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Pilot and Feasibility Test of an Implementation Intention Intervention to Improve Fruit and Vegetable Intake Among Women with Low Socioeconomic Status

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ABSTRACT

Fruit and vegetable intake (FVI), a modifiable risk factor for chronic diseases, is lower in low socioeconomic status (SES) populations. Implementation intentions (a specific type of planning that extends the Theory of Planned Behavior) have been studied to improve FVI, but not exclusively with low SES groups. Using mixed methods, we evaluated the feasibility, acceptability, and preliminary efficacy of an implementation intention intervention (versus a general plan) to increase FVI in women with low SES. For the pilot randomized controlled trial, demographics, body mass index, attitude, perceived behavioral control, goal intention strength, and FVI were measured at baseline and FVI again 1 month following the intervention. Feasibility data were collected for recruitment, randomization, retention, and assessment procedures and compared to predetermined targets. Semi-structured interview data was analyzed for emergent themes regarding acceptability of the trial. Preliminary efficacy of the intervention to improve FVI was analyzed descriptively. Feasibility targets were met for randomization (100% vs. $\geq 80\%$ target), retention (93.5% vs. $\geq 70\%$ target) and the assessment metrics missing data points (2% vs. $\leq 10\%$ target) and days from intervention to follow up (mean=69.2, sd=42.6 vs. <180 days). Targets for recruitment were not met with the exception of participants giving informed consent (100% vs. $\geq 70\%$ target). Participants described the intervention as enjoyable and reported behavioral constructs outside of those measured as important to improve FVI. Limited efficacy analysis suggested that both groups increased their FVI (experimental: +0.17 servings per day, 95% CI: -0.85, 1.20; control: +0.50 servings per day, 95% CI: -0.56, 1.58). Further research which examines interventions based upon behavior change models to improve dietary health behaviors in marginalized groups is needed.

Keywords: Implementation intentions; Fruit and vegetable intake; Low socioeconomic status; Theory of Planned Behavior; Public Housing

INTRODUCTION

Fruit and vegetable intake below recommended levels is associated with multiple chronic diseases (Hung et al., 2004; Bowing et al., 2012). Although the US government has suggested that Americans increase their intake of fruit and vegetables (McGuire, 2011), epidemiologic data suggest intake for most Americans does not meet those guidelines. The greatest disparity between recommended and actual intake of fruit and vegetables is seen among people with low socioeconomic status (SES) compared to those with higher levels of education and income (Casagrande et al., 2007; Krebs-Smith et al., 2010). Differences in fruit and vegetable intake between different socioeconomic groups is thought to contribute to the higher incidence of chronic disease that is seen in individuals with low SES (Zhang & Wang 2004a; Zhang & Wang 2004b; Jemal et al., 2008; Stringhini, 2010).

Under-consumption of fruit and vegetables is thought to be the result of both individual and environmental factors (Wang & Beydoun, 2007; Brug, 2008). In terms of individual-level theories, the Theory of Planned Behavior (TPB) posits that intention (and ultimately behavior) is predicted effectively by a person's attitude (personal judgement about the behavior), subjective norms (others judgement about the behavior) and perceived behavioral control (the individual's perceptions about whether or not he/she has the skills and means necessary to bring about successful performance of the goal behavior). The TPB, which extends Ajzen's previously proposed Theory of Reasoned Action (TRA), is important because it allows for not only the prediction of volitional behaviors, but also the prediction of non-volitional behaviors (behaviors that a person cannot carry out willfully) (Ajzen 1991).

Implementation intentions have been identified as an extension of the TPB (Gollwitzer & Brandstatter, 1997; Gollwitzer & Schaal, 1998; Gollwitzer, 1999) to "mediate the relationship between intention and enactment" (Conner & Armitage, 1998, p. 1451), by influencing the area of the TPB described as the "intention-behavior gap" (Sheeran, 2002). An implementation intention is a specific plan created by an individual to perform a goal behavior they have not been successfully enacting. In general, an implementation intention is the identification of a specific time, and place and the specific behavior (the "when, where and what") that will satisfy the individual's goal intention, and usually takes the form of an "if...then..." statement. By setting this specific set of actions, an implementation intention allows the individual to move effortlessly from goal intention to goal behavior without thought, and as such, it increases the likelihood that the goal behavior will occur. Research that has utilized implementation intentions to promote health behavior change have targeted smoking among adolescents (Conner & Higgins, 2010), increasing activity level (Prestwich et al., 2010), improving diet quality (Verplanken & Faes, 1999), reducing dietary fat intake (Armitage, 2004), and improving snack habits (Tam et al., 2010).

Although implementation intentions have been studied as an intervention to modify dietary intake behaviors (including fruit and vegetable intake), to date these intervention trials have only been conducted among individuals with middle socioeconomic status. There are no reports in the literature where an implementation intention intervention has been tested exclusively in populations with low socioeconomic status. Given the disparities in health seen in populations with low SES, it is important to identify low-cost, easy to implement interventions

that can improve health-related behaviors among this group. Although there is some indication in the literature that an implementation intention intervention may be effective (i.e., the intervention produced a beneficial result) to improve health behaviors among individuals with low SES (c.f., Conner et al., 2013), more research is needed to see if an implementation intention intervention is feasible, acceptable or efficacious in this group. The aim of this study is to evaluate the feasibility, acceptability and preliminary efficacy of an implementation intention intervention to improve fruit and vegetable intake in women who have low SES. The results of this research can be used to inform future research and programs which seek to improve diet quality among this group.

METHODS

Study Design

Using a mixed methods approach, we conducted a pilot randomized controlled intervention study (ClinicalTrials.gov NCT02205697) to evaluate feasibility and preliminary efficacy of an implementation intention intervention. We then conducted a qualitative study of data obtained from semi-structured interviews of participants of the experimental group of the pilot trial to evaluate acceptability of the intervention. The protocol was approved by the Boston University Medical Center Institutional Review Board.

Recruitment and Participants. Study participants were recruited from the English-speaking subjects (n=76) included in a cluster-randomized, controlled, multi-intervention study of adult female residents of Boston Public Housing. Details regarding the parent study design have been published elsewhere (Quintiliani et al., 2014). Briefly, the “Healthy Families” study was a cluster-randomized controlled multi-intervention prospective cohort study conducted in 10 randomly-selected Boston Public Housing developments. The study followed mother-daughter pairs for 1 year. Measurements were taken from baseline to 1 year follow-up. Multiple interventions were used in this study (e.g. walking groups, cooking demonstrations, health screenings). The main outcome for this parent trial was change in BMI. Secondary outcomes were change in fruit and vegetable intake and physical activity.

For the pilot randomized controlled trial, subject recruitment and enrollment began in September 2014 and ended in December 2014. For the qualitative study, recruitment and enrollment ran from January 2015 through April 2015.

Data collection. Demographic data, BMI, behavioral constructs, and fruit and vegetable intake were collected and measured on the entire English-speaking cohort of the parent study (n=76) as part of the 1 year follow up survey for that study. This parent study data was collected from May 2014 through November 2014, and constituted the baseline data for this ancillary pilot randomized controlled trial.

Four weeks (30 days) after the implementation intention or control intervention was delivered to the experimental and control groups, fruit and vegetable intake was again surveyed using the same fruit and vegetable intake screener used for baseline intake data collection.

For the qualitative study, participants from the experimental group who completed the pilot randomized controlled trial (n=8) were contacted by the principal investigator (MAD) to see if they would be willing to participate in individual telephone interviews. Semi-structured interview data for the qualitative study was collected on subjects from the experimental group within 3 months of their completion of the pilot randomized controlled trial follow up survey of fruit and vegetable intake so as to maximize their recall of their experience participating in the

trial. Participants were contacted by telephone up to three times to schedule or conduct the telephone interview. Subjects were enrolled and interviewed, and interviews were transcribed on a rolling basis. All interviews were conducted by the principal investigator (MAD) using a semi-structured interview guide. Upon initial contact, the interviewer described that she was interested in learning about the subject's experience participating in the randomized controlled trial. If the subject expressed interest in participating, the interviewer provided a more detailed description of the study as well as information to allow the subject to make an informed consent to participate. Immediately following informed consent, the interviewer proceeded with the interview as outlined on the guide.

The semi-structured interview guide was developed around a phenomenological inquiry paradigm using information gleaned from three sources: the literature regarding the TPB and implementation intentions, feedback from study researchers who have experience conducting and publishing qualitative research (LMQ, DJB, SLP), and the qualitative answers provided by participants in the intervention trial as part of their follow up survey. This interview format was chosen in effort to ensure all questions were asked and answered while allowing for additional probing and exploration of any salient information that arose over the course of the interview (Fontana & Frey, 2003; Rabionet, 2011). The introduction to the interview was the same for all participants to ensure consistency of the background information provided.

The interview guide included questions designed to elicit information in three main topic areas with regard to acceptability: assessment/measurement of study variables; perceptions regarding the intervention; an overall assessment of participation in the study. Each interview was audio recorded (in duplicate) with the participant's verbal permission. In addition, notes were made by the principal investigator during the interviews. Audio recordings were then transcribed verbatim for analysis in a manner which allowed the capture of the subject's words, tone, pauses, etc. (Patton, 2002; McLellan et al., 2003).

Intervention: Approximately 1 month after being informed of participant completion of the 1 year follow up survey for the parent study (i.e. baseline survey for this ancillary study), English-speaking adult parent study participants who agreed to be contacted for additional research opportunities were contacted by telephone up to three times. Participants who were contacted were provided a brief description of the study using a script. Potential participants were then asked if they would be interested in participating in the research. If subjects answered in the affirmative, they were then provided with a description of the proposed study in sufficient detail to obtain informed consent. Individuals who consented to participate were then randomized into the experimental or the control groups using block randomization by housing development. Immediately following randomization, and using a structured guide, members of the control group were asked to form a general plan to increase their intake of fruit and vegetables by one serving each day over the next 30 days. Using the same structured guide, members of the experimental group were asked to set an individualized implementation intention to increase their fruit or vegetable intake by one serving each day over the course of 1 month (Gollwitzer & Sheeran, 2006). Experimental group subjects were asked to write down their implementation intention using an "if, then" format as described in the literature (Webb & Sheeran, 2008), and were instructed to keep what they wrote down at hand as a reference for use during their study period. Control participants were also asked to write down their general plan for future reference. The telephone contact to inform participants about the study design, obtain informed consent, and to perform the experimental or control intervention took approximately 30

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minutes. As there was no outside funding for this intervention study, participants in the pilot randomized controlled trial received a gift card nominally valued at \$5.00 for their participation. A timeline which outlines the research activities for the entire study is provided in Figure 1.

Figure 1. Timeline of research activities for pilot randomized controlled intervention trial and qualitative analyses

2014-2015	M	J	J	A	S	O	N	D	J	F	M	A
Parent study (“Healthy Families”) 1-yr follow up survey (Baseline data collection for pilot RCT*): Demographic data, height, weight, behavioral constructs, and baseline fruit and vegetable intake												
Pilot RCT: Intervention/control and follow-up fruit and vegetable intake assessment for efficacy data analysis; Feasibility data collection and analyses												
Semi-structured interviews: Transcription and qualitative analyses for acceptability of pilot RCT												

*RCT=randomized controlled trial

Measures.

Demographic. Age, education level, and race/ethnicity were collected via survey. Height was measured using a standard measuring tape, and weight was obtained using a digital scale which recorded weight to the nearest 0.01 kg.

Behavioral Constructs. Attitude, perceived behavioral control and goal intention strength were measured via survey using one question for each construct in the form of a bipolar semantic differential scale as informed by the literature (Chapman & Armitage, 2012). Attitude was measured using the question: “For me, increasing my daily intake of fruit or vegetables by one serving every day over the next month is...” to which subjects could respond on a scale between 1 and 7 anchored with “foolish” or “wise”. Perceived behavioral control was measured using the question: “For me, increasing my daily intake of fruit or vegetables by one serving every day over the next month would be” to which subjects could respond on a scale between 1 and 7 anchored with “difficult” and “easy”. Goal intention strength was measured using the question: “I intend to increase my daily intake of fruit or vegetables by one serving every day for the next month.” Subjects could respond to this statement on a scale between 1 and 7 anchored with “disagree strongly” and “agree strongly”.

Fruit and vegetable intake. Fruit and vegetable intake over the past 30 days was measured using the Behavioral Risk Factor Surveillance Survey Fruit and Vegetable Module (BRFSS FVM) (CDC, 2011), a 6-item self-reported questionnaire measuring frequency of fruit and vegetables usually eaten during the past 30 days. The module includes an item designed to assess intake of all fruit and vegetables, including specific questions related to the intake of carrots, potatoes excluding fried potatoes (e.g., French fries, potato chips) as well as an item to

assess intake of green salad. A pictorial reference for serving size was added to improve validity (Serdula, et al., 1993; Smith-Warner et al., 1997; Kim & Holowaty, 2003).

Feasibility. Data were collected throughout the pilot randomized controlled trial to allow for feasibility analyses. A simple “tally” was made for number of participants with non-working phone numbers, number of participants who agreed/declined to participate, number of participants enrolled via telephone, the number of contact attempts via telephone, the number of participants who agreed/declined randomization, subject retention, the number of days between the intervention and the follow up for all subjects in the experimental and control groups, and the number of missing data points.

Analysis Plan

Sample size for the randomized controlled trial was calculated using the simple formula for difference in means of fruit and vegetable intake with an effect size of Cohen’s $d=0.43$ (Chapman & Armitage, 2012), standard deviation of 1.06, $\alpha = 0.05$ and $1-\beta=0.84$ to be 52 subjects in each group. If an effect size of Cohen’s $d = .51$ (Adriaanse, et al., 2011), 36 subjects were needed in each group.

Feasibility analyses were conducted in four domains: recruitment, randomization, retention, assessment procedures (Bowen, 2009; Leon et al., 2011; Tickle-Degnen, et al., 2013). Recruitment was assessed in terms of barriers, refusal, consent and method. Barriers were characterized as the percent of subjects that were unavailable for recruitment (e.g. non-working phone number). This was determined as the number of subjects with barriers (such as non-working phone numbers) divided by the total number of eligible subjects contacted. Refusal was characterized by the percent of subjects who declined to participate. This was determined by dividing the number of subjects who declined by the total number of eligible subjects contacted (Lindner, 2001). Consent was characterized as the percent of subjects who consented to participate. This was determined by the number of subjects who consented to participate divided by the total number of eligible subjects contacted (Lindner, 2001; Wallington, 2011; Lang, 2013). Method of recruitment was assessed for telephone contact. This metric was characterized by the percent enrollment via telephone and determined by dividing the number of subjects enrolled by telephone divided by the total number of eligible subjects attempted to be enrolled by telephone.

Randomization for the pilot study was characterized as percent of participants willing to be randomized. This was determined by dividing the total number of subjects willing to be randomized by the total number of subjects enrolled. Retention was characterized by percent enrolled who completed the follow up survey. This was determined as the total number of participants with completed follow up surveys divided by the total number of subjects enrolled (Gersten, 2005). Assessment procedures were characterized as barriers to the follow up survey completion: the mean number of days to complete the follow up survey (Chapman, 2010), the percent of missing data points (defined as the number of missing data points divided by the total number of data points), and the percent of surveys completed (defined as the number of surveys completed divided by the total number of follow up surveys attempted).

Targets used to determine feasibility were obtained from the literature when possible. When not available from the literature, targets to determine feasibility were drawn from the collective clinical and research experience of the group (Tickle-Degnen et al., 2013).

To assess acceptability of the intervention, we conducted audio-recorded interviews which averaged approximately 30 minutes (range of 23:33-46:06 minutes). The six main topic

areas included in the semi-structured interview guide served as the initial (*a priori*) descriptive codes. Content analysis was conducted by the principal investigator (MAD) who coded all of the text from the transcripts by hand using the constant comparative method (Glaser & Strauss, 1967; Boeije, 2002; Kolb, 2012). Following initial coding, the principal investigator repeatedly analyzed the content of the transcripts for patterns which were then used as secondary (*axial*) codes. From this inductive, iterative process, a final codebook was developed to guide the final analysis.

After six subjects had been enrolled, qualitative data was preliminarily analyzed using initial *a priori* codes developed from the semi-structured interview guide. At that time, the principal investigator determined that the data was near “saturation”. To confirm, another two subjects were enrolled, interviewed and the data was transcribed and analyzed. The principal investigator determined that the data had reached saturation, and enrollment was discontinued. In total, eight interviews were conducted over a four-month period (January 2015 – April, 2015). Each interview lasted for 30-45 minutes. Participants in the semi-structured interviews received a gift card valued at \$25.00 for their participation.

Preliminary efficacy data were analyzed and presented descriptively using frequencies, means and medians. All quantitative analyses were completed using SAS 9.3© (SAS Institute, Cary, NC).

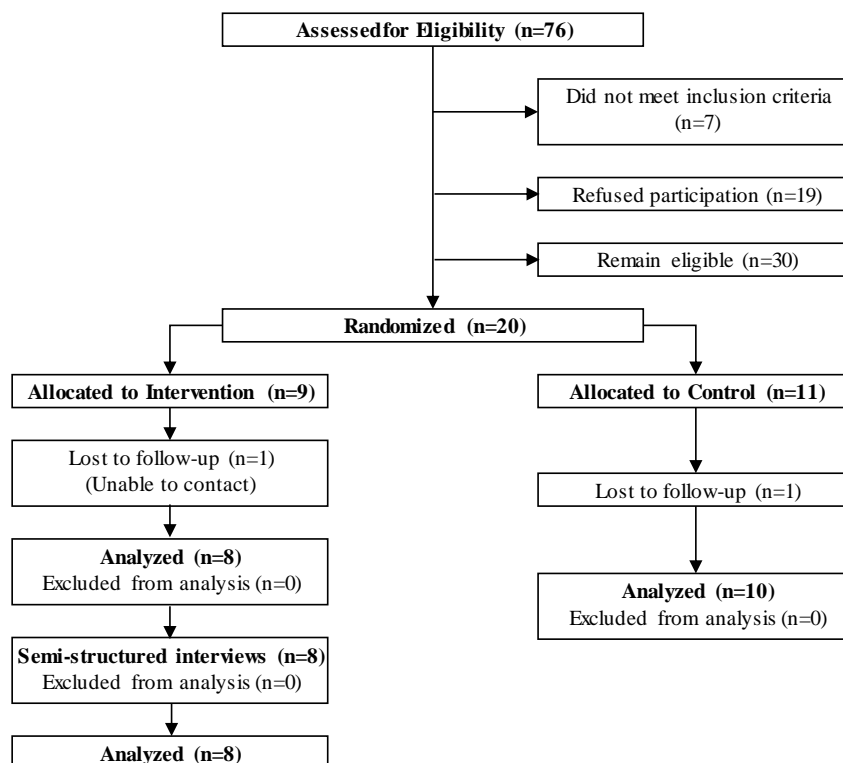
RESULTS

Participant Flow

In response to our recruiting efforts, 76 participants were assessed for eligibility into the randomized controlled trial which commenced September 2014. After exclusion of n=7 subjects for not meeting our inclusion criteria, and n=19 subjects who refused to participate, we were able to enroll and randomize n=20 subjects (intervention group n=9, control group n=11). Enrollment into the randomized controlled trial was terminated in December 2014. One subject was lost to follow up in each group of the pilot randomized controlled trial, so that at the time of data analyses, there were a total of n=18 subjects (n=10 control and n=8 experimental). Figure 2 outlines participant flow through the pilot randomized controlled trial and qualitative study.

Figure 2. CONSORT diagram showing the flow of participants through the pilot randomized controlled trial.

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Participant characteristics: Pilot randomized controlled trial. Analyses were conducted on the entire evaluation cohort who participated in the randomized controlled study (n=20).

Table 1. Socio-demographic, behavioral, and main outcome variables for pilot randomized controlled trial participants

	Intervention n=9	Control n=11	Total ^a n=20
Age, years, mean (SD), range	38.9 (5.94) 38-88	41.8 (11.28) 32-69	40.5 (9.17) 31-69
Race/Ethnicity ^b			
Asian	0	0	0
Black or African American	1(11)	5(45)	6(30)
Hispanic/Latino	5(55)	4(36)	9(45)
White	2(22)	1(9)	3(15)
Other	0	0	0
More than one	1(11)	1(9)	2(10)
Highest level of education			
< High school	2(22)	3(27)	5(25)
High school graduate/GED	3(33)	3(27)	6(30)
Some college or technical college	2(22)	3(27)	5(25)

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	College graduate Other	2(22) 0	2(18) 0	4(20) 0
Adult BMI, kg/m ²		29.25 (4.27)	35.35 (6.13)	32.60 (6.09)
BMI classification ^c				
	Underweight BMI <18.5	0	0	0
	Normal weight 18.5-24.9	1(11)	0	1(5)
	Overweight 25-29.9	4(44)	3(27)	7(35)
	Obese >30	4(44)	4(72)	12(60)
Attitude (median, IQR)		7.00 (0.00)	7.00 (2.00)	7.00 (1.50)
Perceived behavioral control (median, IQR)		5.00 (2.00)	7.00 (2.00)	6.50 (2.50)
Goal intention strength (median, IQR)		7.00 (2.00)	7.00 (1.00)	7.00 (1.50)
Fruits & vegetables, servings/day ^d (baseline) (X, SD)		2.92 (2.30)	3.61 (1.93)	3.31 (2.06)
Fruits & vegetables, servings/day ^d (follow-up) (X, SD)		3.48 (1.98)	3.99 (2.61)	3.75 (2.28)

^aNumbers represent n (% unless otherwise noted)

^bSubjects were able to choose multiple answers

^cClassifications based upon CDC guidelines

^dBREFFS FVM

Participants in the pilot randomized controlled trial had a mean age of 40.50 (SD 9.17), and ranged from 31-69 years of age. Black/African American and Hispanic/Latina subjects comprised the majority race/ethnicity (30% and 45%, respectively), followed white (15%). Participant education was approximately evenly distributed between some high school (25%), high school or GED graduates (30%), some college/technical school (25%) and college graduate (20%). Almost all subjects had a BMI which classified them as either overweight or obese (95%).

Median behavioral construct scores suggest that on average, participants reported high (positive) ratings of attitude, perceived behavioral control and goal intention strength towards eating more fruits and vegetables (median=7.00, 6.50, 7.00; IQR=1.50, 2.50 and 1.50, respectively).

The mean servings per day of fruit and vegetables for the entire cohort (n=20) at baseline was 3.31 (SD 2.06). Follow up fruit and vegetable intake for the entire cohort was 3.75 (SD 2.28).

Feasibility Analyses

Feasibility targets were met for the domains randomization and retention with 100% of enrolled subjects willing to be randomized, 93.5% of enrolled subjects completing the study. In the assessment procedures domain, the feasibility target was met for missing data points (0%), and the mean days from intervention to follow up (mean=69.27, SD 42.67), but the high end of the range (29-197 days) fell outside the 180 day (6 month) limit for intervention intention effectiveness as described by Chapman & Armitage (2010).

Targets were not met for recruitment domain with the exception of subjects enrolled who gave informed consent (100%). Barriers to recruitment accounted for 38.1% of subjects unable to be recruited from eligible subjects; higher than our target of ≤30%. Our refusal rate was also higher than our target of ≤15% (30.0%). Also, our method of recruitment by telephone was not met as only 14.9% of eligible participants able to be enrolled by telephone versus our target of ≥70%.

Acceptability analyses.

Behavioral construct assessment. All of the interview participants stated either that they had “no problem with” or that they “liked” the behavioral construct assessment questions. Of those who stated that they liked the question format, many described that they particularly liked the fact that there were “parameters” or a “scale” to use for answering them. Many stated that they felt that the questions were “straightforward”, “easy to understand” and not difficult to answer. No participants offered any negative comments about the questions content or their format.

Universally, the interviewed participants stated that answering the behavioral construct assessment questions made them think. For most in the group, answering the behavioral construct assessment questions made them think about their current intake of fruit and vegetables, and for some, whether or not they could change their fruit and vegetable intake. As one participant put it: “I think it would be a good thing, I just don’t know, you know, the question would probably be, you know, how feasible it would be...” Then she continues, “It’s thought provoking like, you know? Could, you know, ‘could I or couldn’t I, um...do it?’” For some in the group, answering the behavioral construct assessment questions made them reflect on their current state of health and/or any health issues that they might have. As one participant stated:

“It had me think, you know, like I said, it really does have you think from time to time, ‘you can do it’. I mean, you know, ‘Think about your health. You’re getting older, you have some health issues going on, you know?’”

BRFSS FVM survey questions. All participants felt that the BRFSS FVM survey questions were easy to understand and answer and that they were clearly written. Many stated that by answering the questions, it made them aware of their current intake of fruit and vegetables, and educated them about the different varieties of fruit and vegetables: “...you know, like comparing it... Like was I eating more starchy vegetables compared to like, ah, you know, like green vegetables, compared to like salad, what variety of the vegetables that I’ve been eating?” Some participants stated that answering the questions educated them about what constituted a serving of a particular fruit or vegetable:

“It’s like, ‘I just had a V-8 or whatever’, or ‘I had an apple juice, it counts as a serving.’ Maybe not the best form to get a serving, but it might count as one or two servings a day.”

Forming the implementation intention. All participants expressed that they enjoyed the conversation they had to form their implementation intention, and many felt that forming their plan was “easy”. Participants also stated that the time it took for the conversation to form the implementation intention was “good” and “fine”. No participants stated that they felt that the time spent forming their implementation intention was too long for them. What emerged as the part of the process that participants most appreciated was the “way the questions were asked”, specifically, the “guidance” and the ability to “brainstorm”. For example: “It made me really think of what’s going to work, by talking with you...brainstorming well ‘how can this work for me?’ ‘What would be the best time?’” This comment also exemplifies how participants

appreciated the way that the implementation intention was personalized to fit them as an individual, rather than a general approach designed for everybody.

In terms of the intervention process, participants most often cited the “open-ended” nature of the discussion as being a very helpful to them while forming their plan. As one participant put it: “I think with your assistance, it was sort of self-guiding, you know? Kinda open ended, like ok...you know, ‘what do you think?’...you kind of gave me direction and just let me kinda choose my own path.”

Some participants pointed specifically to the fact that they had a “choice and a voice” when it came to formulating their plan, and felt comfortable talking about the plan with the interviewer because they felt that there was “no wrong answer”. As one participant stated: “To me it was like more playing a little bit...like a puzzle more, and making that schedule on my time. And there was no time of being a wrong time.”

Another participant stated:

“It wasn’t like ‘I’d like you to do this’, or ‘you have to do this’. It was more like ‘try to do this’... in a way that’s gonna work for me, and that’s not...It wasn’t like a cookie-cutter plan, like ‘oh ok, well this is what works for everybody else’.

Study Participation

All study participants stated that they enjoyed participating in the intervention study. About half of the participants expressed that study participation was “motivating” and “inspiring” to them in terms of making positive changes in their eating habits. Most participants stated that study participation caused them to make a “self-assessment” of their current eating behaviors, and as such, they described participation as “thought provoking”. Many participants expressed that they believe their participation in the study was “beneficial” to them in many ways, with two participants expressing that they have continued to make efforts to improve their fruit and vegetable intake even after completion of the intervention.

Preliminary Efficacy Evaluation

The mean difference in intake from baseline to follow up for the control group (n=10) was +0.50 (95% CI: -0.56, 1.58) servings per day and for the experimental group (n=8) was +0.17 (95% CI: -0.85, 1.20) servings per day. Difference in the mean intake from baseline to follow up between the control and experimental group was 0.34 (95% CI: -1.06, 1.73) servings per day favoring the control group.

DISCUSSION

In an effort to evaluate the feasibility, acceptability, and preliminary efficacy of an implementation intention intervention to increase fruit and vegetable intake among women from households with low SES, a cohort of female residents of public housing from a low-income, multi-ethnic background was enrolled in both a pilot randomized controlled trial with feasibility analyses and a qualitative study. Overall, self-reported fruit and vegetable intakes were well below national guidelines with approximately 75% reporting they ate fewer than the recommended five servings of fruit and vegetables per day (USDA, MyPlate.gov, 2011). In addition, the study cohort’s median scores for behavioral constructs were strongly positive for attitude, perceived behavioral control and goal intention strength to consume fruit and vegetables.

The results of our feasibility analyses demonstrate that subject recruitment was the main barrier to the enrollment of sufficient numbers of participants into the randomized controlled trial. The many barriers to effective recruitment and retention among minority groups in research and clinical trials has been well documented (Daunt, 2003; Ford et al., 2004; Bolen et al., 2006; Yancey et al., 2006; Durant et al., 2007; Galea & Tracy, 2007; Ford et al., 2008; Ejiogu et al., 2011; Warner et al., 2013; George et al., 2014). We were able to find reports in the literature about recruitment/enrollment challenges related to an inability to contact (i.e., reach by telephone) potential subjects (c.f. Blumenthal et al., 1995; Loftin et al., 2005). Our study had the added challenge in that our subjects were recruited and enrolled from participants in the Healthy Families parent study, thus limiting our pool of potential participants.

Results from our qualitative analysis suggest that, for this group, study participation was enjoyable overall. Participants related that the survey questions used to measure the behavioral constructs and fruit and vegetable intake were clear and easy to understand. Additionally, participants reported that completing the behavioral construct survey questions caused them to think about their current fruit and vegetable intake and whether or not they could change it. Also, those interviewed stated that the BRFSS FVM survey questions educated them on portion size and what constituted a serving of fruit and/or vegetables.

Participant statements about the process of forming their implementation intention were particularly informative. Specifically, our participants stated what they most appreciated about the process of forming their implementation intention was that it was personalized, and gave them agency and choice. Belief that one has a choice and/or agency to enact a behavior aligns well with the construct of perceived behavioral control as posited by the TPB. Choice and agency are also constructs included in Self-Determination Theory (SDT) (Deci & Ryan, 1985; Ryan & Deci, 2000; Deci & Ryan, 2008a; Deci & Ryan, 2008b). There have been recent studies which have explored the combination of TPB and SDT to describe and influence a variety of health behaviors (c.f. Hagger et al., 2002; Hagger et al., 2003; Chatzisarantis & Hagger, 2009; Fortier et al., 2009; Jacobs et al., 2011; Hagger et al., 2012). To date, there have been no study of health behaviors among women who have low SES using a methodology which combines the TPB and SDT. Given our research has identified constructs of SDT as being potentially important motivators of behavior among women with low SES, future studies which seek to describe and influence dietary health behavior among this population should consider this combined approach.

Our results have a number of implications for behavior change interventions that seek to effect positive dietary behavior change among groups who have low SES; particularly interventions based upon behavioral constructs and implementation intentions. First, in their study of the moderating effect of SES on health behaviors, Conner et al. (2013) have suggested that researchers consider strategies which specifically target perceived behavioral control to promote health behavior change among groups with low SES. Their recommendation stems from their finding that although SES did modify the intention – behavior relationship, it did not modify the self-efficacy - behavior relationship (with self-efficacy often used as a proxy for perceived behavioral control). Our findings suggest that this strategy may not be useful with women who have low SES as the scores we obtained for perceived behavioral control in this group were a) already high, and b) not different from scores in similar studies among groups with higher socioeconomic status, mixed gender and lower age (Kellar & Abraham, 2005; Armitage 2007; Chapman et al., 2009). Secondly, although prior research using select

behavioral constructs and implementation intentions to describe and improve dietary health behaviors have been successful, our previous research suggests that the attitude, perceived behavioral control and goal intention strength explain less of the variability in fruit and vegetable intake in women of low SES (DeBiasse et al., 2016). For these reasons, we suggest that an implementation intention intervention which targets perceived behavioral control or the intention – behavior gap may be less effective to change dietary intake behavior in this group.

A significant limitation to this study is our small sample size which prohibited meaningful hypothesis testing regarding the efficacy of the implementation intention intervention to improve fruit and vegetable intake. Another limitation to this study is the self-reported nature of the behavioral construct and dietary intake measures. We chose the assessment methods used in this study specifically to balance the use of validated instruments with the need for brief measurements that would not be overly burdensome. Additionally, it is possible that the residents from public housing who participated in this study may not be representative of other public housing residents or low-income populations in urban areas, particularly as it relates to access to fruit and vegetables. According to recent data from the USDA, there are only two census tracts which constitute food deserts in the area of Boston. These two areas do not include any of the Boston Public Housing developments included in this study (USDA, Economic Research Service, 2016), so, it appears unlikely that our results were impacted by limited access to fruit and vegetables.

Our sampling approach whereby we enrolled participants from a group known to be willing to participate in research (i.e., the parent study) may have introduced systematic bias into our results, and as such, the ability to generalize our results to all groups with low SES or outside of public housing populations is limited. Finally, although we believe that we reached thematic saturation for our qualitative analysis, we may not have given our small number of participants for the semi-structured interviews. Future qualitative research among women with low SES may want to consider including a larger sample size.

CONCLUSION

The results of our feasibility analyses suggest that an implementation intention intervention to improve a dietary health behavior was feasible in terms of randomization and retention, but not recruitment. Our qualitative examination of the experience of women with low SES who participated in the intervention suggests that this type of intervention is acceptable and we identified behavioral constructs outside of those measured which may be important variables to explain and influenced dietary health behavior change among this group. Efficacy analyses of our pilot randomized controlled trial was limited by our small sample size. Future research which examines interventions based upon behavior change models including implementation intentions is needed to determine the most feasible and efficacious intervention to improve dietary health behaviors in this often-marginalized group.

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