Efficacy of Two Novel Behavioral Post-cessation Weight Gain Interventions

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1. Purpose

Although smoking cessation accrues significant health benefits, regardless of the duration of smoking (4, 25, 26), it is typically accompanied by weight gain. A recent meta-analysis quantified this weight gain as, on average, 1.1 kg, 2.3 kg, 2.9 kg, 4.2 kg, and 4.7 kg at 1, 2, 3, 6, and 12 months after quitting, respectively (9). Concerns about postcessation weight gain are common and are often cited as a reason to delay cessation attempts (10, 11); furthermore, postcessation weight gain is associated with smoking relapse (10-12).

While there is some ongoing debate (13-15) about the effectiveness of behavioral weight management programs in conjunction with smoking cessation programs, it appears that behavioral weight management programs have not been able to successfully reduce postcessation weight gain (16). In addition, contrary to popular belief, there was no indication that involvement in weight management programs impacted abstinence (16, 17). Moreover, while some short-term weight gain attenuation has been observed with some pharmacotherapies (e.g., nicotine replacement therapy, varenicline), there is no long-term weight gain prevention benefit for any of the pharmacotherapies (27-30).

Much like weight maintenance after weight loss has proven to be challenging (18), weight maintenance after smoking cessation has been difficult to achieve. In a trial unrelated to postcessation weight gain, Wing and colleagues (19) hypothesized that making small, consistent changes may be beneficial for weight gain prevention. Wing *et al*. (19) tested this hypothesis in a recent study and found that participants who received their 'Small Changes' intervention gained significantly less weight as compared to the control group. Given these positive results, this approach may be translated to interventions focusing on other individuals at high risk for weight gain (i.e., those who are about to undertake smoking cessation).

While a weight gain prevention intervention is one promising approach for managing postcessation weight gain, another viable option is induction of weight loss prior to smoking cessation to offset anticipated postcessation weight gain. To develop an intervention producing pre-cessation compensatory weight loss, it is logical to draw from the breadth of knowledge in adult weight management. Many recent behavioral lifestyle interventions, such as the Look AHEAD Intensive Lifestyle Intervention (ILI), have successfully produced clinically significant long-term weight losses (20) and have demonstrated improved health outcomes (31). While promising, it is not yet clear whether lifestyle programs developed for weight loss can be effective in "counteracting" the weight gain associated with smoking cessation. Given that the ILI produced the largest long-term weight losses to date (20), translation of this intervention to postcessation weight management makes sense. Thus, in the proposed study, we will determine whether a weight gain prevention intervention and/or a weight loss intervention followed by a behavioral smoking cessation intervention (together with 6 months of varenicline pharmacotherapy) are efficacious for reducing postcessation weight gain.

2. Rationale

Previous research has shown that interventions have not been successful in significantly reducing postcessation weight gain (16). Our proposal is highly innovative in that we will evaluate two new and promising interventions for their ability to reduce postcessation weight gain at 12 month follow-up. The first intervention, the 'Small Steps' intervention, is not only a cutting edge study in the area of weight management (19), it is an innovative approach for postcessation weight management, where the goal is not weight loss but weight gain prevention (i.e., "weight stability"). Thus, the weight stability intervention will be the first novel approach for treating postcessation weight gain that we will test. Our second intervention is also innovative and tests whether long-term postcessation weight gain can be prevented by first initiating a weight loss prior to smoking cessation. To accomplish this weight loss, we will translate the most efficacious weight loss intervention to date, the Look AHEAD ILI (20). By

testing both of these interventions against a comparison group receiving the smoking cessation intervention with bibliotherapy support, we will move the field forward in identifying the most promising approaches to reducing postcessation weight gain.

Another novel feature of the proposed study is our target population. While previous studies have largely focused on women (16), we will have targeted recruitment of men, so that we recruit both men and women to this study, to facilitate the generalizability of our findings. In addition, men were found in previous research (32) to be more likely to relapse after weight gain. Furthermore, most previous studies of postcessation weight gain interventions failed to even report the race/ethnic composition of their sample (17), let alone focus on recruiting a diverse sample, as we plan to do. For these reasons, we expect our proposed interventions, if as effective as expected, will make a significant public health contribution to curtailing escalating obesity in this vulnerable population.

3. Study/ Project Population

In this study, we will determine whether two very promising methods of reducing postcessation weight gain, namely a weight stability intervention versus a weight loss intervention followed by a smoking cessation intervention, are efficacious for reducing postcessation weight gain. Given the negative health implications of weight gain after smoking cessation and the difficulty in reducing postcessation weight gain in previous interventions, **we propose the following:**
To randomize up to 400 smokers to 1 of 3 arms: a) a weight stability intervention prior to cessation (Group 1); b) a weight loss intervention prior to cessation (Group 2); or c) a self-guided weight management prior to cessation (Group 3) and to determine the efficacy of the interventions on preventing weight gain at 12 month follow-up. All 3 conditions receive a highly efficacious behavioral smoking cessation program and 6 months of varenicline pharmacotherapy (Chantix™), the most efficacious medication for smoking cessation (21, 22). Since smoking cessation and body weight are confounded, smoking cessation status and duration of cessation will be examined as covariates.

Inclusion Criteria:
-Participants must be 18 years or older
-Participants must wish to quit smoking in the next 30 days
-Participants must have smoked 5 or more cigarettes a day for at least 1 year
-Participants must have a self-reported BMI of 22 kg/m^2 or greater, as it would not be recommended to have those who are underweight or the lower end of the normal BMI range attempt a 5% weight loss (if assigned to Group 2)
-Participants must have access to a telephone and daily access to email. If using a cell phone, participants must be willing to use their cell phone minutes for weekly phone interventions as well as for some or all of the remote data collection visits
- All women of childbearing age must have a negative pregnancy test and must agree to use contraception during participation in the study
- Participants must also be willing to be randomized to the study conditions and wait eight weeks prior to beginning smoking cessation (during which they will participate in the weight management intervention to which they are assigned)
-Participants must have blood pressure that is < 150/95 mmHg and heart rates of >40 beats per minute and <120 beats per minute (according to their health care provider)
-Participants must be able to exercise for at least 10 minutes
-Participants must also have the ability to understand the consent process in English

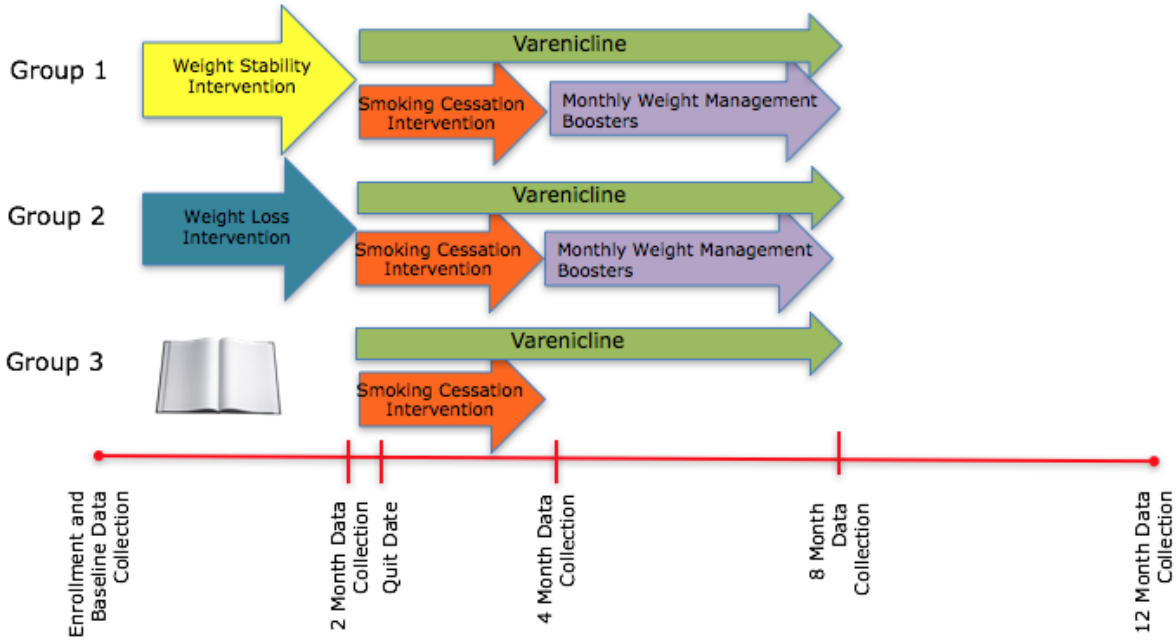
Exclusion Criteria:
-Have a known contraindication, allergy or hypersensitivity to Varenicline

- Are currently (in the previous 30 days) participating in other behavioral or pharmacologic weight or smoking cessation interventions
- Have used an investigational drug within the last 30 days
- Have current suicidal thoughts or have a lifetime history of a suicide attempt as defined by the Columbia-Suicide Severity Rating Scale (C-SSRS) (76)
- Have a self-reported history of psychosis, bipolar disorder or anorexia nervosa
-Self-report current alcohol abuse or illicit substance use
- Have kidney disease or liver disease; HIV; have unstable cardiovascular conditions, or have history of cancer in the last 5 years
-Taking medications that impact weight (see list)
-History of gastric bypass, stomach stapling, banding or other weight loss surgery
-Lost ≥ 10 pounds in the last 6 months
- Have another member of their household already participating in this study
-Pregnancy within the last 6 months, breastfeeding or planning to become pregnant during the study follow-up time (12 months)
-Weight limit of 385 pounds

4. Research Design

As seen in Figure 1, we will randomize up to 400 participants to 3 conditions: a) a weight stability intervention (Group 1); b) a weight loss intervention (Group 2); and c) a minimal intervention condition (Group 3). All 3 conditions receive a highly efficacious smoking cessation program and 6 months of varenicline pharmacotherapy (Chantix™). Those participants randomized to Group 1 & 2 will receive monthly booster weight management sessions, after completing the smoking cessation intervention.

Figure 1. Study Design



5. **Study Project Procedures**

Intervention Trial Screening and Baseline Procedures. Individuals who meet the phone screening eligibility criteria will be invited to schedule a remote Screening Visit (via phone) and the participant's e-signature will be obtained via DocuSign. If the self-reporting questionnaires cannot be done via phone they may be emailed or mailed (along with an addressed and stamped envelope) to the participant for completion. If the participant does not want to use DocuSign, the consent form may be mailed to prospective participants with a return envelope and staff will conduct the consent process over the phone prior to the participant signing the consent form and mailing it back. If consent is done in this way, staff will wait to complete the rest of the remote Screening Visit until receiving the signed consent form. If appropriate, a pregnancy test will be mailed to the participant along with instructions and staff will obtain their self-reported pregnancy test result via a follow-up call. If the participant is willing, they may email a picture of their test result. Participants will receive information regarding how to complete 3 behavioral run-in items, as an indicator of their motivation to participate in the trial over the next 12 months.

Behavioral run-in tasks include:

1. A daily diet and exercise journal (3 days)
2. Liking the study on Facebook (encouraged, but not required)
3. Obtaining physician permission to participate

Participants will complete another remote study visit ("Baseline") to evaluate behavioral run-in performance and determine randomization eligibility. A BodyTrace e-scale will be mailed to the participant and they will be asked to weigh to confirm eligibility. If participants meet eligibility requirements, they may begin the randomization process.

The biostatistician will randomize the participants to one of the three study conditions. Participants (n=400) will be randomly assigned in a ratio of 2 (Group 1, n=160): 2 (Group 2, n=160): 1 (Group 3, n=80). However; when less than 40 participants are recruited for a wave, the biostatistician will more evenly distribute the participants. Participants will be asked to complete another remote study visit for their randomization assignment and to meet their interventionist. Prior to this visit, participants will be mailed their study materials. After this visit, participants will be asked to weigh again on the BodyTrace scale.

Weight Management Interventions. Participants will complete their randomly assigned weight management intervention before initiating the smoking cessation intervention.

Weight Stability Condition (Group 1). Participants will be asked to keep their weight stable during the initial 8 weeks of the study.
Intervention Components:
1) Participants will receive **lesson materials** adapted from the Small Changes intervention (19).
2) As frequent weighing is a key component to this and most weight management programs (82), participants will be encouraged to engage in **daily weight self-monitoring** on the BodyTrace™ e-scale (http://www.bodytrace.com/), which they will be given at randomization. Each time a participant weighs, the e-scale will upload the weight automatically to a secure database, so that timely tailored feedback on weighing frequency/progress can be provided by the interventionist through email.
3) Participants will be provided with **Fit Bit activity trackers** to self-monitor their steps, consistent with the Small Changes intervention.
4) If subjects are randomized to Group 1, they will receive via mail a small reward valued less than two dollars, each week during the weight and smoking cessation sessions, then monthly during the booster

sessions, if they maintain their baseline weight or maintain a weight that is less than 1.4 kilograms above their baseline weight.

Weight Loss Condition (Group 2). Participants will be asked to achieve a weight loss goal of at least 5% of their baseline weight by week 8.
Intervention Components:
1) Participants will receive **tailored calorie and fat goals** based on their baseline weight (83).
2) Participants will be encouraged to engage in **daily dietary intake and physical activity self-monitoring** using a website or app, as these electronic tools facilitate self-monitoring (84).
3) Like the participants in Group 2, participants will be given a **BodyTrace™ e-scale** at randomization and will be asked to **weigh themselves daily**. Each time a participant weighs, the e-scale will upload the weight automatically to a secure database, so that timely tailored feedback on weighing frequency/progress can be provided by the interventionist each week through email.
4) **Lesson materials** for each session with be drawn from the Look AHEAD ILI and will cover core concepts of weight management (e.g., self-monitoring, exercise, portion size estimation, stress management, stimulus control, goal setting, problem solving).
5) **Meal replacements** will be provided to participants for 8 weeks as a method to achieve the study's calorie and fat goals and as a strategy to control portions. Participants will be encouraged to replace 2 meals (typically breakfast and lunch) with a meal replacement and will be advised to consume a third meal of conventional foods as well as additional fruits and vegetables until they reach their daily caloric goals.
6) Participants will be provided with **graded physical activity goals** to reach the goal of at least 175 minutes of moderate intensity exercise (e.g., brisk walking) per week (83), similar to physical activity goals set in a previous weight management trial with smokers (67), or 10,000 steps per day. Participants will be provided with **Fit Bit activity trackers** to self-monitor their steps, consistent with the Look AHEAD protocol (83)

Bibliotherapy Condition (Group 3). Participants randomized to Group 3 will wait for 8 weeks before initiating the same smoking cessation intervention as the other two conditions, while they review the provided weight management focused book.
Intervention Components:
1) At randomization, participants will receive the **EatingWell Diet book**, as a minimal intervention that will provide information regarding weight management.
2) Like the participants in the other conditions, participants will be given a **BodyTrace™ e-scale** at randomization and will be asked to weight themselves daily. However, they will not receive interventionist feedback about their weighing frequency or weight trajectory

Behavioral Smoking Cessation Intervention. Participants in all conditions will get our evidence-based in-person 6 session group-based smoking cessation intervention (44, 45, 89). Participants will transition to the smoking cessation intervention at week 9; they will receive the smoking cessation intervention with the same group with whom they received the weight management intervention, in order to preserve group social support as well as reduce contamination concerns. First, we will prepare participants for the quitting process, including providing varenicline at the first session. We will guide them through setting a quit date, implementing smoking cessation "rituals" (e.g., getting rid of ashtrays), reducing the number of cigarettes per day, and what to expect when they quit (e.g., withdrawal symptoms). By anticipating these issues, participants are able to better cope with them when they do arise. The second phase is the actual quitting process and getting through the first several days of being a nonsmoker. Given that this is the most difficult phase for participants (and is when the most relapse occurs), we will schedule an

individual telephone call during this week for problem solving with the participant. Finally, we will discuss both short-term and long-term relapse prevention strategies in the third phase.

Pharmacologic Intervention. All participants will receive varenicline (i.e., Chantix™) in conjunction with the behavioral smoking cessation intervention. All participants will receive varenicline 0.5 mg once daily for 3 days, increasing to 0.5 mg twice daily for days 4 to 7, and then to the maintenance dose of 1 mg twice daily for a total of 6 months of treatment.

Booster Weight Management Sessions: Participants randomized to Group 1 and 2 will receive monthly booster weight management sessions, after completing the 6-week behavioral smoking cessation intervention. There will be 5 booster sessions (week 16, 20, 24, 28, and 32) that will focus on problem solving related to weight management. Participants will receive the booster sessions with the same group with whom they received the weight management and smoking cessation interventions, in order to preserve group social support as well as reduce contamination concerns. We decided to focus these booster sessions on problem solving for both Group 1 and 2.

Intervention Fidelity Monitoring. Our previous experience in weight management and smoking cessation research suggests that the following quality procedures will help ensure treatment fidelity: 1) detailed intervention protocol development; 2) careful interventionist training, certification, and periodic re-training; 3) *r*andomly select 20% of intervention sessions to record and code to ensure protocol adherence and to provide corrective feedback; 4) documentation of all intervention contacts to monitor participant exposure to treatment; and 5) weekly study meetings to review overall adherence to structured protocols and prevent any drift between interventionists. These study meetings (attended by the supervising investigators and the behavioral interventionists) will also include problem solving related to challenging cases and refining skills.

Measurement. Data collection visits will be scheduled at baseline, randomization, and at 2 month (after the weight management component), at 4 month (after completion of the smoking cessation intervention), at 8 month (after completion of the varenicline pharmacotherapy), and at 12 month follow-up. Follow-up measures will be obtained by trained staff who are blinded to treatment assignment (Table 1). Participants who complete the 4 month, 8 month and 12 month visits will receive a financial incentive. Participants will be asked to weigh themselves on their BodyTrace e-scale. If they report point prevalence abstinence, a cotinine test will be mailed to the participant along with instructions for use and reporting of the results. For all visits, if completely phone-based visits are not possible, then the self-reporting questionnaires may be emailed or mailed (along with an addressed and stamped envelope) to the participants for completion and entered into the database by trained staff who are blinded to treatment assignment.

Table 1. Study Phases and Measurement (X=for all participants; 0=for Group 1 & 2 participants)

	Phone Screening	Screening	Baseline	Randomization	Weight Management Phase								Smoking Cessation Intervention +Varenicline Phase						Weight Booster Sessions + Varenicline Phase					Follow-up Phase
	-2	-1	0	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	20	24	28	32	52
Inclusion/Exclusion	X																							
Informed Consent		X																						
Demographics		X																						
Urine Pregnancy Test (self-reported result)		X																						
Smoking History		X																						
Why Do You Smoke		X																						
Self-Efficacy		X																						
Treatment Preference		X																						
Weight Concern		X										X												
Return to Smoking		X										X												
Importance of Weight and Smoking Cessation		X										X												
Smoking Behaviors		X										X							X				X	X
Difficulty of Weight Program and Perceived Effectiveness		X										X												
Difficulty of Smoking Cessation Program												X							X				X	
Weight Efficacy Lifestyle		X										X							X				X	X
Weight Management Behaviors												X							X				X	X
Perceived Stress		X										X							X				X	X
Healthy Days		X										X							X				X	X
Physical Activity		X										X							X				X	X
Depression		X										X				X			X	X	X	X	X	X
Suicidality		X										X				X			X	X	X	X	X	X
Height (self-reported)		X																						
Bodytrace Weight		X*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Events			X	X								X				X			X	X	X	X	X	X
Intervention Adherence					0	0	0	0	0	0	0	0	X	X	X	X	X	X	0	0	0	0	0	
Varenicline Adherence														X		X			X	X	X	X	X	
Salivary Cotinine												X							X				X	X
Program Satisfaction												X							X				X	X

*Self-reported weight rather than BodyTrace will be recorded at SV

Study Measures.

Demographics and Contact Information**:** Participants will complete a questionnaire regarding their gender, age, marital status, race, ethnicity, education level, income, as well as provide contact information to facilitate high retention rates, which will be updated at each data collection visit.

Smoking History: We will assess the age at which participants first started smoking cigarettes regularly, whether they have smoked at least 100 cigarettes in their life, how many years they have been a regular smoker, number of cigarettes per day smoked in the past year, number of quit attempts, and the length of the most recent quit attempt. We will also assess the frequency of use of various nicotine and tobacco containing products over the past year.

Why Do You Smoke: We will utilize the "Why Do You Smoke?" questionnaires that was adapted for assessing smoking specific weight concern. The scale shows evidence of predictive validity. A score of 7 or below indicates a low level of weight concern, whereas a score of 22 or greater indicates a high level of smoking specific weight concern. Participants will complete this 18-item measure by indicating their degree of agreement on a 6-point scale.

Self-Efficacy: We are assessing general self-efficacy with the Self-Performance Survey short form. These 4 items are rated on a 5-point scale.

Treatment Preference: We are assessing participants' preference for each of the treatment conditions at baseline to explore whether match or mismatch to treatment preference influenced outcome.

Weight Concern: We will measure participants weight concerns related to smoking. The 6 items on this scale are scored on a 10-point scale.

Return to Smoking: The 11 item scale (63) will be used to assess the degree of weight loss that may precipitate a return to smoking. Participants are asked if they would return to smoking after a gain of less than 2 pounds, and each subsequent question adds 2 pounds until the participant is asked, "If after quitting smoking you gained 20 pounds or more, would you start smoking?" Those that indicate that they would return to smoking after any weight gain will be classified as "weight concerned."

Importance of Weight and Smoking Cessation: The extent to which participants prioritized weight control and smoking cessation will be measured using 2 items rated on 10-point scales.

Smoking Behaviors: We will assess nicotine dependence with the Fagerström Test for Nicotine Dependence (100) and smoking status (both point prevalence and prolonged abstinence). For those participants who report point prevalence abstinence, we will test cotinine levels. Cotinine, a direct metabolite of nicotine, will be measured using the iScreen® OFD Cotinine test. iScreen is a valid and reliable method for verifying smoking status, with a specificity of >99%, a sensitivity of 97.6%. We will consider participants with at least 30 ng/mL cotinine in their saliva to be smokers; this liberal definition will avoid false positives due to secondhand smoke.

Difficulty of Weight Program, Perceived Effectiveness, Difficulty of Smoking Cessation Program: We will measure program perception by having participants use 10-point scales to rate their expectations about the degree to which treatment would help them quit smoking, minimize weight gain, and be effective overall, similar to previous research. Participants will also rate how difficult each condition (Group 1, 2, or 3) will be to implement as well as the difficulty of the smoking cessation program. Participants will also be asked which approach they thought would be most effective.

Weight Efficacy Lifestyle Scale: We will assess self-efficacy for restricting eating in 20 high-risk situations. The Weight Efficacy Lifestyle Scale has adequate internal consistency (alpha= 0.70-0.90) and shows significant increases over behavioral weight management treatment.

Weight Management Behaviors: We will examine expected dietary and physical activity behavioral differences between the three conditions, using 19 questions which will be rated on the self-reported frequency of use (1=never to 8=always), consistent with previous research.

Perceived Stress Scale: We will assess the degree to which participants find their lives to be stressful using the 10 item Perceived Stress Scale. Perceived Stress Scale scores have previously been shown to be related to smoking relapse.

Healthy Days Core Module: We will assess general health using the CDC Health-Related Quality of Life 4 item measure.

International Physical Activity Questionnaire: We will assess self-reported physical activity using the International Physical Activity Questionnaire, as it has been validated against accelerometry and has good test-retest reliability.

Weight: At all measurement visits, weight will be recorded in kilograms. Weight will be measured on the Body Trace e-scale (except for at the Screening Visit) in duplicate, with the participant wearing light clothing and no shoes.

Height: Height will be self-reported. BMI in kg/m^2 will be calculated from measured weight and height.

Safety Measures: We will assess depressive symptoms using the 20-item **CESD-R scale** (75), which is a validated and frequently used self-report measure of depressive symptoms. Scores ≥16 are considered to be suggestive of clinically significant depression. In the event that someone reports worsening depression, suicidal ideation, or an adverse event, we will involve the study physician, Dr. Womack. At measurement visits and monthly medication calls, we will assess adverse events and suicidality using the **C-SSRS** (76). We have a safety plan for management of depression and suicidal ideation, including follow-up to ensure that care has been obtained.

Intervention & Varenicline Adherence: Process variables will be a critical element of the data collected, both to assure treatment fidelity and to inform potential dissemination of the intervention. Interventionists will carefully monitor session attendance, dietary/physical activity/weight self-monitoring (if in Groups 1 or 2), meal replacement utilization (if in Group 2), and varenicline utilization to monitor implementation and to capture intervention exposure. Treatment engagement is a

consistent predictor of weight management success in our work and others (38, 97, 98); thus, we expect that treatment engagement will also be important in the management of postcessation weight gain.
Program Satisfaction: Program satisfaction will be assessed to offer insight into program acceptability for each of the conditions and get feedback on specific intervention components. We propose to adapt the treatment satisfaction measure we are currently using in the Fit Blue study (39), which will inform program refinement and future implementation.

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