Engaging men from blue-collar industries in weight loss: Study 3- Evaluating the Acceptability of Weight Loss Treatments

Unique Protocol Identification Number: 18013105-IRB01

National Clinical Trial (NCT) Identified Number: NCT05386238

Principal Investigator: Melissa M. Crane

Sponsor: Rush University Medical Center

Grant Title: Engaging men from blue-collar industries in weight loss: Tailoring recruitment and treatment approaches

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Title:	Engaging men from blue-collar industries in weight loss	
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Study Description:		
Objectives*:	Primary Objective:	Aim 1: Examine the acceptability of tailored behavioral weight loss program and a standard program in men working in blue-collar occupations. Aim 2: Compare recruitment approaches that vary on trust-based messaging to recruit men with overweight/obesity who work in blue-collar occupations.
	Secondary Objectives:	Determine the feasibility of retaining participants to a randomized trial over six months. Determine the reach of recruitment messages.
Endpoints*:	Primary Endpoint:	Aim 1: Participant reported satisfaction at 3 months. Aim 2: Proportion of participants who enroll in study by recruitment type.

Secondary Endpoints:	Number of visits to recruitment websites by recruitment type. Participant reported satisfaction at 6 months. Percentage of participants who complete a weight assessment at the 6-month assessment timepoint.
Study Population:	Men working in blue-collar occupations with overweight or obesity.
Phase* or Stage:	Feasibility testing
Description of Sites/Facilities Enrolling Participants:	Single site
Description of Study Intervention/Experimental Manipulation:	This protocol is for a randomized pilot study that will test the acceptability of a novel weight loss program and a standard weight loss program in men with overweight or obesity who work in blue-collar occupations. The secondary aim of the study is to test in a randomized comparison the effect of recruitment messages that enhance trust in two ways: researcher trust enhancement (Yes, No) x participant endorsement (Yes, No).
Study Duration*:	18 months
Participant Duration:	6 months

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

Principal Investigator or Clinical Site Investigator:

Signed: Melissa M Crane Date:05/11/22

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Engaging men from blue-collar industries in weight loss	
Grant Number:	K01DK119457	
Study Description:		
Objectives*:	Primary Objective:	Aim 1: Examine the acceptability of tailored behavioral weight loss program and a standard program in men working in blue-collar occupations. Aim 2: Compare recruitment approaches that vary on trust-based messaging to recruit men with overweight/obesity who work in blue-collar occupations.
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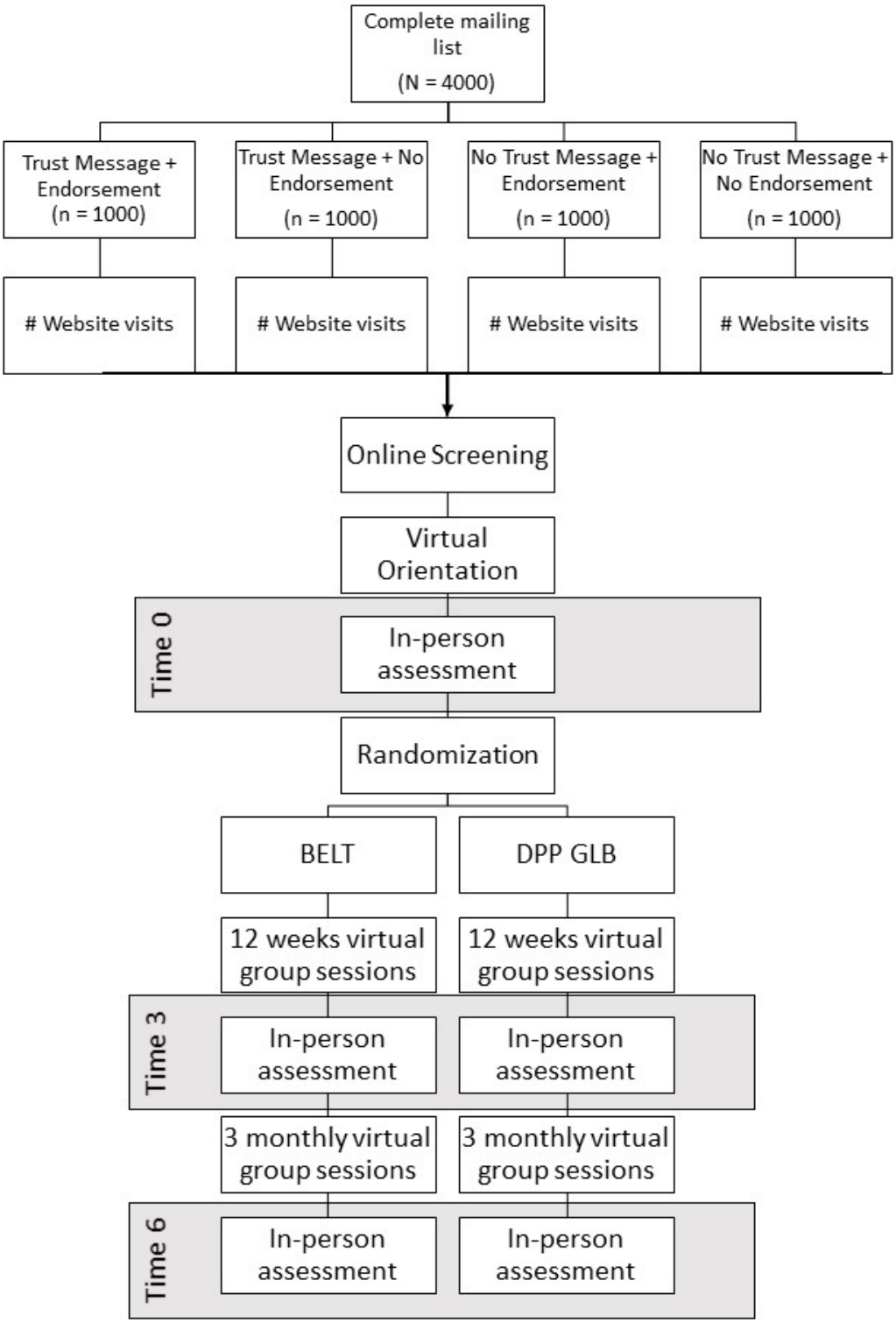
	Secondary Endpoints:	Number of visits to recruitment websites by recruitment type. Percentage of participants who complete a weight assessment at the 6-month assessment timepoint. Participant reported satisfaction at 6 months.
Study Population:	Men BMI>25	
Phase* or Stage:	Feasibility testing	
Description of Sites/Facilities Enrolling Participants:	Single site	
Description of Study Intervention/Experimental Manipulation:	This protocol is for a randomized pilot study that will test the acceptability of a novel weight loss program and a standard weight loss program in men with overweight or obesity who work in blue-collar occupations. The secondary aim of the study is to test in a randomized comparison the effect of recruitment messages that	

enhance trust in two ways: researcher trust enhancement (Yes, No) x endorsement (Yes, No).

Study Duration*:	18 months
Participant Duration:	6 months

1.2 SCHEMA


Complete mailing list
(N = 4000)
Trust Message + Endorsement (n = 1000)
Trust Message + No Endorsement (n = 1000)
No Trust Message + Endorsement (n = 1000)
No Trust Message + No Endorsement (n = 1000)
Website visits
Website visits
Website visits
Website visits
Online Screening
Virtual Orientation
Time 0
In-person assessment
Randomization
BELT
DPP GLB
12 weeks virtual group sessions
12 weeks virtual group sessions
Time 3
In-person assessment
In-person assessment
3 monthly virtual group sessions
3 monthly virtual group sessions
Time 6
In-person assessment
In-person assessment

1.3 SCHEDULE OF ACTIVITIES

	Screening	Baseline: Time 0	Time 3: Week 12 ± 4	Time 6: Week 24 ± 4	Reference	Measure type
Contact information	X					SR
Basic demographics	X					SR
Occupational situation	X		X	X		SR
Alcohol use	X				[1]	SR
Physical activity readiness questionnaire	X				[2]	SR
Weight		X	X	X		Physical measure
Waist circumference		X	X	X		Physical measure
Physical activity		X	X	X	[3].	Staff interview
Program satisfaction			X	X	[4].	SR
Healthcare climate questionnaire			X	X	[5].	SR
Program satisfaction interview				X		Interview
Sugary beverage screener		X	X		[6].	SR
Fast food screener		X	X		[7].	SR
NCI Fruit and Vegetable Screener		X	X	X	[8].	SR
Weight loss strategies		X	X	X	[9].	SR
Self-weighing frequency		X	X	X	[10].	SR
Food shopping habits		X	X	X	[11].	SR

Adverse Events Reporting		X	X		SR
Sessions attended		X	X		Staff report
Tracking submitted		X	X		Staff report
Demographics	X				SR
Patient preference for treatment	X				SR
Weight loss history/Motivations for weight loss	X				SR
Tobacco use	X				SR
Health literacy	X			[12].	SR
Delay discounting	X			[13].	SR
Medical conditions	X				SR

2 INTRODUCTION

2.1 STUDY RATIONALE

Men working in blue-collar occupations have a high prevalence of overweight and obesity and have high rates of comorbidities associated with obesity. Unfortunately, these men are unlikely to participate in evidenced-based weight loss interventions. Further, few efficacious interventions have been developed that target this population for weight control.

The purpose of this study is to test the feasibility and acceptability of tailored recruitment messages and a novel, tailored behavioral weight loss intervention in the context of a randomized trial.

2.2 BACKGROUND

The prevalence of obesity has reached an all-time high in the United States,[14] and the connection between obesity and numerous comorbidities and excess mortality has been well established.[15] [16] [17] The combined prevalence of overweight and obesity is greater in men than women (79.2 *vs.* 76.8%), [18] and both genders experience various related conditions, including diabetes, heart disease and stroke, and some cancers.[2] [3] [4] Despite these similar risks, men are significantly less likely than women to attempt weight loss,[19] participate in behavioral weight loss research studies[20] [21] or commercial weight loss programs,[22] or bariatric surgery[23] .

One subgroup of men with especially low participation rates in weight loss programs includes those working in blue-collar industries, which the U.S. Department of Labor defines as “precision production, craft, and repair occupations; machine operators and inspectors; transportation and moving occupations; handlers, equipment cleaners, helpers, and laborers.” [24] These industries are male-dominated, and men who work in these industries are at increased risk for obesity and related comorbidities compared to the general population.[25] .[26] .[27] For example, the prevalence of type 2 diabetes is twice as high among truck drivers compared to the general population.[26] Compared to other industries, overweight or obesity in blue-collar industries yields greater reduction in job performance and productivity, increases risk for injury, and generates higher indirect costs associated with obesity (e.g., costs due to absenteeism). [28] .[29] .Together, these data indicate men from blue-collar industries would greatly benefit from participation in weight loss programs.

Men-only weight loss programs that integrate men’s preferences have begun to be developed and evaluated. In a meta-analysis and a systematic review, these programs led to increased weight loss compared to no intervention. [30] .[31] My prior work adds to this literature [32] . Collectively, growing evidence suggests this type of weight loss program has higher acceptability to men than traditional approaches.

A glaring limitation of the male-targeted weight loss studies conducted thus far is that they are comprised primarily of men with high levels of education. The exact occupational representation of these samples is difficult to quantify because occupational background is rarely assessed in health research.[33] However, because only 7% of individuals working in blue-collar industries hold a Bachelor's degree, [34] this educational threshold can be used as an indicator of an *absence* of individuals working in blue-collar industries. Like many other men-only weight loss programs, my previous intervention was applied to a highly educated sample in which 83% of participants had at least a college degree. Because research on men's weight loss has predominately been conducted with a small, potentially non-representative subgroup of men, we cannot assume these programs will work equally well among men from blue-collar industries.

Tailoring interventions to occupational groups may be an effective way to reach underserved populations. Occupational groups have shared common experiences and social norms that promote/inhibit health behaviors. [33 35] Addressing these experiences and norms may be an effective way to tailor programs but the efficacy of this tailoring is not known. First, health promotion programs targeting blue-collar occupations may need to tailor content considering the masculine norms, including a drive towards independence and eating "masculine" foods, which are highly prevalent in this group.[36] .[37] . Mahalik & Burns, 2011; Mahalik, Burns, & Syzdek, 2007; Roos, Prattala, & Koski, 2001) How to do this is not currently known. Second, workers in blue-collar occupations are at increased risk for injury, especially musculoskeletal injuries;(Charles, Ma, Burchfiel, & Dong, 2017; Dembe, Erickson, & Delbos, 2004; Farnacio, Pratt, Marshall, & Graber, 2017; Ma et al., 2018) thus, inclusion of injury prevention strategies may be a key consideration. Research has demonstrated this is an effective strategy for smoking cession(Sorensen et al., 2002) but has not been tested for weight loss. Third, blue-collar occupations often, but not always, include high levels of physical activity. A common misperception among individuals in high-activity occupations is that they have a reduced need for leisure-time physical activity.(Caban-Martinez et al., 2014) However, multiple studies have shown that higher occupational physical activity is associated with increased all-cause mortality in men even when controlling for other health behaviors (e.g. smoking).(Clays et al., 2013; Coenen et al., 2018; Harari, Green, & Zelber-Sagi, 2015; Wang, Arah, Kauhanen, & Krause, 2016) Leisure-time physical activity reduces this risk; (Clays et al., 2013; Harari et al., 2015; Wang et al., 2016) therefore, explicitly promoting the need for leisure-time physical activity, regardless of occupational activity may be needed. Finally, many workers in blue-collar industries report few options for healthy foods at work,(Nagler, Viswanath, Ebbeling, Stoddard, & Sorensen, 2013) which has been confirmed by objective assessments of work environments.(Apostolopoulos et al., 2011; Shimotsu, French, Gerlach, & Hannan, 2007) Providing guidance on selecting healthy foods in this challenging setting may be an important feature of a tailored intervention; but again, this has not been demonstrated.

In preparation for this study, we have conducted formative studies that have focused on evaluating preferences men working in blue-collar occupations have for weight loss programs. These studies (Crane et al., under review and in preparation) have indicated that to reach this population, the intervention

should be delivered online, easily incorporated into their daily lifestyles, and be presented in a trustworthy fashion. There was little support for programs conducted in worksites indicating a need to reach this population at home (versus work). As a result, this study will use a randomized design to test the acceptability of an intervention that incorporating these program features into a novel, tailored intervention. Additionally, this study will incorporate factors found to be important to participants into recruitment messages.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The foreseeable physical, psychosocial, legal, and financial risks associated with participation in this study are minimal. There are minimal risks for individuals who receive the mailings as no personal health information will be included. The physical risks associated with participating in the intervention include an increased risk minor injury due to increasing leisure-time physical activity. This risk has been minimized by prescribing a gradual increase in physical activity, recommending walking as the primary form of physical activity, and repeated discussion of maintaining safety while exercising. Study assessments include widely used questionnaire measures. There is a very small chance that some items could be mildly distressing. In this event, subjects may postpone answering or opt out of distressing questions.

There is a risk of loss of confidentiality of participant data. Steps will be taken to maximize confidentiality of data . Also, other participants who attend the group-based weight loss program may share information about their interactions with you outside of the group. The research team will ask all group members to respect each other's privacy, but cannot guarantee they will do so.

There are no foreseeable legal or financial risks associated with participation.

2.3.2 KNOWN POTENTIAL BENEFITS

Subjects may experience an improvement via weight loss. Subjects participating in the post-intervention interviews are not expected to directly benefit from that component of the study. The potential benefits to future participants are that this study may advance the knowledge of the development and promotion behavioral weight loss interventions to reach and engage men from blue-collar industries.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

There are minimal risks associated with this study and the potential benefits to both the participant and society outweigh the potential risks. This study has the potential to provide information on how to best reach and engage men working in blue-collar occupations in behavioral weight loss program. This is important due to the high rates of overweight and obesity in this population and the very low levels of

participation in weight control efforts.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Aim 1: Examine the acceptability of tailored behavioral weight loss program and a standard program in men working in blue-collar occupations.	Participant reported satisfaction with program at 3 months.	Participant satisfaction is a proxy for acceptability.
Aim 2: Compare recruitment approaches that vary on trust-based messaging to recruit men with overweight/obesity who work in blue-collar occupations.	Proportion of participants who enroll in study by recruitment message type.	The goal of recruitment is enrollment in the study. Using the proportion of participants who received the postcard as the endpoint provides an assessment of the effectiveness of the message.
Secondary		
Determine the feasibility of retaining participants to a randomized trial over six months.	Percentage of participants who complete a weight assessment at the 6-month assessment timepoint.	High retention to the study will indicate the study procedures are feasible for a fully powered trial.
Determine the reach of recruitment messages.	Number of visits to recruitment websites.	The website is the first indication of participant interest in the study.
Determine the acceptablity of the intervention.	Participant reported satisfaction with program at 6 months.	
Tertiary/Exploratory		
Determine percentage of participants who achieve a clinically significant weight reduction (5% of initial weight).	Weight objectively assessed by study staff at baseline, 3 months, and 6 months.	5% weight loss is an established indicator of clinically significant weight loss.
Evaluate participants perceptions of program components.	Semi-structured interviews.	We will conduct semi-structured interviews with participants to gain a deeper understanding of their perceptions of program components and their experiences in the program.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study is a two-armed randomized controlled trial with assessments at baseline, 3 months after randomization, and 6 months after randomization. The objective is to assess the acceptability of the intervention to participants at 3 months and the feasibility of study procedures at 6 months with retention to the study as the outcome. This is a single site, Stage 1 study.

Participants will be randomly assigned to study groups by a biostatistician who is not involved with the study assessments or interventions using a random number generator. Individuals will be randomly assigned to study conditions in cohorts of approximately 30 individuals. Randomization will be concealed from participants until their first treatment session.

Participants will be randomized to receive either the tailored BELT (Better Energy through Lifestyle for Tradesmen) treatment or a standard weight loss program (Diabetes Prevention Program Group Lifestyle Balance; DPP GLB). The groups will be matched on number of weeks of treatment, mode of delivery, and contact time.

During recruitment for this study, we will conduct a randomized comparison of recruitment messages. This comparison will use a factorial design testing the effects of enhancing trust in the researchers (Trust Messaging: Yes, No) and the effects of a participant endorsement (Endorsement: Yes, No). Names and addresses for individuals from a purchased marketing list will be randomly assigned to be sent a postcard with a recruitment message matching their assigned condition. Recruitment reach will be assessed through website visits and number of participants responding to each message.

This is a feasibility study with no formal hypotheses to be tested.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This study will use a randomized design to test the feasibility of recruiting and retaining men working in blue collar occupations into a study of multiple weight loss programs. This study will use a previously tested, effective, publicly available program as the comparison group [38]. The benefits of using the program include that all participants will receive an active intervention and we will have data on men's performance in a standard weight loss program as well as our tailored program at the end of this study. This will be key preliminary data for future grant applications. A potential problem associated with using this control group is that participants may not be interested in a non-tailored program if a tailored program is available. This may decrease both recruitment and retention to the study.

To enhance recruitment for this study and future studies, we will use a randomized, factorial design to test the efficacy of two components of recruitment messaging. By using this factorial design, no participants will be randomized to a true control group: all participants will receive a message we believe may be effective for recruitment of this population.

4.3 JUSTIFICATION FOR INTERVENTION

This protocol is a randomized feasibility trial where participants will be randomized to a standard, non-targeted behavioral intervention (DPP GLB) or a novel tailored intervention (Better Energy through Lifestyle change for Tradesmen: BELT). The goal of the BELT intervention is to produce weight loss in via small but sustainable changes to eating and through an increase in leisure-time physical activity. The BELT intervention is a translation of our previously developed and tested intervention for men[32] . This intervention, like the earlier iteration, targets Social Cognitive Theory emphasized building self-efficacy for behavior change through small changes to lifestyle patterns and self-monitoring. In the earlier intervention, men lost an average of 5% of their starting weight. The intervention has been modified based on formative studies targeting men working in blue-collar occupations. Most notably, the changes include 1) delivery via online video conferencing, 2) modification of physical activity goals, 3) change to the framing of the eating modification goals (from “making 6 100-calorie changes per day” to “use a tool at nearly every time you eat”: see Eating Goals below), 4) shift from written educational materials to videos, and 5) inclusion of more language and examples that tie to blue-collar works and culture. These translations are guided by our formative work and with input from our community advisory board.

The comparison will be a group-based delivery of the Diabetes Prevention Program Group Lifestyle Balance (DPP GLB 2017). This is a manualized weight loss program designed to produce moderate weight changes through lifestyle change. The leader guides and handouts will be minimally modified for this study (e.g., changes appropriate for delivery via online group sessions vs. in-person) to provide a “standard” weight loss program comparison. The two interventions will be matched for number of group sessions and will be delivered by the same interventionist.

One of the challenges for targeting men working in blue-collar occupation in this context is that many of these men do not consider themselves overweight [25 27] and avoid help-seeking behavior [39 40] . To overcome this, in this study, we will test recruitment messages that will not focus on weight per se and will instead focus on the target behaviors (eating and physical activity) and outcomes reported by participants in formative work as important to them (improved energy and feeling better). The messages will explicitly target the identity of tradesmen to increase the likelihood that men working in blue-collar populations will identify with the message. This tailoring of messages theoretically increases the effort recipients exert to process the messages, as described by the Elaboration Likelihood Model [41] .

In our experimental comparison, this study will focus on evaluating the effects of including information to increase trust in the program in two ways. First, trust will be enhanced by increasing the transparency of the intervention development and testing process. Transparency is key to building trust in medical research.[42] "Effects of a methodological infographic on research participants' knowledge, transparency, and trust." 40 41 In our formative work, participants nearly universally reported that they would join a program if someone personally recommended it to them. Unfortunately, relying on person recommendations is not possible in a large-scale study nor would the results be generalizable. Instead this study will test whether including an endorsement of the program by a former participant would be enough to increase interest in the program.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he has completed the baseline assessment and the 6-month follow-up assessments.

The end of the study is defined as completion of the 6-month follow-up assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Age 18 years and older
2. Male
3. Overweight or obesity (body mass index (BMI) > 25 kg/m^2)
4. Employed >20 hours per week in an occupation classified as blue collar
5. Ability to communicate in English
6. Provision of signed and dated informed consent form

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. History of bariatric surgery
2. Diabetes managed with insulin
3. Diagnosis of a serious mental illness
4. Conditions contraindicated to exercise independently (determined using four questions of Physical Activity Readiness Questionnaire)[2]
5. Report of potentially hazardous alcohol use (ASSIST $\geq$27) [1] .
6. Weight loss in the prior six months of 10 pounds or greater
7. Body mass index ≥60 kg/m2, due to increased injury risk with exercise
8. Diagnosis of an eating disorder
9. Any major medical condition that could increase risk for injury or other contradictions for treatment (e.g., cancer treatment) or high likelihood of attrition (e.g., recent hospitalization for depression, psychosis) as determined by the study team

5.3 LIFESTYLE CONSIDERATIONS

During this study, participants are asked to:

- Refrain from starting medications or dietary supplements for weight or appetite control and
- Refrain from participating in another weight loss program.

5.4 SCREEN FAILURES

During this study, participants are asked to:

- Attend an in-person assessment visit and complete questionnaires online.
- Attend at least one treatment session.

Participants who do not complete the baseline assessment visit will not be randomized into the study.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Participants will be recruited via the postcards mailed to their homes. They will be directed to a study website where a brief description of the study will be presented. Participants recruited through the four recruitment messages will be sent to separate but identical websites. Participants who are interested will be asked to complete an online screening form. Those who appear initially eligible will be contacted to schedule a time to attend a study orientation. This orientation will allow participants the opportunity to gain information about the study and to experience the web conferencing platform (if they have not used it before). The session will describe the study and will use the motivational interviewing approach described by Kiernan and colleagues [44] .[45] .[46] to enhance engagement and retention to the study. Following this, participants will attend an in-person assessment visit where they will sign consent before completing the physical measures and self-report questionnaires. Participants who complete the baseline visit and measures will be randomized to receive either the tailored intervention or the generic intervention following a 1:1 randomization ratio.

Recruitment will be supplemented by recruitment through flyers, notices on a hospital "on-hold" line, and online recruitment messages as needed. These potential participants will be encouraged to contact the study through the study website and will go through the recruitment process described above.

All recruitment materials and plans will be reviewed and approved by the Rush University Institutional Review Board prior to implementation.

To maximize retention, we will collect multiple methods for contacting participants (e.g., email, telephone) at baseline. Participants will tentatively schedule their follow-up assessment during their initial treatment session, a method we have used in prior studies to increase retention rates. During the intervention, participants have not engaged with treatment for at least one anticipated sessions will be contacted directly by intervention staff to encourage reengagement with the program.

Guidelines for attempting to schedule intervention visits. These general guidelines are intended only to set norms around how frequently attempts should be made to contact participants for intervention visits. Each attempted contact should be tracked in Research Electronic Data Capture (REDCap). Unlike scheduling outcomes assessments, clinical judgment can play a larger role in determining how "aggressively" interventionists should seek to communicate with participants. In general, it is likely most effective to adopt a non-judgmental tone, normalize the difficulty a participant may be having with engaging in the intervention, and invite participants to outline when and how we can stay in touch with them until they are hopefully able to reengage with the study.

WHAT TO TRY	**WHEN TO TRY IT**
Call and/or email participants the day after missed session and encourage their return to group the following week.	When first session is missed
Increase variability and/or frequency of attempts to every 3-4 days, while trying to not overwhelm the participants using calling, text or email.	After 1 week of no contact with study (e.g., no session attendance or self-monitoring reported)
Send a letter asking them to get in touch	No contact for 3-4 weeks
Call from Principal Investigator to probe for concerns or barriers to engagement	When deemed appropriate, but no later than 5 weeks overdue

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Recruitment substudy

During recruitment for the trial, we will test the effects of recruitment messages using mailing postcards with four different recruitment messages to addresses of men believed to work in blue-collar occupations. The intervention exposure is the receipt of the postcards by potential participants. The four recruitment messages:

- Standard recruitment message alone (e.g., "Tradesmen: Boost your energy and feel better through changes to eating and physical activity!")
- Standard message plus messages to enhance trust (e.g., "Join the BELT study: built for tradesmen with tradesmen" and "Why we are doing this: Our team wants to understand how to help men like you improve their health. We've developed a new program with input from men like you for men like you. It's designed to fit into your life!"),
- Standard message plus an endorsement from a prior participant ("This is a great program…safe, thoughtful, and effective.")
- A combined trust and endorsement message.

An identical description of the program plus a call to action "Go to [study website] to see if you are eligible!] will be included in all postcards. Participants will be sent to separate but identical websites to allow us to track the reach of the messages via the number of independent website visits. The remaining recruitment process will be identical for all participants, regardless of recruitment message received. From the website, participants can choose to be screened for eligibility and will be randomized into the trial as appropriate.

The BELT Intervention

The BELT intervention will be delivered via 16- group session conducted via web-conferencing (i.e., Zoom) supported by short, educational videos hosted on the study website. Online groups sessions will allow participants to give and receive social support from peers while also minimizing disruption to lifestyle that would be needed for a face-to-face group session. Study staff will help troubleshoot any issues using this system during the intervention. Importantly, all participants will have chance to use the platform during the online orientation session for the study. Group sessions will be 60 minutes per session and will occur weekly for months 1-3, twice in month 4, and once a month in months 5 and 6.

Group sessions will be accompanied by short videos that participants will view asynchronously that align with the topics discussed in the group sessions. These videos will be used in lieu of traditional printed handouts. Short videos can be an efficient way to convey the educational materials and is a familiar approach to participants who may have viewed educational on workplace safety in the past. Videos will

be short (maximum of 3 minutes) to encourage participants to view the videos regularly. Similar to previous men-only weight loss interventions, these will feature straight forward language, include humor, and will include a conversational style of speech. New videos will be posted at least once each week to encourage participation with the program throughout the 6-month study. Scripts for videos will be developed simultaneous to the leader guides for the groups sessions to ensure overlap between topics. The intervention guides and scripts will be developed to take an autonomous support approach (e.g., present multiple options for participants to choose from in making changes).

The lessons in this study focus on target behaviors and skills that will aid participants in reducing their intake below their baseline levels (see topics in Table). The behaviors and skills align with what we used in our earlier study. These were identified by reviewing the literature and finding specific activities that have either been associated with weight loss in past studies—for example, reducing caloric beverages can produce weight loss over time[47] or behaviors that have be targeted in other successful weight loss studies.[48] [49]The goal of selecting these specific behaviors was to select behavioral targets that can be articulated to participants in a simple manner, monitored in a simple manner, and implemented with minimal lifestyle disruption. The behaviors that were expected to yield to greatest caloric reductions will be presented first. This is designed to help participants to begin to losing weight earlier in the intervention in order to prevent discouragement. Four additional lessons that focus on weight loss maintenance skills will be presented during months four through six. These lessons ("Relapse Prevention", “Eating in Social Situations”, “Slips, Slides, and Falls”, and “Maintaining Your Momentum”) are skill based versus focusing on specific eating behaviors. These topics were selected for use during the tapered contact period of the program because these are skills that support making long-term changes to eating and exercise behaviors.

Eating behavior

Participants will be encouraged to make several small changes to their diet throughout their day. Rather than providing calorie goals to stay beneath, participants will be encourage to use the “tools” (i.e., specific eating behaviors or change techniques) presented during group sessions and videos. Examples of these tools include: reducing portion sized, replacing with a lower calorie option, removing extras, skipping extra servings. Starting during the second group meeting, participants will be asked to identify aspects of their eating and physical activity habits that are not aligned with their desire to lose weight and that they were willing to change. Based on this self-evaluation, participants will be asked to set weekly goals for eating behaviors they wanted to change. As part of the self-evaluation, participants will be given an estimate of their daily caloric needs as well as the prescribed intake level to produce a one- to two-pound weight loss per week based on their weight and level of physical activity reported during their baseline assessment. Participants will be given a list of upcoming lesson topics and a description of the behaviors that indicate tools that may useful strategies to help them lose weight (see Table X). Taking an autonomy supportive approach, participants will be asked to consider which behaviors they would be most willing to change and which behaviors they are not ready to change, emphasizing their autonomy in the program

Physical activity

Goals for leisure-time physical activity will be matched across interventions groups at 150 minutes of moderate-to-vigorous physical activity per week. In the BELT condition, participants will be given progressive exercise plans (starting at 0, 50, 100 minutes of activity per week) that encourage exercise 5 days per week and will increase by 5 minutes per exercise session until the goal is reached. A distinction will be made between occupational activity and leisure-time physical activity with an emphasis on the health benefits associated with leisure-time activity.

Goal setting

At the end of each group session, participants will set a SMART goal (Specific, measurable, attainable, relevant, time-bound) that they will strive to achieve over the next week. Theses goals will be encouraged to focus on the behavior topic presented in the group session or another behavior of interest.

Self-monitoring

BELT will use a simplified approach to self-monitoring where participants will be encouraged to monitor (at a minimum) their daily weight, minutes of leisure-time physical activity, and the "tools" participants used to modify their eating that day.

Participants will be encouraged to track this information using the diary section within the MyFitnessPal app. The study will create accounts within the app for participants that will give the intervention team access to the self-monitoring information. The team will log into the platform and email feedback on participant progress (e.g., monitoring completeness, weight loss, progress towards eating and activity goals). Participants will also use the MyFitnessPal app to closely monitor their intake during week 1 of the program. Continued detailed self-monitoring will be presented as a tool participants can use to help increase weight loss as needed but will not be required.

BELT Lesson Topics

Session	Topic Title/Primary Video	Secondary video	Topics covered
1	Lifestyle change for weight control	Self-monitoring 101	Energy balance, weight loss goals, self-monitoring to increase nutrition knowledge
2	3RS: Replace, reduce, remove, skip seconds: Your everyday tools	Self-weighing as a tool	Self-regulation process; introduction to tools for weight loss; motivation for weight loss
3	Balance your beverages	SMART goals	Beverages; goal setting for self-regulation
4	Preventing snack attack	Hungry, bored, or habit?	Excess calories from snacks, choosing healthier snack options, evaluation of hunger as eating cue (vs. other cues)

5	Move more!	Do I have to exercise if I work all day?	Exercise principles (FITT), exercise safety, goals, the importance of leisure-time PA
6	Portion distortion	Nutrition facts or fiction?	Reading nutrition labels, estimates of portion sizes, how to reduce portions using stimulus control
7	Reduce in restaurants	Quick and easy meals on the go*	Eating in restaurants and on the go
8	Increase to decrease	Plan your plate	Tips for incorporating more fruits and vegetables into diet; introduce balanced plate with half fruits/vegetables
9	Cutting the fat	Winning with water	Reduce fat intake to reduce caloric density; cutting empty calories from fat; revisit beverage concepts and ways to increase water consumption
10	Start with breakfast	Breakfast FAST!*	Importance of maintaining regular eating patterns; suggestions for breakfast alternatives
11	Swap out sweets	Grab and go at the gas station	Reduce calories from sugar. Healthier alternatives when buying on the go
12	Fitness fights fatigue	Round out your routine	Reducing sedentary behavior to make time for PA; including stretching and resistance training to activity routine
13	Eating in social situations	Get the help you need	Social cues for eating and how to manage them; Identifying places where social support can help with example scripts
14	Do you know your zone?	Problem solving	Self-regulation for relapse prevention; check in on concerns about transitions to independence; encourage problem solving around weight loss
15	Slips, Slides, and Falls	Rework what's around you	Relapse prevention; stimulus control
16	Maintaining your momentum		Maintaining motivation during maintenance

*Written recipes will be provided instead of videos for these topics

DPP GLB

The Diabetes Prevention Program Group Lifestyle Balance program[50] will be used as the comparator in this study. The first 16 lessons will be covered over 16, hour-long group sessions conducted online via Zoom. The intervention will be minimally modified from the published version except to make the program appropriate for online delivery (e.g., no supervised exercise sessions). The published behavior targets will be used (e.g., calorie and fat goals set by beginning weight). The lessons will be provided to

participants as PDF files. These lessons will be minimally modified (e.g., remove reference to pedometers).

Comparison of BELT to the DPP GLB

	BELT	DPP GLB
Contact	16 60-minute group sessions conducted over Zoom	16 60-minute group sessions conducted over Zoom
Educational materials	Pocket guide + videos	PDF handouts
Dietary goals	Small changes to eating behaviors	Moderate changes to diet
Physical activity	150 minutes of leisure-time physical activity	150 minutes of leisure-time physical activity*
Self-monitoring	Daily tracking of weight, physical activity, and tools used to change eating	Daily tracking of weight, physical activity, and calories (after session 6)

*Note. This is change from the DPP GLB as published due to the difficulties of providing pedometers during a remotely delivered program.

6.1.2 ADMINISTRATION AND/OR DOSING

Participants in both randomized groups will be encouraged to attend weekly group sessions months 1-3, two sessions in month 4, 1 session in month 5, and 1 session in month 6. All group sessions will be one hour in duration.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The program interventionist is an registered nurse with many years of experience delivering behavior change interventions. Prior to the intervention beginning, the PI and interventionist will develop (BELT) or review (DPP GBL) all group leader guides. The PI and interventionist will meet weekly to review the previous week's sessions and review the next sessions materials.

A subset of group intervention sessions will be audio recorded and reviewed by the primary investigator using a treatment fidelity checklist. The investigator will monitor for contamination of the tailored program material appearing in the standard program but not vice versa. A subset of feedback provided to participants will also be reviewed for contamination and completeness.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Randomization to treatment conditions for the recruitment message substudy will be conducted by the study Principal Investigator using a random number generator. Participants will not be blind to the study condition but will be blind to hypotheses. Staff cannot be blinded to study arm as they will need to ask which recruitment message was received.

In the main trial, randomization to treatment condition will be conducted by a statistician not involved with treatment delivery. Randomization will be revealed to participants at their first treatment session. Outcome assessors will be blind to treatment assignment.

Though it is not possible to blind participants to the nature of the treatment they are receiving, both arms will be named and described as (and truly are) active treatments to eliminate expectancy effects. As both arms will receiving information remotely, risk of contamination is minimal.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

The interventionist will record attendance during each of the group sessions.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a subject discontinues from study intervention but not from the study, remaining study procedures will be completed as indicated by the study protocol. If a clinically significant finding is identified after enrollment, the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant finding will be reported as an adverse event (AE).
The data to be collected at the time of study intervention discontinuation will include the following:

- The reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue
- The participant will be included in all future scheduled assessments, even though not participating in the intervention.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded in the study record. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

7.3 LOST TO FOLLOW-UP

Participants will be considered lost to follow-up if they cannot be contacted for the 24-week study assessment within the assessment window. To minimize missing data, staff will attempt to follow up with all participants randomized into the study regardless of their level of participation in the intervention or completion of the 12-week assessment (i.e., those who fail to complete the 12-week assessment will be contacted to complete the 24-week assessment). Importantly, no subject is considered lost to follow up at any earlier point in the study, even if they miss other assessments. Retention efforts should continue throughout the entire duration of the study

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Assessments will occur at baseline and 3 and 6 months post-randomization. Assessments will occur in three parts: in-person assessment, online questionnaires, and (optional) semi-structured interviews.

In person assessment visits

Participants will come to the study site for in-person assessments. Assessments will be conducted by study staff in private rooms. Measures include weight (measured in duplicate in street clothes with shoes removed and heavy objects removed from pockets), height (baseline only), and a physical activity interview. The physical activity interview is based on the Paffenbarger physical activity measure[3] [4] but will be conducted as an interview to allow follow up questions to correctly categorize physical activities reported.

Online questionnaires

Participants will be provided with a personalized link to an online survey where they will complete all of the self-report measures for each time point.

Satisfaction with program (3 and 6 months): Satisfaction with the program questions are modeled after other weight control program evaluation questions[51] .[52] .and ask the participant to consider their satisfaction and their satisfaction given the effort they put into the program. The participants will also rate the likelihood they will continue to engage in the behaviors encouraged by the program. Participants in the BELT intervention will also be asked to evaluate specific program components.

Eating behaviors: Vegetable intake will be assessed using the all-day Screener developed for the NCI Eating at America's Table Study (EATS). This 10-item questionnaire asks participants the frequency and amount of vegetables they consumed over the past month. Frequency of fast food consumption will be assessed using the questions from the CARDIA study Participants will be asked to report how frequently they eat fast food in a week and whether the meals are for breakfast, lunch, dinner or snacks. Beverage consumption will be assessed using the Family Life, Activity, Sun, Health and Eating (FLASHE) beverage screener. This screener assesses the frequency of drinking seven common beverages.

Weight control behaviors: a 45-item questionnaire will assess how frequently participants engaged in specific weight control strategies [53] . These strategies include approaches to weight control encouraged by the program and strategies not included to assess the intervention effects.

Healthcare climate questionnaire: The Healthcare climate questionnaire is an established scale[54] .that asses the study team provided the level of autonomous support.

Substance use: Tobacco use will be asked via four yes or no questions taken from the Population Assessment of Tobacco and Health Study (PATH). This assesses current and lifetime smoking, use of electronic, smokeless, and other forms of tobacco. Alcohol consumption will be assessed using two questions including the number of days in the last month alcohol was consumed and the number of drinks consumed each time. Alcohol misuse will be assessed during screening only and will use the alcohol related items from the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) measure.

Weight history questions: The survey will ask participants to report their highest, lowest, and ideal weight; the weight they would like to lose during the program, frequency of self-weighing, their number of prior weight loss attempts, their reasons for losing weight, and approaches to weight loss they have used before (e.g., commercial program).

Demographic characteristics: Demographic characteristics as age, marital status, household members, income, education, occupational status, race, and ethnicity will be collected. Self-reported history of medical conditions will also be collected.

Optional Semi-structured interviews

Up to five participants in each treatment arm will be asked to complete a brief semi-structured interview about their experiences in the weight loss program they have received following the in-person assessment visits at 3 and 6 months. These interviews will focus on their motivation to join the program, their satisfaction and evaluation of the program components, and their suggestions for future changes to the program.

8.2 SAFETY ASSESSMENTS

Data on adverse events will be collected at each assessment point after baseline and documented as they arise. Unanticipated problems that are also deemed to be serious adverse events will be reported to the IRB immediately, and not later than 24 hours from the time the investigator becomes aware of the event. Any other unanticipated problem or adverse event will be reported to the IRB within 1 week.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

The DHHS Office of Human Research Protections (OHRP) defines the following types of events in research involving human subjects: Any untoward or unfavorable medical occurrence in a human

subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An adverse event that results in death; is life-threatening; results in inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; or may jeopardize the subject's health and may require medical or surgical intervention.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

The following guidelines will be used to describe the severity of an adverse event:
Mild: Events require minimal or no treatment and do not interfere with the participant's daily activities.
Moderate: Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
Severe: Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Definitely Related**: There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.

- **Probably Related**: There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.

- **Potentially Related:** There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant? clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.

- **Unlikely to be related**: A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study procedures) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant? clinical condition, other concomitant treatments).

- **Not Related**: The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.

8.3.3.3 EXPECTEDNESS

A clinician with appropriate expertise in will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and treatment sessions of a study participant.
All AEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.
Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.
Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.
Study staff will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of an adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of an adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome

- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP

- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the funding agency within 24 hours of the investigator becoming aware of the event

- Any other UP will be reported to the IRB and to the DCC/study sponsor/funding agency within 7 days of the investigator becoming aware of the problem

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

The primary aims of this study are to examine the acceptability of tailored behavioral weight loss program to a standard program in men working in blue-collar occupations and to compare recruitment approaches that vary on trust-based messaging to recruit men with overweight/obesity who work in blue-collar occupations. There are no formal hypotheses to be tested.

9.2 SAMPLE SIZE DETERMINATION

This is a feasibility study. No formal sample size estimations were conducted. Instead the sample size was selected to produce appropriate size treatment groups (n = 15) for two interventions across two cohorts (N = 60).

9.3 POPULATIONS FOR ANALYSES

We will use an intention-to-treat analysis population where we will include all participants randomized to the study. Similarly, the population for the recruitment substudy includes the 4000 addressees that sent the postcards minus those addresses who's postcards are returned.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

General presentation of data will be dependent on the distributions of the final data. The majority of outcomes reported will be descriptive in nature.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary outcome is acceptability of the interventions. These will be presented descriptively and will be reported as continuous data unless data is highly skewed in which case, the proportion of participants that reported that the treatment is acceptable will be reported. We will compare differences in the portion of participants randomized into the study by recruitment message type using chi-square analysis.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

The proportion of participant who complete the 6-month assessment visit will be compared across study arms descriptively. We will use binomial proportion tests to compare the number of website visits by recruitment message type.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

N/A

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

N/A

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

None

9.4.9 EXPLORATORY ANALYSES

We will explore effect sizes for differences in proportion of participants achieving a 5% weight loss between groups.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. A copy of the consent form and consent process documentation form are submitted with this protocol.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

During the online screening, participants will be asked to read a brief statement about the screening process before they submit their contact information and complete the online screening form. This brief consent will cover only the screening process and associated data. Participants who are eligible to participate in trial will be required to attend an online orientation meeting where the study will be described in detail (described above). Following this, participants will meet with a study staff member individually, in-person to review the consent document. Participants will have time to consider their participation in the study between the orientation session and the consent session. Participants will be given the opportunity to ask questions about the study and will receive answers before the consent is signed. A written signature from the participant will be obtained. Participants will be given a copy of the consent form for their records.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the IRB, and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable

- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, Food and Drug Administration (FDA), or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

Data management support for this project will be provided by the Data Management Center (DMC) within the Rush Department of Preventive Medicine. The DMC has extensive experience in the acquisition, maintenance, and analysis of both large and small clinical trial databases. Risks to privacy and confidentiality will be minimized by following a strict data management protocol. All data will be stored in a de-identified format. Only members of the research team will have access to identifiable private information. All interviewer-administered and self-report questionnaire data will be collected via Snap© survey (Portsmouth, NH) online data capture or REDCap (Research Electronic Data Capture; Nashville, TN) via laptop computers using mobile internet connections/WiFi or paper case report forms. Both Snap and REDCap are fully HIPPA compliant web data collection tools. Both websites and databases are hosted by the Rush Information Services Group.

All Rush issued laptops and tablets are encrypted using Advanced Encryption Standard (AES) algorithm by TrendMicro. No data stored in an encrypted volume can be read without using the correct password. The DMC Server is supported by Rush Information Services. Rush servers are maintained and secured as follows: Rush University has two data centers in Chicago, with one located at 1700 W. Van Buren St. and the other at 711 S. Paulina St. All servers are located in locked data centers with access limited via a biometrics access system to authorized personnel. The data network is segmented and protected from the internet by a Palo Alto firewall. Access to the network from the internet requires multi-factor authentication. All network users are required to have unique logins and passwords. Complex passwords are required, and passwords must be changed every 180 days. Systems are backed up nightly and the data is duplicated and sent to an offsite storage facility.

After the study investigators have had a reasonable period of time to prepare manuscripts, study data sets will be stripped of all PHI to allow sharing of data without compromising participant confidentiality, privacy, and safety. All identification covered under HIPAA will be removed. All remaining variables not covered under HIPAA will be evaluated in terms of risk for deductive disclosure of identity, and appropriate measures will be taken to protect confidentiality.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/sharing.htm). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see https://humansubjects.nih.gov/coc/index). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at the Rush Department of Preventive Medicine. After the study is completed, the de-identified, archived data will stored with Rush Information Services, for use by other researchers including those outside of the study.

No biological data will be collected in this study.

10.1.6 SAFETY OVERSIGHT

Subject safety will be closely monitored by the investigators in conjunction with a Data and Safety Officer (DSO). The DSO for this study will be Lisa Ravindra, MD, an internal medicine physician who is familiar with the procedures for monitoring and reporting events related to safety in the context of research.

During the study startup period, Dr. Ravindra will review and approve a detailed study protocol prior to its implementation. She will approve the content and format of safety, accrual, and retention reports that will be generated by the research team. These reports will be issued every 3 months during intervention delivery.

Dr. Ravindra's role will also include reviewing all Adverse Events, Serious Adverse Events, and Unanticipated Problems, and verifying that these have been correctly adjudicated. It is within the scope of the DSO's role to request additional information on any AE, and to view events in an unblinded fashion. The DSO will assist the PI in reporting all adverse events to the appropriate regulatory bodies in a timely fashion (see below). Any feedback or concerns raised by the DSO will be reported, in writing, to the investigators, the Rush University Medical Center IRB, and the NIH program officer.

10.1.7 CLINICAL MONITORING

See Section 10.1.8, Quality Assurance and Quality Control

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The site will perform internal quality management of study conduct, data collection, documentation and completion. All sites will follow a common quality management plan.
Quality control (QC) procedures will be implemented as follows:

Informed consent - Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data - Data will be initially captured on source documents (see Section 10.1.9, Data Handling and Record Keeping) and will ultimately be entered into the study database. To ensure accuracy site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Intervention Fidelity - Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in Section 6.2.1, Interventionist Training and Tracking.

Protocol Deviations - The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Study documents will be retained for a minimum of 2 years after the last approval of a marketing application in an International Council on Harmonisation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10.1.9.2 STUDY RECORDS RETENTION

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.
These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the investigator to use continuous vigilance to identify and report deviations. Within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing IRB per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:
National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 4 years after the completion of the primary endpoint by contacting Melissa Crane, PhD. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIDDK has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms

FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale
1	05/11/22	Initial protocl	

11 REFERENCES

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