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# A multi-level intervention in worksites to increase fruit and vegetable access and intake: Rationale, design and methods of the 'Good to Go' cluster randomized trial

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#### **Abstract**

**Background**—Fruit and vegetable (F&V) consumption is an important contributor to chronic disease prevention. However, most Americans do not eat adequate amounts. The worksite is an advantageous setting to reach large, diverse segments of the population with interventions to increase F&V intake, but research gaps exist. No studies have evaluated the implementation of mobile F&V markets at worksites nor compared the effectiveness of such markets with or without nutrition education.

#### **Authors' contributions**

PR was the evaluation coordinator of the project, led the writing about statistics and measures and edited the entire paper; KMG conceived of the study, was the PI of the study, took the lead in its design and coordination, led the writing of the manuscript; LD was the Data Manager for the Project, assisted with writing the methods section, created the study flow chart, and edited the entire paper; WN was a Brown graduate student who conducted a literature review to inform the background and discussion sections of the paper, contributed to the background section, worked on the references and edited the entire paper; RA is a UConn graduate student who also contributed to the literature review. RM was a Research Assistant for the project who conducted study activities and also helped to write the recruitment and intervention sections of the paper. JM was the statistical programmer for the project. She wrote the statistical analysis section and contributed to the measures section. DN was the video producer and later research assistant for the study. He assisted with writing the intervention section, contributed to the literature review and read and edited the entire paper. KG is a UConn graduate student who summarized the findings of the focus groups and contributed to the formative research section. GG also conceived of the study, served as Program Director (starting in November 2012), led the writing on the intervention sections of the paper and edited the entire paper; All authors read and approved the final manuscript.

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**Methods**—This paper describes the protocol for Good to Go (GTG), a cluster randomized trial to evaluate F&V intake change in employees from worksites randomized into three experimental arms: discount, fresh F&V markets (Access Only arm); markets plus educational components including campaigns, cooking demonstrations, videos, newsletters, and a web site (Access Plus arm); and an attention placebo comparison intervention on physical activity and stress reduction (Comparison). Secondary aims include: 1) Process evaluation to determine costs, reach, fidelity, and dose as well as the relationship of these variables with changes in F&V intake; 2) Applying a mediating variable framework to examine relationships of psychosocial factors/determinants with changes in F&V consumption; and 3) Cost effectiveness analysis of the different intervention arms.

**Discussion**—The GTG study will fill important research gaps in the field by implementing a rigorous cluster randomized trial to evaluate the efficacy of an innovative environmental intervention providing access and availability to F&V at the worksite and whether this access intervention is further enhanced by accompanying educational interventions. GTG will provide an important contribution to public health research and practice.

Trial registration number NCT02729675, ClinicalTrials.gov

#### Keywords

Worksite; Diet; Food access; Fruit and vegetable; Farmer's market; Mobile market; Nutrition education

# 1. Background

Fruit and vegetable (F&V) consumption plays an important role in the prevention of chronic diseases such as cancer, type 2 diabetes, and cardiovascular disease [1–8]. Americans aged 19–60 should consume 2.5–3 cups of vegetables and 2 cups of fruits daily according to the U.S. Dietary Guidelines [9]. However, more than two-thirds of Americans do not consume this amount, and intake differs widely by demographics [10–12]. Thus, cost-effective approaches to help large and diverse segments of the population eat more F&V are needed.

The Socioecological Model (SEM) suggests that health behaviors (including eating habits) are "a dynamic interaction between the individual and the environment." [13] Thus, establishing meaningful change in health behaviors involves multiple levels of influence including personal characteristics, interpersonal relationships, organizational factors, and physical environments [14–18].

One advantageous setting for multi-level interventions is the workplace [13,19]. The American workforce includes over 158 million people working an average of 34.6 h per week [20,21]. The average worker spends 8.9 h or 37% of each weekday at the workplace [20,21]. Additionally, workplace environments provide access to a variety of demographic groups, including those at high risk for low F&V intake [20]. The workplace also provides modifiable physical environments and pre-existing organizational structures that allow for the implementation and dissemination of behavioral modification strategies [22–24].

A variety of workplace interventions to increase F&V intake have been studied with varying levels of success [22–60]. These include behavioral/nutrition education interventions [22,24–39,41,42,59], increasing access to F&V [37,45,47,49,60–62], and multilevel interventions that combine environmental strategies with behavioral nutrition programs [30,37,46,50–55,60,62]. Systematic reviews of F&V interventions at worksites have concluded that workplace health promotion efforts need to include both educational and environmental changes to have a significant impact on dietary behavior [23,48,56].

Most environmental worksite interventions to increase F&V intake have focused on changing cafeteria or vending offerings and/or making fresh fruit available at no cost to employees [45,47–49,60,61]. No studies have evaluated the implementation of regular, mobile, fresh F&V markets at worksites. Two studies have piloted the sale of F&V at worksites, one through a farm stand and another through online ordering of produce baskets [47,58], though neither included rigorous evaluation methodologies. In addition, the current literature is missing studies that compare the effectiveness of mobile markets with or without nutrition education.

The objective of this paper is to describe the "Good to Go" (GTG) cluster randomized trial, which is evaluating an innovative multi-level workplace intervention that includes a discount, mobile, fresh F&V market alone or in combination with behavioral nutrition education strategies at worksites to determine which interventions are most effective at increasing employee F&V consumption.

# 2. Study design

#### 2.1. Aims, study design and hypotheses

The primary aim of the GTG study is to implement a cluster randomized trial in 21 worksites to assess the efficacy of interventions to increase F&V intake. The study will compare the efficacy of delivering: discount, fresh F&V markets (Access Only arm); versus delivering discount, fresh F&V markets along with educational interventions (Access Plus); versus a comparison intervention to serve as an attention placebo (Comparison arm). GTG will compare the efficacy of the Access Only intervention with the Access Plus intervention and compare both of these interventions with the comparison Arm.

Secondary aims include: 1) Implementing extensive process evaluation to determine costs, reach, fidelity, and dose response as well as the relationship of these variables with changes in F&V intake; 2) Applying a mediating variable framework to examine relationships among important psychosocial factors/determinants with changes in F&V consumption; and 3) Analyzing the cost effectiveness of the different intervention arms. The study's hypotheses are that employees in both the Access Only and Access Plus arms will increase F&V intake significantly more than employees in the Access Plus Arm will increase F&V intake significantly more than employees in the Access Only arm.

**2.1.1. Study design considerations**—This three group study design will provide assessment of both the F&V access intervention and the educational intervention without

the expense of a larger, more resource-intensive two-by-two factorial design (access alone, access plus education, education alone, neither). We will not include an arm that receives an education intervention alone (without market access) for several reasons. Worksite-based nutrition education/promotion interventions to increase F&V intake have been previously studied [22,24–39,41,42,59], but no research has been dedicated to the efficacy of a F&V market intervention alone or in combination with educational strategies. Moreover, worksites have been most interested in the mobile market access intervention; the mobile market intervention is more innovative and more replicable due to its potential self-sustainability, and research is needed on whether mobile F&V markets alone can increase F&V intake or whether nutrition education needs to accompany the markets.

An attention placebo control (physical activity and stress reduction intervention) was chosen rather than a no-contact control group to match the attention received between groups, but also because it was not ethical or fair to require evaluation but provide no intervention to half the worksites in the study. This study is approved by the Brown University Institutional Review Board. Latest approval date is 01/11/2016. All study participants will consent to participate prior to involvement in the study.

#### 2.2. Recruitment of worksites

Eligible worksites within 60 miles of Providence will be recruited into the study through a variety of methods including personalized mailings of recruitment letters and brochures to worksite human resource directors followed by telephone contact as well as networking events, news and media coverage stories and press releases. Meetings will then be convened with interested human resource directors and/or other key administrators to discuss the study in more detail, and to provide a Memorandum of Agreement delineating the responsibilities of research staff and the participating worksite. We originally planned to recruit 24 worksites (8 per condition), but dropped our sample size slightly (7 sites in each condition = 21 sites) because of large budget cuts from the funder at the beginning of the funding period. See sample size calculations in Section 5.3.

#### 2.3. Eligibility criteria for worksites

To be eligible for the study, a worksite will need to have at least 135 employees working at a single site (or combined with a second site nearby); at least 75% of the employees speak English (as the intervention materials are in English only); expect to be in operation for the next 12 months; agree to be randomized to any of the three experimental conditions and to complete all of the study's intervention components; and not have a recent or current worksite nutrition education program. All interested worksites that meet the eligibility criteria will be grouped with two other worksites, that are matched on size, employee demographics and type of worksite, i.e., hospital, manufacturing, financial, high-tech, etc.

#### 2.4. Recruitment of evaluation cohort

A random sample of employees from each worksite will be recruited to participate in the evaluation cohort; however, the interventions are made available to all worksite employees. This conservative design will likely "underestimate" the effect of the interventions as all individuals in the evaluation cohort may not participate in all the interventions. However,

this approach of evaluating across the entire worksite, not just with employees who choose to participate in the various intervention components, is the most scientifically rigorous design to assure external validity and for collection of valid cost data. Also evaluation of only those who participate in the interventions would be complicated, as participation will likely differ by intervention component. Moreover, employees who participate in all intervention components would likely have characteristics that may not be generalized to others, potentially introducing a selection bias. To estimate the effect of participation we will assess intervention dose of each component and of all components together on change in F&V consumption. We also will conduct a cohort outcome evaluation rather than a cross-sectional evaluation to capture changes at the individual level among employees "exposed" for the entire intervention period. Also, cohort data has lower sampling variability than estimates of change from repeated cross-sectional surveys [63,64].

To recruit the evaluation cohort, all employees will be contacted to provide the opportunity to 'opt out'. Each participating worksite will provide the team with a list of all permanent employees to generate personalized opt-out letters for each employee. Letters notifying employees of the study and giving instruction of how to opt-out of the evaluation will be then distributed to employees through normal worksite communication channels. After the letters are distributed, employees will have 10 days to have their name removed from consideration for the evaluation cohort by calling the 1–800 number, by emailing the research team, or by returning the opt-out letter to a locked, drop box at the worksite. During the ten-day opt-out period, project staff will conduct an informational, Kick-Off Event at the worksite where they will distribute popcorn and answer employee questions about the study.

After the "opt-out" period, the study data manager randomly will assign the remaining list of employees into batches using a computer generated algorithm. A batch list of potential evaluation cohort employees will be then sent to the designated worksite representative to request contact information for each listed employee. Employees will then be contacted by the research team to complete a short survey of eligibility criteria.

Employees found to be eligible and interested in participation will then proceed to the research consenting process and baseline survey. If the targeted number of participating employees (94 from each site) is not enrolled into the evaluation cohort through the first batch list, contact information for a second or third batch list will be obtained from the worksite representative by the aforementioned process. Employees in each batch will be contacted until a final disposition is reached (e.g. enrolled, ineligible, declined, bad contact information or the maximum number of call attempts were made). This method will avoid a sampling bias associated with assessing only the easiest employees to reach, but could result in slightly different cohort sizes for each work site. The baseline sample will be treated as a cohort and is contacted to be re-measured at six and twelve-months post baseline.

#### 2.5. Eligibility of evaluation cohort participants

To be eligible for the evaluation cohort, employees will need to be: at least 18 years old; working at least 25 h a week; working onsite at least half of every day shift during the week (to increase the likelihood of intervention exposure); without a medical condition that would prevent them from consuming F&V and able to read and understand English.

#### 2.6. Randomization

After the baseline survey has been completed in all three paired worksites, the sites will then be randomized to one of the three experimental intervention conditions (Access Only, Access Plus and Comparison) by the data manager using a random-number generating function in Excel.

See Fig. 1 for the Good to Go study flow diagram.

#### 3. Interventions

#### 3.1. Formative research and intervention development

Formative qualitative research was conducted prior to intervention development to inform the creation of all intervention components. Nine focus groups were conducted at worksites similar to those that will be involved in the evaluation study. Worksites participating in the formative research represented a broad spectrum of worksite types. Focus group participant recruitment methods included flyers, posters, and email distributed by worksite liaisons, as well as face-to-face contact by project staff. Focus groups were held in conference rooms at the worksites. Informed consent was obtained from all participants prior to participation. At the beginning of the focus groups, participants completed a brief questionnaire about their demographic characteristics and F&V-related habits.

A total of 81 employees participated in nine focus groups, of which five were conducted with white collar employees and four were conducted with blue collar employees. Focus group participants averaged 44 years of age. Most were college graduates (53%) or had some college or post high school training (27%) or were high school graduates (12%). Most participants were married (59%) or single (30%). The majority of participants (79%) were born in the US; those born elsewhere averaged 22 years in the US. Most participants described themselves ethnically as non-Hispanic (89%); racially as white (79%), though several participants described themselves as Black (3.7%), Asian (2.6) or of mixed race (2.5%). Participants were employed mostly (96%) full time, worked mostly daytime shifts (98%) and had been at the company for an average of 10 years. They averaged 40 h of work per week being paid mostly hourly (52%) or on salary (38%), though some also participated in piece work (10%).

The focus groups, lasting about 1 1/2 h, were led by a trained moderator and comoderator using standard focus group procedures, and were recorded. Each participant received a \$25 cash incentive at the completion of the focus group. Transcriptions of the recordings (without participant names) were summarized by the group moderators and team investigators. Findings from these focus groups were used by the research team to design the project logo/name, adapt and refine intervention materials and programs, develop promotional materials, determine potential incentives, and finalize evaluation measures. Focus group findings are summarized in Table 1. The findings from the focus groups informed the content development for all the educational intervention components as well as the plans for the F&V markets.

#### 3.2. Intervention theoretical framework

All intervention components are guided by the SEM framework, which recognizes that behavior is affected by multiple levels of influence, so that interventions should be most efficacious when they target changes in intrapersonal, interpersonal (social), and environmental domains [65–69]. We expect that the Access intervention will improve the nutrition environment of the workplace by increasing F&V availability and access. We expect that the educational/promotional intervention in the Access Plus arm will improve the social environment (social support, norms, reinforcement) at the workplace and will increase personal determinants such as skills, self-efficacy, knowledge, outcome expectations, and readiness to change, improve perceived norms, perceived social support, and F&V taste perceptions, and decrease perceived barriers of employees. We expect that the Access Only intervention may also change some of these determinants. Moreover, the markets will improve the F&V taste perceptions of the employees because the F&V will be so fresh. In addition, lower F&V costs at the markets may encourage employees to purchase and try new F&V. See the intervention logic model in Fig. 2.

The theoretical framework for the educational intervention focuses mainly on the social cognitive theory (SCT) [70–74], which defines behavior as a triadic, dynamic, and reciprocal interaction of personal factors, behavior, and the environment [70–74]. Behavior change is facilitated if the individual believes change is possible, has an opportunity to develop and practice new skills, and receives support from the environment [73]. Thus, the Access Plus intervention will specifically target changes in individual behavior as well as the availability of and access to F&V.

Vicarious learning will be employed as employees may try out new behaviors during food demonstrations. Coping models for potential challenges are also highlighted in the DVDs and newsletters. The educational intervention components also address outcome expectations (i.e. eating more F&V will lead to positive outcomes like weight control and better health). The campaigns and self-help materials use goal setting and feedback, and other SCT-based self-regulation techniques such as self-monitoring and problem-solving around barriers. Additionally, barriers are addressed including those that constitute personal impediments (e.g. pressure from work, being tired, depressed, desire for more "tasty" things to eat) in the educational materials. Environmental challenges (e.g. cost, lack of access and availability of high quality F&V, lack of social support and social norms) are addressed directly with the F&V delivery intervention. External motivation is enhanced through the use of incentives for participation and reaching goals in campaigns, and internal motivation is encouraged through recommendations for self-reinforcement in the educational materials.

Self-efficacy, or belief that a person can exert control over their behavior and over their social environment [75] can be increased using role modeling, which is portrayed via success stories in newsletters and on the website, as well as employees seeing others purchasing F&V. Social and moral standards are addressed using direct instruction, feedback from others, and role modeling by others as discussed above [76–78] and the F&V market intervention.

#### 3.3. Intervention components by experimental group

All worksites receive the intervention over the course of twelve months. All intervention components for the given experimental group are available to all employees of the worksite (including evaluation cohort participants) to use or participate in as much or as little as they decide. All materials are provided in English and will be developed by Brown staff and investigators. The details of the components for each intervention group are detailed below.

**3.3.1. 'Fresh to You' (FTY) discount, fresh F&V markets**—The Access Only (n= 7) and the Access Plus (n = 7) intervention worksites receive weekly, discount, fresh F&V markets for one year. These FTY markets are not local farmer's markets, but rather mobile markets selling both local and non-local produce on a year-round basis at prices at or below local supermarket prices [79]. The best times and locations for the weekly markets are identified through a negotiation process with worksite contact personnel and market staff. The produce distributor brings between 50 and 70 different produce items, including staples (e.g., potatoes, onions, carrots, celery, tomatoes and bananas); seasonal items (e.g. clementines in the winter and peaches and blueberries in the summer); and exotic produce (e.g. Asian pears and purple eggplant) to introduce new F&V to employees.

The FTY Markets are held either indoors or outdoors depending on the weather and the preference of the worksite administrators. When held indoors, F&V are arranged in boxes on the tables in a central location, usually a cafeteria or other highly trafficked area. In good weather, the markets are held outside in a designated area on the worksite property. Our produce distributor retrofitted a car trailer to serve as an outdoor, 'mobile fresh F&V market'. This retrofitted trailer is pulled by a van and brought weekly to each of the intervention group worksites at pre-determined days and times. The produce items are set up on racks affixed to three sides of the trailer and shoppers enter through the side and rear doors and exit through the rear door. See Supplementary Figs. 1–3 for market photos. A scale, cash register (accepting cash, debit/credit cards and Supplemental Nutrition Assistance Program Electronic Benefit Transfer (SNAP-EBT) cards) and point of sale (POS) data collection system are set up on a table separate from the produce (for indoor markets) or outside of the rear door of the trailer (for outdoor markets). Each market lasts two hours and the produce is sold on average between 15 and 20% below retail supermarket prices.

Research staff, with the help of a graphic designer, created a logo for the FTY markets, which is included in all promotional materials. Signs, posters, email blasts and flyers are used to advertise the markets. The FTY Market intervention begins at each site with a highly-publicized 'Kick-Off' event at the first FTY market for each site. Each employee who attends the first market receives a large, reusable shopping bag with the 'FTY' logo on it. The bag also contains a freezer pack that can be used to keep the F&V fresh during the work day until the employee goes home.

**3.3.2. Educational Interventions**—Participants from worksites enrolled in the Access Plus group receive access to the markets, as described above, as well as set of educational/behavioral interventions. At the Kickoff event, these employees receive the first month's newsletter and an educational DVD (see below) in addition to the reusable shopping bag and

freezer pack. At these sites, a chef-run cooking demonstration/taste-testing (see below) is also presented at the Kick-Off event, along with recipes and information about the upcoming intervention activities. A description of each of the Access Plus educational interventions follows.

3.3.2.1. Access plus intervention campaigns: Two educational/motivational campaigns are conducted. The first campaign, 'Just Add 2', is held within the first six months at each worksite and the second campaign, entitled 'Choose Color, Choose Health', takes place after the six-month surveys are completed at each site. Both campaigns include full-color booklets with goal-setting activities, educational and motivational content, and F&V trackers as inserts that ask participants to record the servings of F&V they eat each week. Participants are instructed to read a section of the booklet each week and complete the activities in that section. At the end of the week, participants are asked to deposit their F&V intake trackers into a raffle box kept at each worksite. A midpoint event and a final event are also held as part of the campaigns with chef-led cooking demonstrations and taste-testing events (see below). At these events, a staff member pulls several participant trackers out of the raffle box and distributes prizes (blenders, microwaves, woks, crock pots, etc.) to the winners. Approximately \$500 in incentive prizes are given away at each site over the course of the intervention. The campaigns are designed to be 'self-directed'; however, staff members attend the markets to answer any questions.

'Just Add 2', the first, six-week kick-off campaign, is designed to increase participants' F&V consumption by two servings by the end of the campaign. Participants receive a full-color, campaign booklet, which includes: a description of the campaign; instructions; a table of recommended daily F&V intake (in cups) by age, gender and activity level; a goal-setting form; the weekly F&V tracker as well as motivational and informational, tips and interactive weekly activities. The weekly chapters and activities are: 1: Getting Started; 2: Cooking with Fruits & Vegetables; 3: Fruits & Vegetables when you're on the go; 4: Stocking your shopping cart with fruits & vegetables; 5: Variety is the spice of life: Add some this week and 6: Staying on Track.

'Choose Color, Choose Health', the second, six-week campaign, is focused on increasing the variety of F&V that participants eat by the end of the campaign. Campaign participants receive a colorful campaign booklet that includes a F&V tracker, a laminated information sheet that includes the health benefits of each F&V color group, as well as educational and motivational content for each of the six weeks. Each weekfocuses on a specific F&V color. The weekly chapters are: 1. Record your baseline colors; 2. Green F&V; 3. Red F&V; 4. White and Brown F&V; 5. Yellow and Orange F&V; and 6. Blue and Purple F&V. Each weekly section includes a daily chart where participants record how many F&V of that color they eat each day of the week. Each section also includes tips for how to eat more of that color F&V during the week and the associated health benefits of those F&V. Then, at the end of the week, participants are instructed to add up the numbers in this chart and write the total number on the weekly F&V tracker, which they can deposit into the raffle box for prize drawings as above.

3.3.2.2. Videos: A DVD containing 14 video segments (90-minutes of content in total) was created to provide practical suggestions and visual examples to support and encourage employees in the Access Plus intervention group to increase their F&V intake. The DVD includes a menu so participants can easily navigate to specific segments. The DVDs include information about the FTY markets; cooking demonstrations showing how to prepare healthy meals for less than \$6.00; guidance and a cooking demonstration regarding how to plan quick, healthy, inexpensive meals; information on how to save money while eating healthy; and how to prepare and eat unusual F&V such as starfruit, jicama and yucca. This DVD is distributed at the first kick-off market in the reusable shopping bag and is also be sent to employees in the evaluation cohort in their six month follow up letter.

- 3.3.2.3. Newsletters: A two-page, full-color monthly newsletter is distributed at the beginning of the month at each market, emailed to study cohort participants who have an email address, and is also posted on a bulletin board for employees to read. Each newsletter highlights a particular F&V in season that month, as well as key nutrients and health benefits associated with the featured F&V and information on how to choose and store them. The newsletters also feature a section on different topics related to healthy eating. Topics include: eating on the run, increasing F&V at breakfast, lunch and dinner, keeping F&V fresh, organic vs conventional vs local produce, food safety and how to stretch your F&V budget. The back side of each newsletter includes a complete recipe that features a F&V with a colorful photo and nutritional information.
- **3.3.2.4.** Cooking demonstration/taste testing: Food demonstrations/tastings are delivered once a month by chefs throughout the one-year period delivered in worksite cafeterias and break rooms. Each demo session includes an easy to prepare, F&V-based recipe, has opportunities for audience participation, culinary and nutrition information, free samples, and take-home recipes.
- <u>3.3.2.5. Recipes:</u> A total of 12 recipe handouts were created, each of which correlates with the monthly cooking demonstration at the worksite. These recipes were chosen because they are easy-to-follow, healthy, relatively quick to prepare, inexpensive and include seasonal produce.
- 3.3.2.6. Website: The Good to Go website is a way for employees to find helpful information on topics related to F&V and to help keep employees informed about Good to Go events taking place at their worksite. Within the main Good to Go website, there are links to individual websites for each company. When employees access the main website, they use a drop down to click on their worksite name. Then they log in using the given password for their company to enter the website and access the various components.

The Good to Go web site includes resources for recipes, cooking and food prep video clips, general F&V information and a calendar of events at the worksites. The website also includes a tailored program titled "Are you eating right?" that provides employees with individually tailored information to help them eat more F&V. The content was modified from a previous tailored F&V intervention entitled Good For You [80]. Employees answer a brief survey about their F&V consumption including questions about stage of change,

attitudes, barriers and F&V habits at meals and snacks. At the end of the questionnaire, employees are provided with tailored feedback in downloadable pdfs based on their responses to the questions including recipes and information on cooking and preparing F&V and how to incorporate them into their life.

**3.3.2.7. Bulletin boards:** Each worksite has a study bulletin board located in a central location. Content consistent with the intervention including posted newsletters, recipes and campaign flyers is changed monthly.

3.3.2.8. Comparison/attention placebo control intervention: Brown University contracted with the Greater Providence YMCA to provide physical activity and stress reduction interventions at the 7 worksites in the comparison group. Two, six-week campaigns were developed jointly by the Brown study team and YMCA staff. These campaigns follow the same format as the Access Plus intervention group campaigns and are provided during the same time periods as those at the Access Plus intervention sites. Everyone who participates in the campaigns also receives a free, six-week membership to the YMCA.

3.3.2.8.1. 'Take 10!' campaign: The 'Take 10!' campaign is delivered during the first six months and aims to increase participants' daily physical activity by 10 min per day until they reach the goal of at least 30–60 min per day. Participants are given a campaign booklet with six weekly sections focused on a particular goal and includes: educational and motivational content, a goal setting and action step form, tips and suggestions for how to achieve that goal and the benefits associated with reaching the goal. The focus areas for each week are:

1. Move More, Sit Less; 2. Strength Training; 3. Increase Flexibility; 4. Walk More; 5. Add Intensity; and 6. Make Simple Changes.

Each week, participants are encouraged to read through that week's section of the booklet, review their weekly goals and do the activities included in that week's 'Action Plan' along with the bonus point activity. At the end of each day, participants are asked to write down the total number of minutes they spent being physically active on the activity tracking sheet. Then, at the end of each week, they are asked to fill out the weekly raffle form and return it in order to earn points toward the incentive prizes. For every ten points earned, participants receive a raffle ticket that will be entered into a drawing at the midpoint and final events when prizes are given to participants. Approximately \$500 in incentive prizes are given away at each site.

3.3.2.8.2. 'Stress Less' campaign: The 'Stress Less' campaign is delivered in the second six months and aims to help participants reduce the amount of stress that they experience by adding stress reduction activities into their daily routines. Campaign participants are given a booklet that includes six weekly sections focused on a particular stress reduction technique. Each section includes: educational and motivational content, a goal setting and action step form, tips and suggestions for how to achieve that goal and the benefits associated with reaching the goal. The focus areas for each week are: 1. Muscle Relaxation and Tension Release; 2. Visualization; 3. Adequate Sleep; 4. Mindfulness and Meditation; 5. Time Management for Stress Reduction; and 6. Music for Relaxation. Each time the participants try one of the recommendations, they record it on their activity tracking sheet along with

how they feel about the techniques. Then, at the end of the week, participants are asked to submit forms indicating activities they tried. Points are attributed to each activity recorded and raffle tickets are given to employees based on the points they earn. These tickets are drawn for incentive prizes at the midpoint and final events with approximately \$500 in prizes given away at each site.

#### 4. Process evaluation

#### 4.1. Fidelity and dose

For the Access Only intervention, detailed FTY market sales data, including total sales, number of shoppers, items purchased and tender types are captured by the FTY POS cashiering system. For the Access Plus intervention, research staff record the number of participants who participate in the kick off events, campaigns, and taste-testing events. Project staff also keep records of the number and type of educational materials (newsletters, food demo handouts/recipes, campaign materials, DVDs, etc.) distributed to employees as well as those materials that are picked up at intervention activities. We also assess actual use of the web site including number of hits; hits/use of various parts of the website; and number and types of materials downloaded.

The six and twelve month surveys include questions about participation in each component of the intervention including frequency of shopping at the FTY markets; perceptions of prices, quality and availability of F&V; participation in, or reasons for not participating in, each campaign; helpfulness of each campaign; participation in, and usefulness of, the cooking demonstration and taste testing events; and the use and usefulness of the recipes, newsletters, DVDs and website. These surveys also include open-ended questions that ask participants about what they learned and the behavioral changes that they made as a result of the intervention as well as suggestions for how the intervention could be improved.

#### 4.2. Costs

We will estimate the costs that would be necessary to replicate the intervention delivery as well as cost-effectiveness. Measures of cost include only the costs related to intervention delivery, not the costs related to intervention development or evaluation/ research. Component costs include research staff time to promote and deliver the intervention, and the direct costs for the intervention components themselves. For the F&V delivery intervention we measure the direct costs of bringing the markets to worksites including staffing, transportation, insurance, shrinkage (F&V loss), bags and signage, etc.. We also include direct costs for the educational interventions: staffing, reproduction of the DVDs, newsletters, campaign booklets and other printed materials; campaign prizes; food demonstrations; promotional materials; website hosting costs, etc. For each intervention arm we will determine costs per participant as well as costs per worksite.

#### 4.3. Context

To measure context, we use key informant interviews. Interviews of key worksite gatekeepers including the CEO and the human resources director are conducted at baseline and twelve months at all study worksites. All of these interviews are audiotaped, with

consent for research, taping, and later use of audio footage for research purposes obtained from all participants. These interviews provide us with data on organizational factors that may influence implementation of the proposed intervention or influence employee outcomes. These interviews also provide data to monitor organizational changes in policies, procedures and/or norms that could be related to F&V access and availability. The follow-up interviews also help us to gain a better understanding of the perceptions of these worksite gatekeepers to the overall intervention and key intervention components, perceived changes attributable to the program, and provide process evaluation context data on barriers/impediments/facilitators to implementation, and opportunities for sustainability of the program. These data will be helpful for future dissemination purposes as well. The majority of the interview responses are in survey format so will be analyzed in a similar manner to other surveys. However, answers to open-ended questions will be transcribed and coded similar to the focus group data.

# 5. Impact evaluation methods and measures

#### 5.1. Survey methods and measures

The baseline, six and twelve month surveys are created and programmed in DatStat Illume software, a tool that allows for secure, web-based data collection. Participants with active email addresses are invited to take the survey online via an email that includes a link to a self-administered survey. If they do not complete the online survey within seven days, participants are then contacted by phone and invited to complete a Computer Assisted Telephone Interview (CATI) survey. Employees without active email addresses are also contacted by phone to take the CATI survey. The primary outcome is F&V intake, which is measured using several validated instruments. We will analyze changes in fruit intake alone, vegetable intake alone, and F&V together; specifically, we will look at fruit and F&V measures without juice and vegetable and F&V measures without French fries. Outcome measures, demographic questions and measures of potential mediating variables are described in Table 2.

#### 5.2. Data analysis

To evaluate potential differences between groups that may have occurred by chance in the random assignment process, demographics will be assessed by group using chi squared tests for categorical data and analysis of variance for continuous data. Also, group differences in baseline values for outcomes and mediators will be assessed using ANOVA models. To assess demographic differences in baseline F&V intake and mediators, ANOVA models will be constructed to assess outcomes and mediator variables (dependent variables) by demographic categories (independent variables). To examine F&V intake, mixed-model analysis of variance using SAS PROC MIXED will be used to account for a potential cluster effect within each worksite. All analyses will be performed using SAS version 9.4 (SAS Institute, Cary, NC).

Cost-effectiveness will be calculated looking at costs related to mean change in F&V intake as measured by the F&V screener between baseline and twelve months. We will look at this both at the participant and worksite levels. Costs will be calculated as described above. We

will then divide the cost per participant by the mean F&V change per participant to calculate cost per unit change in F&V intake for each of the three interventions. We will also divide the cost per worksite by the mean F&V change per worksite to calculate cost per unit change in F&V intake for each of the three interventions at the worksite level. Cost effectiveness will then be compared by intervention condition. Incremental cost-effectiveness ratios will be calculated and compared by intervention group.

#### 5.3. Sample size considerations

The sample size calculation is based on the simple pre-post design with 2 time points that uses the estimated variance that one would obtain from a repeated measures regression model. Our effect size is estimated as the difference in the change scores between the Access Only group and Access Plus group, i.e., = (F&V Screener<sub>Post</sub>-F&V Screener<sub>Pre</sub>)<sub>Access</sub> Plus – (F&V Screener<sub>Post</sub>-F&V Screener<sub>Pre</sub>)<sub>Access</sub>, using Murray [102] as a reference for power calculations that account for clustering. Using reasonable estimates of the ICC (0.01) and S.D. (2.5) based on previous worksite studies, and with 80% power, the sample size projections show that with 75 participants in each worksite and 7 sites per experimental condition, we will be able to detect a difference of 0.62 cups of F&V using the NCI screener. We anticipate this effect size to be the smallest incremental change between the Access Plus intervention and the Access Only intervention. The effect size between these intervention groups and the Comparison group is expected to be even higher.

Since 75 participants is the number of participants who need to complete the 12-month follow-up, and we assume that approximately 20% of participants will be lost to follow-up between baseline and twelve months, we plan to enroll 94 participants at each worksite into the evaluation cohort.

#### 6. Discussion

Good to Go is the first study to rigorously evaluate the efficacy of a discount, mobile F&V market at worksites on employee F&V intake. Moreover, it is one of the few studies examining the efficacy of a F&V access intervention with and without an educational/behavioral intervention. Additionally, no other published studies have examined the efficacy of F&V market interventions in rigorous cluster randomized trials in any setting. This study will also fill other research gaps identified in the literature for worksite based nutrition interventions [103–106] including a rigorous cluster-randomized design with well-matched comparison groups; addressing cost as a barrier; and clearly linking behavioral theory constructs with intervention components. We will also use mixed methods to examine not only what changes using quantitative measures, but also 'how' and 'why' these changes take place by identifying mediators of F&V change and using qualitative measures (i.e. key informant interviews) to better evaluate reasons for success or failure of the intervention, which few other studies have done. We will also be conducting detailed process evaluation including assessing cost-effectiveness, which will fill important research gaps.

Other strengths of the study include the large number of worksites of varying types, which increases the potential generalizability of the results. The variety in worksite types and the recruitment methods used will also likely result in recruitment of a broad spectrum of

employees representing very different job types. Lastly, the Good to Go intervention covers several levels of the socioecological model.

One limitation of the study is that our research design will be unable to differentiate the effects of the educational/promotional intervention separately because we did not use a factorial design. However, we will be able to estimate the efficacy of this intervention alone by subtracting the effect of the Access Only intervention from the effect of the Access Plus intervention. Another limitation is that our research design will be unable to differentiate the effects of the specific educational interventions (campaigns, website, food demonstrations, newsletter, and self-help program) in the Access Plus intervention. While our research design will not allow for specific effect sizes to be calculated for each specific intervention component, our process evaluation will allow us to examine reach, dose and participant satisfaction for each intervention component and the relationship between dose and F&V change. If the educational interventions are shown to enhance the environmental access intervention, future implementation deconstruction research could decipher the incremental effects of each educational component.

Another potential limitation is that we will be measuring the efficacy of the interventions at the worksite level by evaluating a random sample of employees who may or may not have participated in the interventions, which may limit the effect size observed. We feel that this type of evaluation is most appropriate for examining the efficacy of a worksite-wide intervention. Only measuring the efficacy of the intervention in those employees who participated fully would not provide much external validity. With our extensive process evaluation, we will be able to examine whether F&V consumption increases with intervention dose, and we will describe the employees that participated compared with those that did not to define characteristics of employees who may be targeted to increase participation.

The FTY discount mobile markets are an innovative environmental intervention providing access and availability to F&V at the worksite. Such markets have the potential to be highly sustainable and replicable if found to be efficacious, cost effective and financially viable for the produce distributor. As such markets are becoming more numerous in the community, it is important to know whether they can improve dietary habits alone or whether accompanying educational interventions are also necessary. Thus, the Good to Go study will provide an important contribution to public health research and practice.

### **Supplementary Material**

Refer to Web version on PubMed Central for supplementary material.

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#### **Abbreviations**

**F&V** Fruits and Vegetables

GTG Good to Go

FTY Fresh To You

**DVD** Digital Video Disk

**EBT** Electronic Benefits Transfer

**SCT** Social Cognitive Theory

**SNAP** Supplemental Nutrition Assistance Program

**POS** Point-of-Sale

NCI National Cancer Institute

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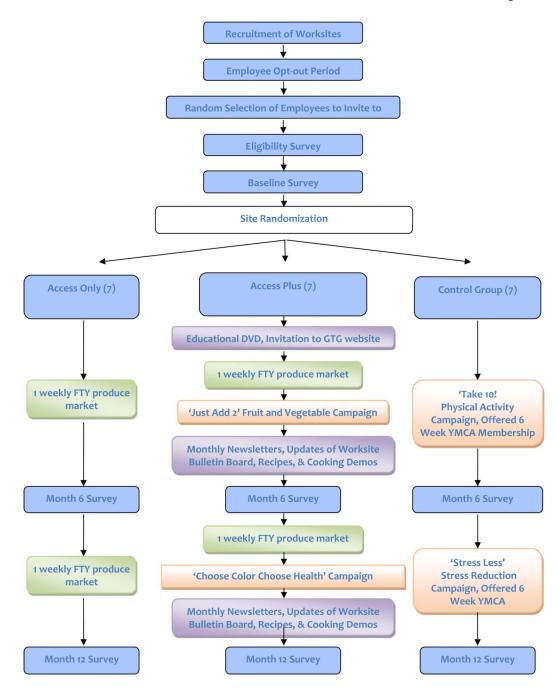
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**Fig. 1.** Study flow chart.

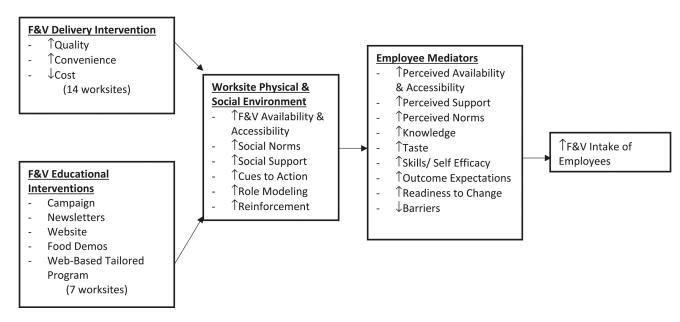


Fig. 2.
Intervention Logic Model.

Table 1 Focus group findings overall and by blue/white collar groups.

Question/ content	Overall finding	Blue/White collar differences
Why Americans eat inadequate F&V	Americans eat few F&V primarily because of cost, poor quality and the time required to prepare	Blue collar groups also discussed the importance of culture and that many [people like them] were not raised to eat many F&V
		Blue collar specifically mentioned lowering the cos of F&V as something that would make it easier to eat more F&V
		<ul> <li>White collar groups discussed more access, variety of F&amp;V, time for advanced planning and preparation, and packaging (ready to go) as well as the need for more F&amp;V in their worksite</li> </ul>
F&V availability at the worksite	There is clearly a need for more F&V at the worksite	Blue collar workers mentioned having more F&V available in vending machines
		White collar groups mentioned the need for greater F&V availability in the cafeteria, specifically F&V as side dishes as well as the need for employee access to refrigeration to store F&V
F&V market coming to their worksite	Both groups mentioned reasonable prices, convenient hours and having high quality produce as the most important factors to make employees likely to use the market	<ul> <li>Blue collar groups focused more on the presentation of the market possibly in a canteen truck and the availability of convenient F&amp;V (e.g. cut up and prepared)</li> </ul>
		<ul> <li>White collar workers identified a good selection of organic produce and having different items each week, as well as the cleanliness of the market and space to store their purchases during the day</li> </ul>
Strategies for improving F&V consumption at the worksite	Discussions indicated that healthy eating initiatives would be well received, and that it would be helpful if coworkers did not bring junk food	<ul> <li>Blue collar respondents also added that finding techniques to get their family members to eat healthier with them would be a good source of support for their own healthy eating initiatives</li> </ul>
	Participants also mentioned the utility of recipes, techniques for preparing F&V and nutritional information	<ul> <li>White collar groups specifically mentioned that it would be useful to know where F&amp;V come from, how long they stay fresh and when certain types are in season</li> </ul>
	<ul> <li>Competition was identified as a good motivator for the educational programs with incentives in the form of money or gift cards</li> </ul>	
	<ul> <li>Coupons were identified as a potentially helpful strategy for supporting healthier eating habits</li> </ul>	
Suggestions for making the intervention	Newsletters were recommended by groups to be plain, simple, and readable, with easy-to-follow recipes	<ul> <li>Blue collar groups mentioned the importance of nutritional information</li> <li>White collar groups mentioned providing materials</li> </ul>
components (e.g. newsletters, web site and videos)	<ul> <li>with colorful pictures</li> <li>For the video footage, participants</li> </ul>	in an electronic format
appealing	overall were interested in cooking segments and that cooking	<ul> <li>For the web site, blue collar groups recommended an email teaser to bring users to the website</li> </ul>
	information might be more useful provided on a DVD rather than on a web site. However, they were not hopeful that family members would watch the DVD with them	<ul> <li>White collar groups recommended making the website bright, appealing, simple to navigate, having search options available and links from the newsletters</li> </ul>

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Table 2

Evaluation measures including behavioral outcomes, demographics and potential mediators.

Type of variable	Construct	Number of items	Measure	Description or response options	Validity/internal validity <sup>d</sup>
Behavioral outcomes	Fruit and vegetable intake	2	F&V intake screener [81]	"About how many cups of fruit (including 100% pure fruit juice) do you eat or drink each day?" and, "About how many cups of vegetables (including 100% vegetable juice) do you eat or drink each day?" Each question includes a description of the amount of F&V in one cup to aid participants in choosing their portion size. Portion size options range from none to 4 cups or more	Estimated correlations between F&V intrace measured on the two-item Screener and "true" F&V intake (measured by 24-h recalls) were 0.42 for both men and women [81]
	Fruit and vegetable intake	61	National Cancer Institute (NCI) Eating at America's Table All Day Screener [82]	This instrument queries the frequency of usual consumption of 10 categories of F&V consumed over the past month: Fruit, 100% juice, lettuce salad, French fries/fried potatoes, other white potatoes, cooked dried beans, other vegetables, tomato sauce, and vegetable soups and mixtures that included vegetables. Participants are asked to think about the F&V they usually ate last month and to report the frequency (from never to 5 or more times per day) and serving size (from less than ½ cup to more than 1 ½ cups) for each F&V. The responses to the frequency questions are recoded to daily averages based on standard NCI methods	Correlations between F&V intake measured on the Screener and "true" F&V intake Measured by 24-h recalls) were 0.66 for men and 0.51 for women [82]
	Fruit and vegetable intake habits	4	F&V Habits Questionnaire [83–85]	This measure examines change in behaviors related to F&V intake. It queries how often in the past few months participants: ate fruit at breakfast; added vegetables to breakfast dishes; ate more than one type of fruit per day; ate more than one type of vegetable per day; at a lettuce-based salad or vegetable at lunch; ate fruit at lunch; eat a lettuce-based salad or vegetable at dinner; ate two or more different vegetables or a vegetable and a salad at dinner; added vegetables to or more different vegetables or a vegetable as a snack in-between meals; and ate just fruit as dessert instead of a rich dessert. All questions have five levels of response (always, often, sometimes, rarely or never). The sum of all responses is taken to get the total Fruit and Vegetable Habits Questionnaire score. Higher scores are indicative of higher F&V intake behaviors	a = 0.64
Demographics	Gender	1	Are you male or female?	Male, Female	
	Age		What was your age on your last birthday?	Open end (years old)	
	Marital status	1	What is your marital status?	Married/domestic partner, divorced, widowed, separated, never been married	
	Ethnicity (Hispanic or	-	Do you consider yourself to be Hispanic or Latino?	Yes, No	
	not)		If Hispanic or Latino, which of these cultures do you most identify with?	Dominican, Puerto Rican, Colombian, Guatemalan, Mexican, Other	

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Type of variable	Construct	Number of items	Measure	Description or response options	Validity/internal validity <sup>a</sup>
	Race	-	Of the following racial groups, which best describes you? You may choose more than one	American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White, Other	
	Education		What is the highest level of education that you have completed? Please choose only one	8th grade or less, some high school, high school or GED, some technical school or community college, technical school or community college grad, some college, college graduate, post grad or professional degree, other	
	Income	-	Which of the following categories best describes the total yearly income of your household from all sources? Remember, your answers are kept strictly confidential and will never be matched to your name	Less than \$25,000, \$25,001–\$50,000, \$50,001–\$75,000, \$75,000–\$100,000, \$100,001 or more	
	Employment status		What is your current employment status?	Full-time, part-time, per diem, seasonal, temporary, out on disability	
	Job category/ type		Which of the following categories best describes your job or the type of work that you do?	Scientific/Technical, Clerical/Office/Sales, Manual Labor, Professional/Managerial, Service Worker, Machine Operator, Other	
	Employment length	-	How long have you worked for the company (open ended)		
	Shift	_	What shift do you work?	Daytime, evening, night, rotating	
	Union membership	-	Are you a member of a union?	Yes, No	
Potential mediators	Knowledge	7	Knowledge of Fruit and Vegetable Intake [86–88]	Items queried perceptions of the appropriate amount of F&V an adult should eat. We adapted previous measures to use cups instead of servings, to be consistent with U.S. Dietary Guidelines [89]	$\alpha = 0.80$
	Availability	17	Fruit and Vegetable Availability adapted from the "Home Environment Survey." [90]	This instrument asks: "How often are available in your home," (including apples, bananas, melons, grapes, oranges, strawberries, mangoes, broccoli, carrots, lettuce, avocados, green beans, potatoes, and tomatoes. Responses are on a five-point scale ranging from never, rarely, sometimes, often and always	$\alpha = 0.82$
	Barriers	6	Barriers to Eating More Fruits and Vegetables drawn from previous studies [91–95] and our own formative research	These questions assess common barriers including: "Don't know how to prepare vegetables in ways that my family would eat them", "Vegetables are too time consuming to prepare", "The high cost of F&V keeps me from buying them as much as I'd like to", Fresh F&V spoil too easily", "It's hard to find affordable, high quality F&V near my home", "I don't have time to shop for F&V" "My family prefers other foods for snacks", "People in my family don't eat a lot of F&V" and "My co-workers don't eat a lot of F&V. Responses are on a five point Likert format ranging from agree a lot, to disagree a lot	$\alpha = 0.69$
	Self-efficacy	7	Self-efficacy [78,96]	Questions drawn from the Townsend F&V Inventory including "How sure are you that you can: Plan meals or snacks with more F&V during the next week," "Eat F&V as snacks this week," "Buy more F&V the next time you shop," "Add extra vegetables to casseroles, stews or other mixed dishes," "Have F&V available at home for snacks next	$\alpha = 0.83$

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Type of variable	Construct	Number of items	Measure	Description or response options	Validity/internal validity <sup>a</sup>
				week," "Have at least 2 vegetables with dinner," and "Have at least one F&V with every meal". Responses are on a five-point scale ranging from very sure, to very unsure	
	Readiness to change	2	Stage of Change for F&V Intake questions adapted from previous instruments [94,97–99]	Readiness to eat more and to buy more F&V. Responses for these questions include not even thinking about, thinking about, will, or already are eating (or buying) more F&V. The responses correspond to stages of change categories including pre-contemplation, contemplation, action and maintenance	$\alpha = 0.87$
	Importance	7	Importance of Buying/Eating more Fruits and Vegetables adapted from [100]	Questions were adapted to ask, "How important is it to you to buy more F&V" and "Eat more F&V." Responses ranged on a five-point scale from not at all important to extremely important	$\alpha = 0.87$
	Social support	4	Workplace Social Support for F&V Intake [100]	During the past three months, how often did your co-workers encourage you to 1) buy more F&V 2) eat more F&V 3) serve your family more F&V 4) criticize you when you bought F&V. Responses were from never, rarely, sometimes, often or very often	$\alpha = 0.68$
	Workplace environment	٢	Workplace Environment adapted from psychosocial measures of support in other environments [101]	Participants were asked to agree or disagree to several statements pertaining to whether the workplace makes it easy to eat healthy; F&V are easily available at your worksite; and if there is a lot of information on eating healthy at your worksite. Questions are asked also with regard to both supervisors' support for healthy eating/wellbeinig. Your supervisor cares about your health and wellbeing?" and, "Your supervisor encourages you to lead a healthy lifestyle," Responses for all these questions ranged from disagree a lot to agree a lot. Regarding coworker's support we asked: "How often do you talk to your coworkers about healthy eating?" with response options never, rarely, sometimes, rarely, and never. And "How much encouragement for healthy eating do you get from your coworkers?" Responses were: none, very little, some and a lot	$\alpha = 0.72$

Note: all measures were asked at baseline, 6 and 12 months except for the demographic questions which were only asked at baseline.

<sup>a</sup>Validity data is provided for the primary outcome measures of F&V intake and internal validity data (Cronbach's alphas) are provided for the fruit and vegetable habits questionnaire and mediating variable measures.

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