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Design of a randomized trial testing a multi-level weight-control intervention to reduce obesity and related health conditions in low-income workers

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ABSTRACT

Weight-control is a major public health focus for preventing multiple obesity-related health conditions. While clinic-based intensive lifestyle interventions are successful, low-socioeconomic-status (SES) populations, which have a higher burden of obesity, are difficult to reach; thus, the workplace offers a useful setting to target low-SES workers. The current paper presents the design of a study testing a workplace intervention aimed at low-SES employees. Partnering with a large healthcare system and affiliated university, this project will test an innovative multi-level intervention (*"Working for You"*) adapted from existing group- and individual-level intervention models to promote healthy weight among low-wage workers. The individual-level component is an interactive obesity treatment approach (iOTA) program that involves assessment of behavior risks, collaborative goal-setting with a health coach, and interactive SMS text-messages for ongoing support and self-monitoring. This mHealth intervention is embedded in the group-level component, a workplace participatory program that involves worker teams engaged in the design and implementation of interventions to change their workplace environments. These nested interventions are being tested in a group-randomized trial among 22 work groups (~1000 total workers, ~300 workers with obesity). The primary outcome will be program effects on weight at 2-year follow-up, compared to control, and the secondary outcomes will be effects on diet and physical activity; iOTA adherence, process measures, and work environment/support will also be examined. This pragmatic clinical trial will test scalable interventions that can be translated to other work settings to reduce obesity and related health risks among low-SES workers.

Trial registration: ClinicalTrials.gov Identifier: NCT02934113

1. Introduction

Weight-control is a major public health goal for preventing obesity-related health conditions. While intensive lifestyle interventions are successful for weight-loss and reducing disease risk [1,2], there is a need for lower-intensity, readily-disseminable programs. Low-socioeconomic-status (SES) populations, which have a higher burden of obesity, are difficult to reach with effective health-system- or population-based weight-loss interventions. The workplace offers a potentially effective setting for health-promotion programs specifically aimed at low-SES populations, though few workplace studies have done so. Indeed, a recent careful review [3] found only 20 studies of clinical trials of interventions, with outcome data, that were specifically designed for low-wage employees; of these 20, very few were broad interventions to target weight-control, and few targeted workplace changes to support weight-loss. To date, weight reduction has been modest in most workplace interventions; many have demonstrated low reach/worker-engagement [4–8]. Few have combined individual weight-loss elements with interventions to change work environmental factors affecting obesogenic behaviors, though meta-analysis suggests such interventions achieve greater effects [8]. The current paper presents the design of a group-randomized trial, "*Working for You*" (WFY), testing a multi-level weight-loss intervention among low-SES workers to change both individual behaviors and work environments. Our group-level intervention is modified from the Healthy Workplace Participatory Program model [9], using components of Human-Centered Design [10]. It

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incorporates employee participation in decision-making to produce workplace interventions that are acceptable, effective, and sustainable [9]. Embedded within this group-level participatory intervention targeted at all workers is an individualized, text-message-based, interactive obesity treatment approach (iOTA) program directed toward workers with obesity.

Using media interfaces like the internet and interactive voice response, iOTA is well-suited for lifestyle interventions, as it facilitates self-monitoring of behavior-change. The first study testing iOTA for weight-control was Be Fit Be Well, a 24-month trial of patients enrolled in a voice- and web-based program through community health centers, which demonstrated that iOTA can help low-SES and racial/ethnic-minority populations achieve and sustain moderate weight-loss [11,12]. These remote forms of treatment-delivery show great promise for weight reduction in low-income groups [13], and can be readily scalable. While internet- and phone-based weight-loss interventions have been tested in workplace settings [14–16], rapid changes in information-technology are leading to new interventions using cellphones and other devices ("mHealth") [17,18]. SMS text-messaging has reached widespread usage [19] and offers increased efficiency, compared to voice response, of self-monitoring behaviors. However, there has been little workplace deployment/evaluation of text-message-based mHealth interventions; thus, in the current study, we have adapted iOTA to be delivered using this medium. An important reason this form of iOTA has potential for high reach of vulnerable groups is that these groups extensively use text-messaging in their daily lives [19]. Cellphone-based interventions in these populations can thus increase engagement/dose and decrease barriers [20,21].

This paper describes the design of our WFY study, which aims to implement and test our 24-month multi-level worksite weight-control intervention that includes iOTA nested within a workplace participatory health program. Our interdisciplinary team includes specialists in workplace-health interventions, public health, obesity, behavior-change, nutrition, and heath communications. We also have an advisory committee comprised of academic, employer, and worksite administration partners, which meets quarterly and includes those with leadership roles focused on employee wellness and occupational health. The study will assess the program's effects on diet, activity, and weight; iOTA engagement; process measures; and secondary outcomes (e.g., workplace environment/support), compared to a control condition, for up to 24 months.

2. Methods

2.1. Design

We will use a group randomized, controlled study design (Fig. 1) for the nested group- and individual-level interventions. During the randomized intervention period, work groups in the control arm will be offered standard care (i.e., wellness programs already offered by their employer). If the intervention condition is effective, work groups in the control arm may be offered the nested group- and individual-level interventions after the 24-month study period ends.

2.2. Study population and recruitment

Participants will be employees of a large, integrated healthcare system and affiliated university, recruited from work groups with a high proportion of low-wage workers and who have historically had low rates of participation in existing employer health-promotion programs. We will use human resources data to identify work groups, departments, or units that have approximately 40–100 employees with a high proportion of low-SES workers. Work groups will be recruited and enrolled over approximately a 1-year period. We will discuss the list of work groups with our advisory committee and discuss the details of study participation with the managers of the identified groups. Once management agrees to participate, we will begin recruiting employees within the work group. All employees in participating work groups will be invited to participate in a two-year study, during which time they will complete semi-annual questionnaires and weight checks, and after baseline testing, the work groups will be randomized into one of two study arms (intervention or control). Across the work groups, approximately 1000 employees (~45 in each work unit, and ~500 in each arm) will participate in the study, and of these, approximately 300 (~150 in each arm) are anticipated to have obesity. Participants will provide written consent and be compensated for each semi-annual assessment they complete.

2.3. Group randomization

One challenging aspect of worksite group intervention studies such as this one is that the unit of randomization is at the level of existing work groups or work units (e.g., registration department, housekeeping department, or a nursing unit). Group randomization will occur after we complete baseline assessments. The first 8–10 work groups will be recruited in pairs from the same employer and type of location (e.g., hospital, outpatient clinic) that will be ready to start at the same time, and will be assigned to intervention or control arms via a binary random number generator with probability = .5. Recruiting matched work groups that are ready to start simultaneously may become more difficult over time; thus, subsequent work groups will be assigned to study arms via a dynamic randomization scheme [22]. Specifically, in this scheme, employer, facility size, and obesity rates will be considered so that we achieve similar distributions in both arms of the study.

2.4. Intervention

2.4.1. Overview

Work groups randomized to the intervention arm will receive a 24-month, two-component, multi-level worksite weight-loss intervention to help workers attain and maintain a healthier weight and reduce risk for type 2 diabetes (T2D) and other obesity-related diseases. At the group-level, we will use a participatory approach directed at all workers in that work group, to adapt and implement changes in the work environment that support healthy eating and physical activity. Nested within this group-level intervention, workers with obesity (i.e., those with an initial BMI $\geq 30\ kg/m^2$) will be offered participation in an individual-level weight-loss intervention, which involves an assessment of behavior risks, collaborative goal-setting with a health coach, and use of an interactive text-messaging system to provide ongoing support, reminders, and self-monitoring of behavior-change goals.

2.4.2. Participatory workplace intervention [targeted at all workers]

This intervention is modeled after other successful participatory workplace programs, which have had various foci (e.g., injury prevention, stress reduction, ergonomics, mental health, and support for those with disability or chronic diseases) and been implemented with employees from various fields (e.g., construction, retail, assembly line, and healthcare) [23–29].

The participatory workplace intervention approach engages teams of workers in the design and implementation of interventions to change their work environments with support from management [9,30]. In each work unit randomized to the intervention condition, we will select worker volunteers to take part in the participatory work team (design team [DT]). With input from management and workers, we will select employees representing different job categories, who will consider and propose interventions designed to improve healthy eating and physical activity within their work environment. A research team member will serve as a peer facilitator and will train the DT in a seven-step participatory process including how to evaluate the workplace; identify problems; generate solutions; create, test, and modify prototypes; implement solutions; and evaluate their effectiveness. These steps are

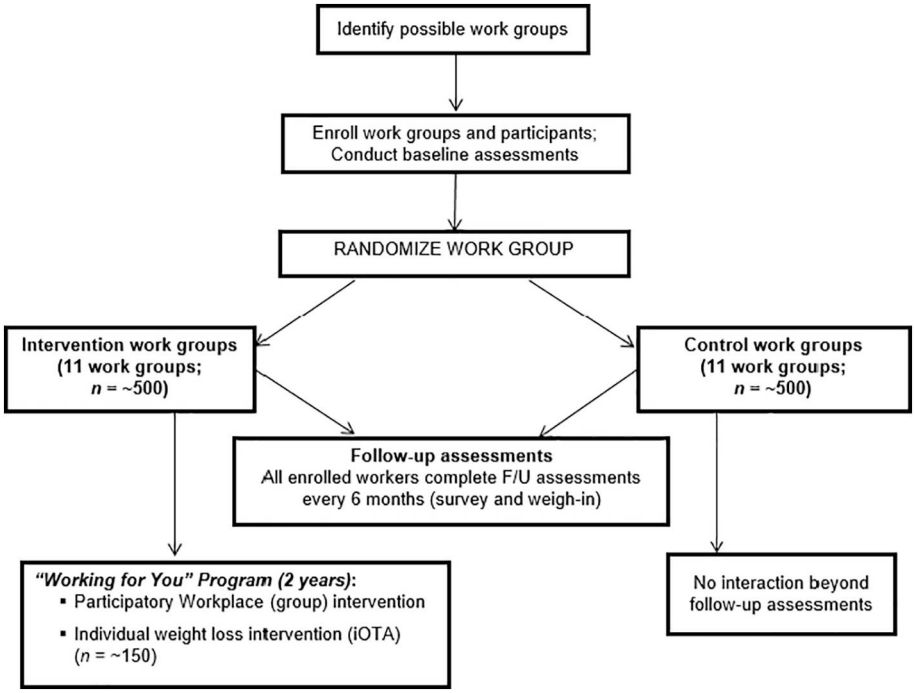

Fig. 1. Study design/flow.

Fig. 2. Participatory design process.

based on the Healthy Workplace Participatory Program's Intervention Design and Analysis Scorecard (IDEAS) [9,31] and guiding principles from Human-Centered Design) [32,33]. This process is illustrated by a Participatory Design Process wheel (Fig. 2).

2.4.2.1. Participatory intervention – Recruitment of DTs. We will recruit 4–6 workers from each group to serve on the DT. The baseline questionnaire will provide a brief explanation of the DT and a place for participants to indicate their interest in being a team member. We will compile a list of workers who expressed interest on the survey, and (for those randomized to the intervention) we will review the list with supervisors to get their input as to who might be suitable for the team. We will look for a DT made up of workers who are representative, as a group, of the demographics (e.g., race/ethnicity, age, seniority), and the full array of line-level jobs and task environments, of the work group. Other considerations are that the workers on the DT are willing to work together, open to learning new skills (e.g., team brainstorming), and able to function as opinion leaders among their peers (respected for their ideas, able to muster coworker support). Finally, we will work with the manager to consider the logistics involved and select workers who will be able to meet for regular, ongoing 1-h meetings, and who can attend meetings at the same time (e.g., not workers who do the same task at the same shift, who cannot all be gone simultaneously). Once we identify potential feasible DT members with the manager, our staff will call those workers and personally invite them to participate.

2.4.2.2. Participatory intervention – Structure and content. The peer facilitator, a research team member, will provide education and guidance as needed. Teams will start off meeting weekly to focus on changing the physical, organizational, and cultural work environment within their work unit to encourage healthier eating and physical activity; meetings will then decrease to every two to three weeks, and ultimately monthly once the program is up and running. The ultimate goal is to transition leadership entirely to the DT so that they can continue to function after the research study ends. Examples of potential interventions, among others, include better places to store or heat food brought from home, easier access to healthy food at the workplace, signage to promote healthy behaviors, encouragement to bring healthier foods for potlucks, weight-loss bulletins, changes in work schedule to provide longer break times that allow for healthy eating/activity, worker participation in walking routes, buddy programs, and other social cues to encourage healthier behaviors. Each DT will be guided by management and the peer facilitator, who will review suggested interventions for feasibility and anticipated impact on energy-balance behaviors, and will aid in their implementation. We will guide the DTs to select interventions supported by (a) what literature does exist in this area [34–37], (b) our own formative work [38], and (c) the state of the science on participatory and environmental changes that are most likely to improve energy-balance behaviors (diet and physical activity) which are, in turn, directly linked to body weight. We will have an advisory committee of internal and external academic advisors as well as

advisors from the employee wellness programs of the worksite (i.e., the healthcare system and affiliated university with which we are partnering). Together with this committee, the unit-level directors and managers will also provide connections at the corporate and individual facility levels as well as links to existing employer-provided programs at each facility, in order to ensure that the worker DTs have knowledge of and access to existing employee health-promotion programs and resources.

2.4.3. Individual-level weight-loss intervention (iOTA) [targeted at workers with obesity]

We will attempt to recruit all eligible workers with a BMI ≥ 30 kg/m^2 to participate in a multi-component iOTA intervention that includes weekly SMS text-messaging and quarterly counseling with a health coach. The goal will be to lose ≥5% of body weight through changing diet and physical activity both at and outside the workplace. The intervention and targeted behaviors are adapted from the Be Fit Be Well study [11,12] and the Shape Plan study [39].

2.4.3.1. iOTA structure and content. The iOTA intervention includes tailored behavioral goals, skills training, informational and motivational text messages, and behavior self-monitoring delivered by SMS text-messaging several times a week, as well as quarterly one-on-one counseling with a health coach. The behavioral goals, scripts for the text messages, and counseling approach are all informed by the literature [40,41], and our formative work [38], on weight-control interventions with low-income individuals and the challenges they face in changing diet and physical activity. At initiation, the health coach will meet one-on-one with each iOTA participant to obtain written informed consent for the iOTA portion of the study, review the individual's health risk assessment, and choose up to three behavior-change goals related to healthy eating and physical activity, prioritizing those behaviors: 1) in highest need of change, 2) for which the participant has high self-efficacy and readiness for change, 3) for which the participant identifies few change barriers, and 4) that fulfill the intended impact on energy-balance. Goals were selected to be a set of simple, concrete behavior-changes, based on empirical evidence of link to energy-balance/weight and relevance to the target population. Table 1 presents the options for goals that iOTA participants can choose from; details of the iOTA intervention are presented elsewhere [42,43].

Participants will perform self-monitoring via SMS text-messaging; they will participate in weekly, automated "check-ins" that prompt them to reply with data on their weight and their chosen behavior goals. Automated, individually tailored self-monitoring feedback messages will be immediately provided and will reinforce successes and/or offer motivational strategies and the automatic opportunity, if appropriate, to increase their goal levels (e.g., increase the number of days per week they will try to meet the dietary or physical activity target).

Participants will also meet with the health coach quarterly to review their progress and select new goals if necessary based on mastery and/or preference. Coaching meetings will be conducted on personal time, but in private meeting places within participants' workplaces for convenience. The iOTA participants will also receive a Fitbit (worn at the hip or on their wrist, as they prefer) to track their physical activity during the course of the study. They will be asked to sync their Fitbit data to our study database using Fitabase, a data management platform that captures and summarizes Fitbit data for research purposes (https://www.fitabase.com/).

2.4.3.2. iOTA eligibility and recruitment. We will identify potential iOTA participants from the enrolled participants in the intervention work groups using our inclusion criteria that are designed to target the vast majority of employees with obesity, as follows: that is, BMI ≥ 30 kg/m^2, owning a personal cell phone with text-messaging capability, and working in the unit within 12 months of his/her work group's randomization. The only exclusion criteria for otherwise eligible employees are if they are currently pregnant, recently undergoing chemotherapy or radiation treatment for cancer, have had a bariatric procedure in the past year, and/or are planning to leave the work unit within the next month.

Our study team will be carefully trained in appropriate language to use, as recruitment for iOTA participants has to be done with sensitivity in order to avoid stigmatizing employees with obesity. First, a research assistant will call eligible workers to provide an introduction to the iOTA program, verify the worker's eligibility for iOTA, and invite him/her to participate in the iOTA intervention. (In the rare case where workers are unable to be reached by phone, after multiple attempts, study staff will try recruitment in-person at the worker's jobsite.) Interested workers will be scheduled for an enrollment call with the health coach, where the coach will start forming rapport, answer questions, and complete a "barriers interview" with the worker, to inform and individualize coaching by identifying potential obstacles to participation in the iOTA program that they can problem-solve with the participant. The most common barrier that typically comes up is a lack of time caused by work hours (e.g., working a late shift or irregular

Table 1
Goal choices for iOTA participants.

Domain	Goal reminder/assessment messages, with options in brackets
Steps	Get [2500, 5000, 7500, 10,000] or more steps per day 5 or more days per week.
Sugary drinks	Limit sugary drinks to [0/under 2/under 6/under 9/under 13] twelve-ounce servings per week.
Healthy Breakfast	Eat a healthy breakfast (under 400 calories with 2 food groups, like a low-fat protein or dairy, a whole grain, or fruit) [3/5] or more days a week.
Purchased Food - Healthy meal choices	Choose lower-calorie option at least half the time each week when buying meals at restaurants, cafeterias, and fast food places.
Purchased Food – Limit at work	Limit food and drinks bought while at work to [0/under 2/under 4] times per week.
Free Food – Limit at work	Limit the amount of free food you eat at work to [0/under 2/under 4] times per week.
Purchased Food – Meals at home	Outside of work, fix meals at home [3/5/10/14] or more times per week.
Low-fat dairy	Replace full-fat dairy foods with low-fat choices [1/3/5] or more days per week.
Fruits and vegetables	Get [2/5] or more servings of fruits and vegetables five or more days a week.
Vegetables	*[if 3+ fruit but too few vegetables]:* Get [1/2/3] or more servings of vegetables five or more days a week.
Whole grains	Replace refined grain foods with whole-grain foods [1/3/5] or more days per week.
High-fat meats	Limit high-fat meats to [0/under 2/under 4] servings each week.
High-calorie snacks	Limit high-calorie snacks to [0/under 2/under 6/under 9/under 13] servings a week.
Screen time snacking	Limit screen time snacking to [0/under 2/under 4] days a week.
Brisk activity	Get 20 min or more of non-stop brisk exercise [1/3/5] or more days per week.
Self-monitoring of diet	Keep a food log on [3/5/7] or more days per week.
Added calories	Use strategies to limit added calories [3/5/7/10/14] or more times a week.
Total calories	Keep total calories in the range set with coach [5/7] days each week.
Portion control	Practice portion control behaviors talked about with coach [3/5] or more days a week.

Table 2
Measurements and time points for control arm, participatory group, and iOTA intervention.

Measure	Administration frequency/Time points			
	Control arm	Intervention arm		
		All workers in this arm	iOTA participants	Participatory team members
Worker Questionnaire	0,6,12,18,24 months	0,6,12,18,24 months	–	–
Demographics, Job characteristics				
Perception of workplace supports				
Awareness/participation in Employee wellness programs				
Health Status & Work Productivity				
Health behaviors/knowledge/attitudes				
Measured Weight	0,6,12,18,24 months	0,6,12,18,24 months	Quarterly	–
Perception of iOTA intervention	–	–	Quarterly	–
Perception of participatory intervention	–	–	–	Continuous
Process measures	–	–	Weekly	Continuous
Goal tracking & self-reported weight	–	–	Weekly	–
Measured physical activity (Fitbit data)	–	–	Continuous	–

Note: 0 = Baseline/enrollment; other time point numbers indicate number of months after that.

shifts), short breaks at work, having multiple jobs, and/or childcare. Other frequent challenges that coaches pick up in the introductory phone call are if the employee feels too tired to work on behavioral changes or is not comfortable with text messaging.

Finally, the coach will schedule the first in-person coaching session, which includes an orientation to the iOTA program and the selection of up to three behavior-change goals for the worker to focus on. To assist with this goal-setting, the worker will be asked to complete a food diary for a few days, and to bring that to the initial coaching session.

2.5. Assessments/data collection

2.5.1. Overview of assessment plan

All employees in both arms (~1000 total) will complete weight measurements and questionnaires (see Table 2 for a list of measures) at baseline, and at 6, 12, 18, and 24 months after randomization ("semi-annual assessments"). Questionnaire domains will include food intake, physical activity, and limitations to work ability due to health or physical limitations; knowledge, attitudes, and beliefs concerning diet and exercise; and degree of participation in weight-loss or other health-promotion programs. We will also ask intervention group workers about their perceptions of the group- and individual-level interventions. Weight measurements and questionnaires will be completed in person at a private worksite location.

2.5.2. Semi-annual assessments

We will collect height/weight measurements and questionnaire data from participants in both arms. These data will be used for primary and secondary outcome analyses, and to examine demographic, psychosocial, and workplace characteristics that may influence the trial.

2.5.2.1. Anthropometric measurements. Weight will be measured on an electronic scale at each in-person visit (2 measurements to 0.1 pounds, with measurements averaged). Height will be measured to the nearest 0.25 in. once at baseline using a calibrated, portable stadiometer.

2.5.2.2. Physical activity. Fitbit devices (worn on the wrist or hip) will be used to measure physical activity *(for iOTA participants only, for the duration of their participation)*. Participants will be asked to wear the devices at all times and to sync data at least once per week. Fitbit data will be shared with the research team via Fitabase, and will comprise a variety of data including steps, time spent in vigorous and moderate activity, and time sleeping.

2.5.2.3. Questionnaires. Table 3 presents the questionnaire-based portion of our assessments.

2.5.3. Process measures

For the group-level intervention, we will collect process metrics to assess the DT's productivity, effectiveness, and perceptions of the process. We will use a logic model [24,54–57] to guide the process evaluation, and data for process measures will be obtained from DT meeting records/minutes and key informant interviews with members of each DT and management.

2.5.4. Goal tracking and self-reported weight

iOTA participants will have weekly check-ins via SMS text-messaging. Each Tuesday, participants will be prompted to report their current weight, and to indicate whether or not they met their behavior goals for the week. They will be asked to respond to a total of 4–5 messages each week; responses will be numeric or Yes/No.

2.6. Quality assurance and quality control

The study's approach to quality assurance and quality control – i.e., promoting high-quality data, and detecting emerging problems/issues – includes preparing multiple manuals of operations, implementing a training model to educate staff, observing staff at least quarterly, routinely calibrating equipment, and regular monitoring of data counts and data-entry quality. Finally, for the iOTA participants, staff regularly monitor and review the text-message data imports to ensure they are accurate and complete.

2.7. Statistical power, sample size, and analysis plan

The primary outcome is change in weight over 24 months; we will also examine weight changes over shorter time frames (6 and 12 months). Secondary outcomes will include changes in self-reported dietary and physical activity behaviors, and we will also examine changes in health-related quality of life and limitations to work productivity. These outcomes will be assessed in all workers, comparing changes between the intervention and control arms, as well as in the subset of workers with obesity (BMI $\geq 30\ kg/m^2$) – comparing workers with obesity who are in the intervention versus control arms. Between-group differences in primary and secondary outcomes will be evaluated using intention-to-treat tests of group-by-time interactions in repeated-measures mixed-effects linear models (for continuous outcomes), log-binomial models (for categorical outcomes), or Poisson regression models (for count outcomes such as the number of workplace supports utilized). The fixed effects of each model will consist of the study arm, time point (baseline, 6, 12, 18, or 24 months), and arm-by-time interaction. The random effects will account for repeated measures with an unstructured covariance matrix and clustering of participants within

Table 3
Questionnaires.

Domain	Questionnaire
General Information/Demographics	Self-report assessment of participant characteristics including age, race/ethnicity, marital status, household details, income, and education level
Job and Worksite characteristics	Participants provide job title, workplace location, time spent working, and workplace health activities (questions taken from the Supports at Home and Work for Maintaining Energy Balance (SHOW-ME) survey [44])
Workplace Health Climate	Participants rate level of agreement about statements related to workplace impact on health and wellbeing (questions taken from the Multi-Faceted Organizational Health Climate Assessment – MOHCA [45])
Psychosocial supports	Participants evaluate perceived support from coworkers and supervisors. They are also asked about familiarity with available wellness support programs offered through employer and if participated in any of them (Karasek Job Content Questionnaire [46])
Physical activity	Self-report of amount and levels of physical activity a participant completes each week during recreation/leisure time (IPAQ) [47]
Dietary assessment	Participant rates how often certain types of food or drink are consumed (Rapid Eating and Activity Assessment for Participants Short Version [REAP-S]) [48]
Health Information	Participants report various health attributes including smoking status, alcohol consumption status, and health insurance status
Productivity	This is used to evaluate participant level of productivity and absenteeism (questions taken from the Work Productivity and Activity Impairment [WPAI [49]] and Work Ability Index [WAI] [50])
Health status and activities	This portion assesses participant health conditions and overall health status (SF-8 [51], PHQ-9 [52], and questions taken from the CAPTURE survey [53])
Willingness to change	Participants self-report willingness to change habits and participate in health improvement activities

work group. Least-square means and standard errors will be obtained from the models. We will verify that mixed-model–based results are not sensitive to violations of modeling assumptions with permutation and bootstrap resampling tests. Models will incorporate effects of relevant covariates on intervention effects including sex, education, income level, race/ethnicity, and intervention engagement. The linear mixed models will be intent-to-treat, as participants with missing time-points are included in the model. These models will give unbiased estimates as long as attrition is unrelated to the outcome. We will conduct sensitivity analyses to assess for possible attrition bias, and if attrition bias is likely, we will use multiple imputation strategies to replace missing values.

Our targeted sample size (22 work groups, enrolling 14 participants with obesity per work group at baseline) was selected to give us 80% power to detect an average mean difference of 1.5 kg weight loss between the intervention and control arms, and similar power to detect changes in health behaviors (diet and activity) in the group-level intervention, allowing for attrition. We based this on multiple recent community- and SMS text-based weight-control interventions [13,54,58–60]. The sample size determinations are based on the requirements for a test of treatment-by-time interaction for designs based on subject-level or cluster-level randomization. The approach is general with respect to sampling proportions and number of groups, and it allows for differential attrition rates over time. With 22 work groups, enrolling 14 participants with obesity per group at baseline, we have 80% power to detect an average mean difference of 1.5 kg weight loss between the intervention and control groups, calculated with the RMASS program [61] using the above assumptions. We are similarly well-powered to detect changes in health behaviors (diet and activity) across a wide range of pre-intervention values, and changes in weight on the order of those found in recent trials based in primary care clinics. One community-based study achieved a 7% weight-loss goal in over 36% of intervention group participants vs. in only 14% of the usual-care group [59]; in another primary care-based trial with > 40% African American participants, 38% of members in a group receiving remote weight-loss support lost 5% or more of their initial weight, compared to 19% in the control group [13]. Another community study in two YMCAs based on the Diabetes Prevention Program (DPP) lifestyle intervention recommendations showed average weight loss of 6% (5.7 kg) over 6 months in the intervention group [54]; a lower-intensity extension study found weight loss of 3.6% (3.3 kg) among the original controls [58]. Finally, an SMS text-based intervention in predominantly African American women found a difference between intervention and control groups of 2.4 kg [60]. These results have all been achieved in community-based trials using approaches of varying intensity to delivering the DPP lifestyle recommendations.

2.8. Data and safety monitoring plan

The intervention and measurement protocols in this study pose minimal risk to participants. To ensure participant safety, we nominated a safety officer – a physician who has no involvement in the trial. Given the low risk status, our data and safety monitoring plan (DSMP) for this trial focuses on close, ongoing monitoring by the investigators in conjunction with the safety officer. In addition, excessive or unexpected adverse events, and any study-related serious adverse events (SAEs), will be dealt with promptly and vigorously, and reported to the funding agency and to the institutional review board (IRB) per their respective guidelines.

3. Discussion

In sum, the present study is testing an innovative, multilevel intervention to address obesity and related health conditions among low-wage workers. The current epidemic of obesity in the United States is projected to greatly increase the prevalence of its multiple health consequences, and obesity is most prevalent among socioeconomically disadvantaged populations, including racial and ethnic minorities [62,63]. National data show that obesity is strongly associated with working-class jobs, low education, and low income [64–67].

Employers, as well as health-oriented government entities like the Centers for Disease Control and the National Institutes of Health, have called for wider use of health interventions delivered at the worksite [4,6,68–72], and in particular as a way to reach socially disadvantaged groups. Worksites offer large groups of people who can be readily targeted and impacted, provide social support for each other (which has been shown to enhance weight-control interventions [73,74]), and capitalize on existing infrastructure for communication and delivery. However, little data exist examining the effects of such worksite-based interventions.

Some workplace programs have shown positive effects on physical activity, fitness levels, weight, and/or diet [4,75–82], but many studies are small, with non-randomized study designs, low rates of engagement and follow-up, and without intention-to-treat analyses [5,83,84]. In addition, despite evidence for the strong effect of the work environment in shaping health behaviors of work groups [5,68,75,85–87], most worksite-based weight-control interventions have only focused on modifying the health behaviors of individual workers [88]. Furthermore, most of these programs have relied on a top-down approach, rather than a participatory approach based on employee involvement in the design of interventions [88,89]. Finally, there has been minimal evaluation of the effectiveness of worksite-based health promotion among the low-SES populations at greatest risk for behavior-driven

health conditions [75,90].

Although the present intervention tries to overcome some of these problems, it does have some challenges of its own. The current study is testing a worksite program in the setting of a large healthcare system and affiliated university, which may be especially focused on wellness and disease prevention, and thus particularly receptive to health interventions for its employees. Worker health interventions have been tested in diverse settings such as housekeeping [91] and construction [92]; nevertheless, it is unclear how likely work settings outside the healthcare industry, including ones that employ a large number of low-wage employees, would be to engage in a similar intervention. Another limitation is that for the employees with obesity, in analyzing the impact of the embedded interventions, there is no way to distinguish the effects of the group-level and iOTA interventions.

Blue-collar, service, and hourly-wage workers are less likely to have access to worksite wellness programs than are white-collar workers, and lower-SES workers are less likely to participate in available worksite health promotion programs [85,87,88,90,93–100]. Thus, the populations most at risk for obesity and other behavior-driven health disparities are least likely to participate in and benefit from current workplace-based interventions [88]. The present study will specifically test the effectiveness of practical worksite health interventions in low-SES workers, in an innovative nested design with components at both the group and individual levels. If effective, our interventions are designed to take advantage of technology available to most low-income workers, and to allow for automated messaging that provides self-monitoring, encouragement, and goal adjustment, and thus be readily scalable to larger populations in various types of work settings.

Competing interests statement

The authors declare no competing interests.

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