changes to their diet and physical activity habits. Participants are first asked to monitor their usual nutrition and physical activity patterns and then make modest alterations to these usual patterns. The SCA encourages individuals to modify their behaviours enough to affect overall energy balance by 100 to 200 kcal per day (reduce caloric intake by about 100 kcal per day through and/or increase daily step count by ~2000 steps (~100 kcal) per day from baseline), but does not require making major lifestyle changes that are difficult to maintain – therefore promoting the prevention of weight gain, or a gradual, modest weight loss across time. Participants may also be more likely to reach the goals they set, experience higher self-efficacy and satisfaction, and lower feelings of deprivation and wanting of foods.

Materials and Methods

Trial Design

The trial is a single centre two arm longitudinal randomized controlled trial performed in a research setting. Subjects were recruited from the Kingston area, a typical suburban region, via mass media including print (newspaper), Facebook and Kajiji. Sedentary, overweight or obese men and women meeting the inclusion criteria (N=320) were randomized to one of 2 conditions: 1) usual care (UC) or 2) small change approach (SCA) (Figure 1). The study has two phases. Phase I is the intervention phase where participants are assigned to and participate in one of the two groups. The duration of the

Phase I is 24 months. Phase II is a one-year passive follow-up wherein SCA participants receive no intervention contact for 12 months. Participants' ability to independently maintain healthy lifestyle practices they developed over the preceding 24 months will be monitored during follow-up assessments at the 36-month mark. All physical activity and dietary changes will be performed outside a laboratory setting, will be self-monitored by the participant using the provided StepsCount Pedometer or an activity tracking device of their choosing, and will be recorded using either paper-copies and/or online recording material. This study was approved by the Queen's University Health Sciences Research Ethics Board.

Figure 1. Study flow diagram

Aims and associated hypotheses

The primary aim of the trial is to determine whether small changes in energy expenditure ¹⁰ and/or energy intake (caloric intake) prevent weight gain in overweight and obese men and women long term (2-years primary, 3-years secondary). We hypothesize that weight gain within the SCA group will be less than the UC group. The secondary aim is to determine the differences between SCA and UC on body

composition (adipose tissue distribution and lean mass distribution) and cardiorespiratory fitness (VO_{2peak}). The driving hypothesis is that the increase in health risk with weight gain is largely explained by associated increases in abdominal obesity, in particular visceral fat, and decreases (or lack of improvement) in cardiorespiratory fitness. It is well established that abdominal obesity is the phenotype of obesity that conveys the greatest health risk ¹¹ and that cardiorespiratory fitness is a strong, independent predictor of morbidity and mortality ¹².

Rationale for physical activity prescription

The feasibility of the SCA option for preventing weight gain in overweight and obese adults has been demonstrated in a series of short-term pilot studies. In two separate studies Rodearmel et al report that the small change approach (increase daily steps by 2000 (~100 kcal) and/or decrease energy intake by 100 kcal) prevented weight gain in a small group of adults and children over 13 weeks ^{8,9}. In a second study the same group reported that both the small change group and controls experienced small, comparable weight losses at 6 months in both obese adults and children ⁸. Larose et al. ¹³ report that the small change approach (2000 steps and/or daily 100 kcal caloric reduction) prevented weight gain in overweight and obese young adults over 4 months. Taken together these series of studies, although small and with methodological limitations, are encouraging and provide consistent and compelling data suggesting that small changes are feasible for participants to implement in their lives and can prevent weight gain or promote modest weight loss. These pilot studies and evidence from existing literature provide the foundation to evaluate the effectiveness of the SCA in a rigorous design within a large randomized clinical trial.

Overview of planned interventions

All UC group participants are asked to maintain their usual lifestyle (diet and exercise) for the duration of the 2 year intervention (Phase I). UC participants will not be discouraged from adopting a healthy lifestyle for the purposes of preventing or losing weight.

All participants randomized to the SCA group will be guided by the trial Interventionist to make small lifestyle changes in diet and physical activity as described below. Self-regulatory principles stemming from control theory underpin this approach¹⁴. Self-regulation is the process of overriding one's natural behavioural tendencies¹⁵; in the case of this trial participants must override their natural tendency to make unhealthy food choices and to be inactive. Self-regulation requires that individuals have a behavioural goal or standard to strive towards, monitor their progress towards this goal, engage in a feedback process comparing their behaviour to the standard, and adjust their behaviour to align with their goals. SCA participants will attend a combination of group and one-on-one sessions that incorporate behaviour change techniques based upon control theory. These techniques emphasize the development and refinement of self-regulatory skills. Specifically, participants will be encouraged to review their progress by examining their diet and physical activity patterns, set new SCA goals, and develop plans for on-going maintenance of their small change goals. To further equip participants with the knowledge and skills to self-regulate their behaviour, the behaviour change techniques from control theory will be supplemented with additional techniques drawn from the health action process approach¹⁶, self-determination theory¹⁷, and social

cognitive theory^{18,19}. Sessions will initially be interventionist-led but will transition to participant-directed thus fostering independent self-regulation of SCA behaviours. Both groups will receive a \$100 stipend upon assessment at each of 6, 12, 24, and 36 months.

Physical Activity Changes

All participants in the SCA group will be asked to wear pedometers (i.e. self-monitor) during the first week immediately following randomization and asked to maintain their normal activity pattern. After establishing an average baseline activity level (steps per day), each participant will be asked to increase their daily physical activity by approximately 2000 steps per day (about 20 minutes) above the baseline value and to maintain this goal as a daily minimum for the duration of the 2 year intervention. Recent evidence from a systematic review of randomized controlled trials revealed that pedometer use in combination with set step goals (e.g. 2000 steps/day) increases physical activity by about 27% by comparison to non-pedometer users²⁰. To encourage step goal attainment SCA participants will be given a list of simple ways to increase steps through lifestyle activities (e.g. use stairs instead of escalator, park further away etc), and will be given resources such as maps of local walking/biking trails, parks and recreation facilities and a list of local fun run/walks. SCA participants will be asked to self-monitor their physical activity by recording their daily steps and submitting their records on a weekly basis electronically through Fluid Survey, by email, by mail, or in person (See Appendix I). At baseline, participants are provided with a StepsCount Pedometer, but are not restricted to wearing this device. If participants choose to wear a different activity tracking device, they will be asked to adjust their goals to correct for

any discrepancies between the two devices. All participants, however, will also be asked to wear the provided pedometer at 6, 12, and 24 months to compare to their baseline activity.

Dietary Changes

All participants will be free living and all foods consumed will be store bought and self-selected by the participants. No vitamins or other nutritional supplements will be prescribed. Each participant in the SCA group will be asked to reduce their usual diet by 100 kcal/day. Usual diet will be determined by completion of a 7-day daily dietary intake record over the two week period immediately following randomization. The diet record information obtained using established procedures in our laboratory ²¹⁻²³ will be used by the study Dietitian to provide participant-specific, pragmatic examples of how to reduce usual dietary habits by 100kcal/day. Examples provided to participants will target particular foods that contribute disproportionately to weight gain ²⁴. To encourage dietary compliance all SCA participants will participate in four educational seminars over the course of Phase I. Topics to be covered include: basic healthy eating principles and interpretation of nutrition labels, strategies for effective grocery store shopping and meal planning, techniques for eating mindfully and the recognition of barriers and strategies to overcome them. SCA participants will be asked to keep a log each day of the strategies they implemented to reduce caloric intake by 100 kcal/day and to submit their records on a weekly basis electronically through Fluid Survey, by email, by mail, or in person. Additionally, participants will have the option to complete dietary records every 3 months during Phase I, with which dietary recommendations/suggestions will be subsequently updated. At 12 and 24 months a full seven day record is required. These

dietary instructional and record keeping procedures are consistent with those used in several directly relevant randomized controlled trials successfully completed by our research team ²¹⁻²³.

Treatment frequency and format

The intervention dose (frequency and duration) and mode of delivery (group and individual) is informed by: a) existent research evaluating the SCA approach, b) trials evaluating intensive weight loss interventions (e.g., the Look AHEAD trial²⁵, and the Diabetes Prevention Project²⁶) and c) practical considerations for the delivery of a self-regulatory skill intervention to a large sample of study participant. The treatment strategy for SCA participants is divided into three phases. Phases 1A and 1B are each 6 months in duration and Phase 1C is 12 months in duration. Sessions with the Interventionist will consist of both group (approximately 45-60 min. in length) and one-on-one sessions (approximately 15-45 min. in length). These sessions are organized such that participants attend three group sessions followed by a one-on-one session in Phase 1A and 1B. In Phase 1A participants attend sessions every other week. During Phase 1B participants attend one session per month. During Phase 1C, one-on-one sessions occur 1 month before every group session, where participants have a 1-month break after every second session (Table 1).

During group sessions, participants will learn self-regulatory skills such as how to create small change goals for caloric reduction and increased energy expenditure. They also will learn behaviour change techniques that will assist them in reaching their goals and integrating them into daily living. One-on-one sessions are structured such that

participants check in after the group sessions to revisit the content and work on accountability. The group-based design is not only a cost effective method of delivering the intervention, but is also thought to provide social support, empathy, relatedness, and healthy competition among participants ²⁷. Results from a previous randomized controlled trial have also noted that group counselling to induce weight loss was the preferred method of treatment over individual counselling ²⁸. The benefit for including individual counselling will provide participants to receive a tailored approach so they may review specific questions or problems, including those related to cultural or ethnic differences ²⁵. Individual counselling should also provide a stronger bond between the interventionist and participants, thus offering a safety net for the participants who struggle with adherence and results ^{25,29,30}.

In addition, participants are allowed a certain degree of flexibility in attending and booking sessions; one-on-one sessions can be done in person, over the phone or by email to accommodate individual schedules. Group sessions are booked according to the availability of the individuals within the group.

Table 1 Intervention Schedule Overview

Phase IA= 9 group + 2 x 1:1= 9, 5-10.25h	Month 1	1	Introduction-Self Monitoring	Group
		2	Goal Setting	Group
	Month 2		Check In	1:1
		3	Goal Setting for Physical Activity	Group
	Month 3	4	Goal Setting for Nutrition	Group
		5	Goal Setting- Do's & Don'ts	Group
	Month 4		Check In	1:1
		6	Motivation	Group
	Month 5	7	Overcoming Barriers	Group
		8	Dietary Topic	Group
Phase B	Month 6		Check In	1:1
		9	Social Support	Group
Phase C	Month 7	10	Problem Solving	Group

	Month 8	11	Positive Thinking	Group
	Month 9		Check In	1.1
	Month 10	12	Dietary Topic	Group
	Month 11	13	Social Cues	Group
	Month 12	14	Building Meaning & Motivation	Group
Phase IC= 4 Group + 4 x 1:1= 5-6h	Month 13			
	Month 14		Check In	1.1
	Month 15	15	Lifestyle Changes- Lapse	1.1
	Month 16			
	Month 17		Check In	1.1
	Month 18	16	Dietary Topic + Managing Stress	Group
	Month 19			
	Month 20		Check In	1.1
	Month 21	17	Lapse & Relapse Prevention	Group
	Month 22			
	Month 23		Check In	1.1
	Month 24	18	Final Check In- Congratulations	Group

*After the initial 1:1 Session, participants can choose the method of contact- phone/email/person – every other should be in person

**Participants in Phase IB/C who are struggling have the option for additional 1:1 session as needed and based on schedule availability

*** Phase IC: Participants 1:1 session will be divided and will be seen every other month

Phase IA: Months 1-6

Phase IA consists of 9 group sessions and 3 one-on-one sessions (Table 1). During this initial phase, participants are introduced to the concepts of goal setting and self-monitoring techniques. Participants are asked to set their own goals in accordance with the principles of the SCA, and then work with the Interventionist to tailor their goal setting techniques and action planning methods. A key strategy of this phase is to get participants to identify their lifestyle patterns and tendencies and initiate realistic, sustainable change.

During Phase IA, participants attend a session every other week. These sessions are structured in accordance with both the LOOK AHEAD and Diabetes Prevention Program trials which showed that 2 contacts per month significantly improved weight loss maintenance and participant retention^{4,25,31}. At the end of Phase IA, participants will

be preparing to reduce the frequency of contact with the behavioural interventionist as they transition into Phase IB.

Phase IB: Months 7-12

During Phase IB, the volume of group and one-on-one sessions is reduced by approximately half from that of Phase IA. Individual counselling will be particularly important during Phase IB and IC of the trial; it is well documented that weight loss and weight regain become common problems for participants after the 6th month^{27,30,32}. It has been reported that participants in weight loss trials typically do not enjoy this stage of therapy as much as the first 6 months, principally because they lose little or no weight^{30,32}. Therefore, providing short yet frequent individual contact will allow those who are struggling the opportunity for individualized support while maximizing retention and participant success. Those individuals not achieving success will be provided the option for assistance to identify the barriers they are experiencing and to utilize the strategies that they feel will be most helpful to them in overcoming these barriers. A crucial part of the strategy during this challenging phase will be to foster participant autonomy; self-efficacy, to maintain change, manage barriers and recover from lapses. At this time participants are offered 3 additional contacts with flexibility to meet with the interventionist in an individual session, or revisiting group topics. This support is carried into Phase IC.

Phase IC: Months 13-24

Phase IC is 12 months in duration, and focuses on reviewing tools and knowledge acquired within the first year, reviewing mistakes and revisiting patterns from the

previous year and season. During Phase IC, the volume of group and one-on-one sessions are again reduced by half from that of Phase IB. This not only reduces the time commitment to participants but also provides the opportunity to develop individual action plans and problem solving techniques ²⁵. Tailoring becomes increasingly important during this phase because participants will differ so widely in their progress to date. Some will regain weight, some will maintain their weight and others will lose weight ^{27,33}. Therefore, one-on-one sessions during this phase are focused on the specific needs and resources of the participant. During months 13-18, autonomy is reinforced. Participants are expected to be more aware of their own patterns and obstacles at this point, and should be able to better self-identify behavioural challenges they continue to face. Furthermore, participants are able to defer one-on-one sessions if they are feeling confident with their progress. During the final 6 months, sessions will focus on preventing lapse and relapse, reviewing dietary and behavioural cues and recovery strategies. During month 22-24 participants have the option of using one of their 'flex' sessions to meet with the Dietitian for an individual session to address concerns and questions that were not covered during the group sessions. This will also encourage the submission of a final diet record.

Phase II

During Phase II, (months 25-36) there is no intervention and participants will be encouraged to maintain their small change goals and lifestyle habits. All participants (both SCA and UC) will be asked to come in for assessments at 30 months and at the end of Phase II.

Questionnaires, newsletters, and greeting cards

Study questionnaires will be given to all participants at 0, 6, 12, 24, and 36 months. The questionnaires are distributed in accordance with participants' preferred method of correspondence – online interface, mail, or in-person. The questionnaire includes: an assessment of time outcome expectations³⁴, goal difficulty³⁵, goal commitment³⁶, healthy eating and exercise outcome expectations³⁷ and exercise barrier self-efficacy³⁸; the weight efficacy lifestyle questionnaire³⁹; an adapted version of the exercise motive inventory⁴⁰; and the goal content for exercise questionnaire⁴¹. The outcomes assessed through the scales relate to participants' self-regulatory behaviours with particular emphasis on goal setting. These outcomes are secondary to the focus of the trial and will be explored as potential mediators of intervention effects. Completing the questionnaire is voluntary and will not affect a person's ability to participate in the study.

Participant Characteristics

Inclusion and exclusion criteria are listed in Table 2. Recruitment of trial participants is complete and their characteristics are described in Table 3. All participants were required to complete a PAR-Q+ screening form to ensure that they were free of known disease or other factors that would influence participation in the program. The revised PAR-Q+ was used to screen whether participants were required to see their family physician for medical clearance to help ensure the participant did not present with contraindications that would prevent participation ⁴².

Table 2 Inclusion and exclusion criteria.

Inclusion criteria:
<ul style="list-style-type: none">• Men and women between 25 and 70 years of age• BMI between 25.0 and 39.9• Sedentary lifestyle (self-reported planned physical activity for the purpose of health one day per week or less)• Self-reported being eight stable (± 2kg) for 6 months prior to the beginning of the study
Exclusion criteria:
<ul style="list-style-type: none">• Physical impairment which would make the intervention very difficult or unsafe according to the participant's physician including history of myocardial infarction, stroke, coronary bypass surgery or angioplasty in the last 6 months; peripheral artery disease, unstable angina or ischemia• Current smoker• Plans to move from the area• Participating in another study• Clinically judged to be unsuitable for participation or adherence as determined by the participants physician• Inability or unwillingness to provide informed consent• For women, planned pregnancy in the next 3 years

Table 3 Baseline Participant Characteristics

	All	Combined		Men		Women	
	(n=320)	Control (n=160)	SCA (n=160)	Control (n=37)	SCA (n=35)	Control (n=123)	SCA (n=125)
Age, y	52.4 (10.3)	52.8 (10.4)	52.0 (10.3)	54.3 (11.0)	54.7 (10.8)	52.4 (10.3)	51.3 (10.0)
Anthropometric							
Weight, kg	90.3 (14.5)	90.7 (14.0)	90 (14.9)	103.3 (11.8)	104.2 (12.8)	86.9 (12.4)	86.0 (13.0)
Waist circumference, cm	107.4 (11.7)	108 (11.8)	106.7 (11.7)	117.5 (9.7)	114.7 (10.7)	105.2 (10.9)	104.4 (11.0)
BMI, kg/m²	32.6 (4.2)	32.6 (4.2)	32.6 (4.3)	33.4 (3.5)	32.7 (3.5)	32.4 (4.3)	32.5 (4.5)
Blood pressure, mmHg							
Systolic	122.3 (14.5)	121.7 (13.9)	122.8 (15.2)	125.8 (11.4)	127.7 (14.2)	120.5 (14.4)	121.5 (15.2)
Diastolic	77.8 (8.3)	77.1 (8.0)	78.4 (8.6)	81.1 (8.5)	82.1 (8.1)	75.9 (7.5)	77.4 (8.5)
Cardiorespiratory fitness							
VO₂peak, L/min	2.4 (0.6)	2.4 (0.6)	2.5 (0.6)	3.0 (0.7)	3.3 (0.5)	2.2 (0.4)	2.3 (0.4)
VO₂peak, ml/kg/min	27.0 (5.5)	26.4 (5.5)	27.6 (5.6)	28.8 (6.8)	31.3 (5.3)	25.7 (4.8)	26.6 (5.2)

Values reported as mean (standard deviation)

Measurement of primary and secondary outcome variables

Anthropometric measurements: A comprehensive set of anthropometric measurements will be collected throughout the intervention (Figure 2). Height and weight will be measured at all assessments along with circumference measures. Body weight (primary outcome) will be measured using the same, calibrated beam scale throughout the trial. Circumference measures include waist circumference (measured at iliac crest and at the midpoint between the iliac crest and last rib), hip, and mid-thigh. Skin fold measures include subscapular, tricep, iliac crest, and thigh. Skin fold data will be acquired at baseline, 24 and 36 months (Figure 2).

Dual-energy x-ray absorptiometry will be used to assess total fat- and fat-free mass, abdominal subcutaneous and visceral fat, and total and regional bone mineral density⁴³. Dual-energy x-ray absorptiometry measures are measured at 0, 6, 12, 24 and 36 months (Figure 2).

Cardiometabolic measurements including serum total cholesterol, triglycerides, apolipoproteins, high-density lipoprotein and low-density lipoprotein-cholesterol will be measured using standard procedures. Plasma insulin will be determined by radioimmunoassay, C-reactive protein by immunoturbidimetric assay, tumor necrosis factor alpha and interleukin-6 by enzyme-linked immunosorbent assay. These samples will be collected following a 12 hour fasted blood draw. A blood draw will be taken at 0, 6, 12, 24 and 36 months (Figure 2).

Blood pressure measurements will be performed by a semi-automated blood pressure machine (BP TRU Coquitlam, BC) in the morning just prior to the blood draw.

VO_{2peak} is measured using a graded exercise test-to-exhaustion on a treadmill. VO_{2peak} values are calculated from the achieved speed and grade of the participant using the ACSM equations for walking/running⁴⁴. VO_{2peak} will be measured at 0, 6, 12, 24 and 36 months (Figure 2).

Measures obtained from SCA and UC Participant groups

Figure 2. Frequency and follow-up for primary (body weight) and secondary (waist circumference, skin folds, fasted blood draw, DEXA, VO_{2peak}) outcomes

Sample size

We had originally planned to enroll 354 participants to achieve at least 90% power at a two-sided $\alpha=0.05$ to detect a 2kg difference between arms in our primary outcome. The sample size conservatively assumed a 5kg standard deviation and up to 25% loss to follow-up. The sample size was conservatively based using an independent t-test of the change, but the actual analysis will use a linear mixed effect model incorporating all available assessments and controlling for some baseline covariates may increase power. Due to a 37% overall budget reduction from the funding source, we had to stop enrollment after 320 patients (Figure 1), which under our initial conservative assumptions would achieve 87% power.

We expect the average weight gain over the duration of the 2-year (Phase I) intervention will be 2kg in the UC group, and given this would consider it clinically important if there was no weight change in the intervention group. The 2kg difference in body weight at 24 months between SCA and UC is based on findings that the average weight gain per year in adult men and women together approximates 0.8kg per year in

obese adults. Thus a proposed difference of 2kg in body weight between SCA and UC at 24 months in the proposed study is feasible.

Statistical analyses

The primary analysis will compare the change in body weight from immediately before randomization (month 0) to the final follow-up 2 years later (month 24) between arms using a two-sided test at $\alpha=0.05$. In accordance with the intent-to-treat (ITT) principal, the primary analysis will include all available data from all participants according to the arm they were randomized to regardless of treatment adherence. The primary analysis will be estimated by a linear mixed effects model with an unstructured mean and covariance. The model will be estimated by restricted maximum likelihood using Kenward-Rodgers degrees of freedom as implemented in the MIXED procedure of SAS version 9.3 or later⁴⁵. The model will include fixed effects for, treatment arm, sex (the stratification factor) and baseline (time 0) weight as well as time and an interaction term between each effect and time. When there is no missing data, this model will provide identical estimates of the two-year treatment effect as a standard analysis of covariance (ANCOVA) with treatment arm, sex and baseline weight as predictors and the 2-year weight as the outcome. However, the proposed mixed model will be more efficient and robust to missing data assumptions than simple ANCOVA if some participants are missing their 2-year assessment. In addition to the primary comparison, the mixed effects model will allow us to construct comparisons (contrasts) at each time point after randomization which we will report graphically with confidence intervals for descriptive purposes.

The patterns of and reasons for missing data will be presented, and if indicated a sensitivity analyses including various multiple imputation strategies and the pattern mixture model will be used to assess the potential impact of missing data on the study conclusions⁴⁶⁻⁴⁸.

The secondary outcomes will be analysed using the same approach as the primary analysis; however, log (or other appropriate) transformations of some of the hematologic variables will be performed before modelling. Although the secondary outcomes will play a mostly supportive and exploratory role, result interpretation will consider the multiplicity of tests, and the false discover rate for correlated tests will be reported ⁴⁹. All other parts of the analysis, including reporting of participant flow and patient characteristics by arm will be presented in accordance with the CONSORT statement ⁵⁰.

Recruitment of couples will create an additional level of dependence in the data structure. We expect that the dependence will be minimal given that less than 10% of participants are couples. However, we will perform a sensitivity analysis which will average each couple's values so that each couple will count as a single subject in the analysis. For this analysis the sex factor in all models will have three categories: male, female, couple.

Allocation of participants to groups

Participants who successfully completed all baseline assessments and agreed to be randomized and continue on for the duration of the trial were randomized 1:1 to either

the SCA or UC. Couples were randomized to the same arm of the trial. Randomization was performed through Randomize.net and was stratified by sex using permuted blocks of random (undisclosed) size. The reason for stratified randomization was to ensure the balance among the two groups at baseline for factors that are known correlates with the primary outcome. The secure online randomization has proven reliable in numerous prior trials.

Discussion

Obesity prevalence is a major public health problem and few would argue that there is a dire need for immediate and effective treatment options. We do not argue against efforts to reduce obesity across all ages but rather, given the strong environmental forces acting against the sustained adoption of large changes in health behaviours, a more feasible approach in the short-term may be to prevent weight gain through the adoption of a pragmatic approach to lifestyle behaviours that may be sustainable long-term. At a minimum this strategy could help stabilize obesity rates and prevent the pandemic from worsening. In fact numerous studies have shown that avoiding weight gain reduces the risk of morbidity and mortality independent of gender and age⁵¹⁻⁵⁴.

Accordingly, this randomized controlled trial will aim to determine whether small changes in energy expenditure and/or energy intake (caloric intake) prevent weight gain in overweight and obese men and women long-term. To date there have been no randomized controlled trials that have considered the effectiveness of the SCA to prevent weight gain or promote modest weight reduction in body weight in overweight and obese adults long term. This is a novel and pragmatic approach to addressing the obesity problem that is based on sound principles of energy balance and the realization that sustaining major changes in behaviours in today's obesogenic environment is not possible for most overweight and obese adults. Our study findings will indicate whether there is value in clinicians (e.g. primary care physicians, Kinesiologists, diabetes educators) adopting a SCA to lifestyle counselling for their patients who are overweight and obese. The results of the trial also have potential to shape the public health messages and programs worldwide. However, our recruitment of a much smaller

sample of males suggests that our findings will be driven in large measure by the female response.

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CONFLICTS OF INTEREST

R. Ross has received honoraria for speaking and/or lecturing from the following industry members: Theratechnologies.

J. Hill is an advisor for Coca Cola, McDonalds, and the Walt Disney Company.

FIGURE LEGENDS

Figure 1. Study Design

Figure 2. Frequency for morphologic and metabolic measurements.

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