

**BEHAVIORAL AND COGNITIVE CORRELATES  
OF WEIGHT LOSS IN A WORKSITE WEIGHT  
LOSS INTERVENTION**

A Dissertation by  
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*We can only be said to be alive in those moments when our hearts are conscious of our treasures.*

~Thornton Wilder

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## ABSTRACT

Overweight and obesity remain at epidemic levels and are associated with increased morbidity and mortality as well as increased health care costs. Both behavioral and lifestyle interventions are recommended for weight loss in obese individuals, but the widely-suggested goal of 5-10% weight loss to achieve significant health benefits is not routinely achieved even in intensive weight loss intervention studies. Identifying behavioral and cognitive correlates associated with successful weight loss in different types of interventions could inform the development of more effective and sustainable programs for weight control. Worksites are increasingly being suggested as important settings for body weight management interventions. However, to date, there have been no studies examining predictors of weight loss in worksite weight control interventions. We examined changes in behavioral and cognitive measures in a group-randomized controlled trial of a behavioral weight loss intervention versus wait-listed control at worksites. Analysis presented here compare participants at the intervention sites versus those at the control sites. Questionnaires administered at baseline and at 6 months measured eating behaviors (Eating Inventory), food cravings (Craving Inventory, Food Cravings Questionnaire-State and Trait), weight self efficacy (Weight Efficacy Lifestyle Questionnaire) and quality of life (WHO-BREF quality of life questionnaire). These indices, as well as measures of program adherence such as frequency of self-monitoring of body weight and meeting attendance were examined as correlates of weight change. To better inform future efforts in worksites we developed an intervention specific feedback questionnaire to determine which programmatic components of the intervention were most useful to participants. Weight change was greater in the intervention participants (I) than in participants in the wait-listed control (C), (Mean  $\pm$ SD  $\Delta$  I=-8.1 kg  $\pm$  6.8 kg,  $\Delta$  C=+0.9 kg  $\pm$  3.6 kg,  $p < 0.001$ ). The intervention resulted in increased restraint ( $\Delta$  I=5.43 $\pm$ 4.25,  $\Delta$  C=0.29 $\pm$ 3.80,  $p < 0.001$ ), decreased disinhibition ( $\Delta$  I=-2.50 $\pm$ 3.63,  $\Delta$  C=0.66 $\pm$ 1.85,  $p < 0.001$ ) and decreased hunger ( $\Delta$  I=-2.79 $\pm$ 3.13,  $\Delta$  C=0.56 $\pm$ 2.63,  $p < 0.001$ ) relative to the control group. These individuals also showed significant reductions in all aspects of craving, increases in weight self efficacy and its 5 situational dimensions, and improvements in the 4 quality of life domains. Within the intervention group, weight change was significantly correlated with decreased hunger ( $r=0.36$ ,  $p=0.001$ ), decreased food craving-trait ( $r=-0.24$ ,  $p=0.04$ ), increased total weight self efficacy ( $r=-0.34$ ,  $p=0.01$ ), session attendance ( $r=-0.4$ ,  $p=0.003$ ) and frequency of weight self monitoring ( $r=-0.3$ ,  $p=0.029$ ). All programmatic components were perceived as useful by participants and each component was correlated with weight change. These findings demonstrate that positive changes in behavioral and cognitive attributes can be achieved in the context of a multi-component group based weight loss program implemented within a worksite setting and advance the understanding of behavioral and cognitive attributes as determinants of weight loss. These findings also provide guidance for refinement of future worksite weight loss interventions.

# TABLE OF CONTENTS

ACKNOWLEDGMENTS.....	i
ABSTRACT.....	iii
TABLE OF CONTENTS.....	iv
LIST OF TABLES.....	viii
LIST OF FIGURES.....	ix
<b>CHAPTER 1</b>	
INTRODUCTION.....	1
Statement of Problem.....	1
Hypotheses and Specific Aims.....	2
Significance.....	4
References.....	6
<b>CHAPTER 2</b>	
LITERATURE REVIEW.....	11
Obesity and Weight Loss.....	11
Obesity-related Worksite Interventions.....	12
Behavioral outcomes and Weight loss.....	13
Eating Behaviors.....	13
Cravings.....	15
Weight Self Efficacy.....	17
Quality of Life.....	18
Adherence and Attendance.....	18

Participant Feedback.....	19
Summary.....	20
References.....	22

**CHAPTER 3**

RESEARCH DESIGN AND METHODS.....	43
Overview.....	43
Recruitment, Screening, and Eligibility.....	44
Wave 1: Worksites.....	44
Wave 2: Employees.....	46
Activities at Intervention Worksites.....	47
Activities at Control Worksites.....	50
Data Collection Procedures.....	51
Statistical analysis.....	56
Adequacy of Protection Against Risks.....	57
References.....	58

**CHAPTER 4**

Eating behaviors as correlates of weight loss in a 6 month worksite weight loss intervention.....	62
--	----

**CHAPTER 5**

Relationship of cravings with weight loss and hunger: Results from a 6 month worksite weight loss intervention.....	92
--	----

**CHAPTER 6**

Self efficacy, QOL and participant evaluation in a worksite weight loss intervention.....	117
--	-----

## **CHAPTER 7**

<b>SUMMARY AND DISCUSSION</b> .....	142
-------------------------------------	-----

Introduction.....	142
-------------------	-----

Overview of Results.....	143
--------------------------	-----

Study Strengths and Limitations.....	147
--------------------------------------	-----

Future Implications and Recommendations.....	149
--	-----

Conclusions.....	151
------------------	-----

References.....	152
-----------------	-----

<b>APPENDICES</b> .....	162
-------------------------	-----

A. Recruitment, Screening and Eligibility Schema .....	162
--	-----

B. Company Eligibility and Interest Survey.....	163
---	-----

C. Employee Web Screening Survey.....	165
---------------------------------------	-----

D. Sample Instinct Diet Menu.....	168
-----------------------------------	-----

E. Overview of outcome measures.....	169
--------------------------------------	-----

F. Employee Demographics Survey.....	170
--------------------------------------	-----

G. Description of Eating Inventory constructs and subscales .....	173
---	-----

H. Eating Inventory and Scoring Summary .....	174
---	-----

I. Food Craving Questionnaire – Trait .....	180
---	-----

J. Food Craving Questionnaire – State .....	183
---	-----

K. Food Craving Inventory .....	184
L. Weight Self Efficacy .....	186
M. WHO-BREF Quality of Life .....	188
N. Intervention feedback survey .....	193

## LIST OF TABLES

### CHAPTER 4

1. Baseline characteristics of participants completing the weight loss program or wait-listed control program.....	86
2. Changes in Eating Inventory constructs for control and intervention groups.....	87
3. Pearson correlations between weight change and baseline and 6 month changes in Eating Inventory variables .....	89
4. Regression models identifying predictors and correlates of weight change from 0-6 months .....	90

### CHAPTER 5

1. Baseline subject characteristics.....	111
2. Changes in cravings and eating inventory for intervention and control groups.....	112
3. Pearson correlations between weight change and craving variables.....	114
4. Regression models identifying predictors of weight loss from 0-6 months.....	116

### CHAPTER 6

1. Baseline characteristics and scores on Weight Self Efficacy and Quality of Life for intervention and control groups .....	138
2. Pearson correlations between weight change and change in WSE and QOL .....	140

## LIST OF FIGURES

### CHAPTER 4

1. Relationship between change in hunger and weight change.....91

### CHAPTER 5

1. Relationship between Craving-Trait and Hunger, Disinhibition and Restraint.....116

### CHAPTER 6

1. Between group differences on Weight Self Efficacy and Quality of life.....139
2. Relationship between change in weight and change in total Weight Self Efficacy and overall perception of Quality of life .....141

# CHAPTER 1

## INTRODUCTION

### **Statement of the problem**

Overweight and obesity are a major health concern worldwide. Numerous studies have demonstrated a strong association between obesity and an increase in morbidity and mortality (1-3). Lifestyle interventions targeting individuals to promote weight loss have shown some success (4, 5), however relapse or weight regain present as persistent problems (6). A key challenge to address the obesity epidemic is thus to develop successful behavioral and cognitive approaches to facilitate weight loss and maintenance. Further, there is substantial evidence that targeting groups of individuals is a more effective medium of change than interventions at the individual level attributable to the availability of social support (7-9). Worksites provide an environment where a large number of people spend considerable amounts of time on a regular basis, and therefore may be the ideal forum in which to implement an intervention encouraging healthier lifestyle behaviors (10-16). The shared environment of the employees can remind and reinforce the healthy behaviors of the program (11) and employees working together are likely to have a positive influence on each-other's behaviors (11, 17). Further, worksites already have an existing support network to effectively reach a large number of people in a time-efficient and cost-effective manner (8, 17-19). Additionally, from an ecological perspective, behaviors adopted by individual employees may also impact their families and communities (20).

Previous worksite interventions have partly been successful at addressing nutritional and lifestyle factors such as increasing the self-reported consumption of fruit and vegetable intake, increasing dietary fiber and decreasing fat intake. However, to date most worksite interventions have had only modest effects on weight and BMI (16, 21-25). One possible reason for this limited success may have been due to the approach used in these interventions. To our knowledge, most worksite weight-loss interventions emphasize modifying behaviors that contribute to energy balance, such as changing portion sizes or meal timing (26), rather than the behavioral and cognitive attributes of individuals such as eating behaviors (restraint, disinhibition and hunger), cravings, weight self efficacy (the belief that one can control one's weight) and quality of life (27-29). Understanding these phenomena will likely improve strategies that best support weight loss in worksite settings. Development and testing of effective worksite weight control programs is indeed needed to identify approaches that are effective at both achieving and sustaining weight loss. It is our belief that identifying behavioral strategies and programmatic components for maximizing weight loss and adherence in the worksite environment are vital to help reduce the national prevalence of overweight and obesity.

### **Study Summary, Hypotheses and Specific Aims**

The Healthy Weight for Life Program (HWLP) was a group randomized, controlled trial of a worksite intervention that incorporated a cognitive-behavioral approach towards weight loss. The study was conducted in worksites within the greater Boston area and was designed to promote healthier dietary and lifestyle behaviors. The *primary goals* of the research reported in this dissertation were to assess the impact of the HWLP intervention on behavioral and cognitive factors, and to provide an understanding

of how these changes influence weight loss. The *central hypothesis* is that the HWLP's novel dietary approach and multiple behavioral components would lead to significant changes in behavioral outcomes including eating behaviors, weight self efficacy (WSE), food cravings and quality of life. The *objective* of this investigation is to gain a better understanding of these behavioral outcomes in relation to the HWLP which will allow for tailoring and scaling up in future interventions. To test the central hypothesis and accomplish the stated objective, the following specific aims have been examined:

**Specific aim 1:** To assess the relationships between change in weight and eating behaviors (including restraint, disinhibition and hunger), weight self efficacy (WSE), cravings and quality of life (QOL).

**Sub Aim 1.1:** To compare change in eating behaviors, WSE, cravings and QOL *between* the intervention and control groups.

*Hypothesis 1.1: We hypothesized that employees enrolled in the 6 month weight loss program at the intervention worksites would have statistically significant increases in restraint, WSE and QOL and statistically significant decreases in disinhibition, hunger and cravings as compared to enrolled employees at the wait-listed control worksites.*

**Sub Aim 1.2:** To explore baseline and change in eating behaviors (restraint, disinhibition and hunger), WSE, cravings and QOL as predictors of weight loss *within* the intervention support group.

***Hypothesis 1.2:** We hypothesized that intervention related changes in eating behaviors, WSE, cravings and QOL will explain the variability in the magnitude of weight loss.*

**Specific Aim 2:** To explore the relationship between additional measures of adherence such as attendance at support group sessions and frequency of use of self monitoring logs and change in weight within the intervention support group.

***Hypothesis 2:** We hypothesized that intervention participants with greater session attendance and frequency of use of self monitoring logs will have greater weight loss.*

**Specific Aim 3:** To examine the relationship between participant feedback on intervention components and change in weight.

***Hypothesis 3:** We hypothesize that participants with positive feedback on the intervention components will have a greater change in weight.*

## **Significance**

Overeating and obesity continue to be a grave cause of concern (1, 30-32). Attempts to combat this complex problem have been very extensive, and yet individual treatment has met with limited success (33-35). There is substantial evidence that group-based comprehensive approaches are a more effective route to change than interventions at the individual level (8, 13). Worksites present one such important avenue with a preexisting network facilitating access to a large number of people in a time-efficient and cost-effective manner (25, 36).

At present, there is no information on behavioral strategies that best support weight loss in such work based group settings. Identifying behavioral strategies and programmatic components for maximizing weight loss are crucial in obesity research. The main impetus to look at behavioral and cognitive outcomes such as eating behavior, cravings and WSE is to be able to adapt the intervention to employee beliefs and needs in future large scale worksite interventions. This research is significant in that it has the potential to improve the health of the employees at target worksites, and perhaps more importantly, to identify effective strategies for disseminating an effective worksite health promotion program to future worksites. As an outcome of these investigations we will determine the behavioral and cognitive strategies best suited for weight control in a work-based setting.

Our hypothesis is based on the current knowledge that worksites are not only a viable setting for reaching large numbers of working adults, but also provide both a physical and social structure conducive to carrying out a weight loss intervention. The aims of this thesis project will advance the understanding of behavioral and cognitive attributes as determinants of weight loss and provide guidance for refinement of future worksite weight loss interventions. Ultimately, the project will aid investigators in planning and implementing sustainable, larger scale weight loss programs in the workplace.

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## CHAPTER 2

### LITERATURE REVIEW

#### **Obesity and Weight loss**

Obesity is a worldwide epidemic affecting an estimated 300 million people and has a profound, negative impact on health in adults, adolescents and even children (1-7). Obesity has received a lot of attention both nationally and internationally due to its detrimental health consequences, the huge economic burden it entails, and its increasing prevalence (8-13). In the United States, approximately 64% of adults are classified as overweight or obese (3). National statistics reveal that weight gain during adult years has increased by > 50% in the past three decades (14). In United States, the annual health care expenditure on obesity and its attributable medical expenses has escalated from 75 billion dollars in 2003 (15) to 147 billion dollars in 2008 (16).

Although the prevalence of obesity has increased dramatically during the past two decades, considerable uncertainty remains over the specific causes (3). The causes of obesity are multifaceted including genetic, behavioral, environmental, physiological and social factors (8, 17). However, behavioral and environmental factors have been identified as primary contributors of excess energy intake and reduced energy expenditure resulting in the dramatic rise in obesity over the past few decades (14, 18-21). Since the 1970's when efforts on treating obesity started in its earnest, the field has seen an explosion of weight loss programs and treatment modalities (12). Despite the explosion of weight loss treatments paralleling this epidemic (22, 23), individual treatment of obesity is frequently unsuccessful and weight regain or relapse continues to

be common (8, 10, 24-29). Insufficient information exists about the behavioral and cognitive strategies which best support successful weight loss (12, 30, 31). Further, recent evidence suggests that comprehensive approaches that target groups of population such as schools, worksites, health care organizations etc could be more effective than individual treatment of obesity because of the social support that groups offer (11, 32). The future holds promise for successful strategies that target the sustainable adoption of healthier eating behaviors in group settings and a better understanding of the behavioral variables associated with weight loss in such settings.

### **Obesity-related Worksite Interventions**

Worksite as an avenue for weight loss has gained interest in recent years (33-37). Based on evidence, the Task force on Community Preventive Services has recognized worksites as an effective medium for multi-component interventions targeting diet, physical activity and cognitive therapy (38). It serves as an environment where a large number of people spend considerable amounts of time on a regular basis, and therefore holds promise as an ideal forum in which to implement an intervention encouraging healthier lifestyle behaviors (4, 32, 33, 39-42). Employees working together may have a positive influence on each other's behaviors (36, 39), and from an ecological perspective, behaviors adopted by individual employees may also impact their families and communities (43). Further, having a full time job is the strongest predictor of drop-out rate in obese and overweight outpatients (44) and based on this observation, worksite weight loss support is a plausible approach for effective weight loss interventions. Some examples of previous worksite interventions that were successful either in making environmental changes or improving health behaviors include the *Seattle 5 a Day*

*program* (45) to increase fruit and vegetable consumption; Take Heart II (46, 47) to reduce smoking, decrease fat and increase fiber intake, the *Next Step Trial* (48) to decrease dietary fat and improve fiber consumption among auto workers through nutrition classes; the *Working Well Trial* (49) that improved the nutrition environments and the *Working Healthy Project* (50) that improved diet and physical activity behaviors.

Although previous worksite interventions have partly been successful at addressing nutritional and lifestyle factors such as increasing the consumption of fruit and vegetable intake, increasing fiber and decreasing fat intake, most have not been successful in significantly reducing weight or BMI (48, 50-53). However, most weight loss interventions emphasize modifying behaviors that contribute to energy balance, such as changing portion sizes or meal timing (54), rather than the cognitive and behavioral attributes of individuals such as eating behaviors, cravings and weight self efficacy (the belief that one can control one's weight) (55-57). Understanding these phenomena will likely improve strategies that best support weight loss in worksite settings. With this understanding of gaps in literature, we implemented and evaluated a 6 month weight loss intervention [Healthy Weight for Life Program (HWLP)] at worksites in the greater Boston area. The focus of this investigation was to interpret the behavioral and cognitive outcomes, assess the perceived utility of the intervention and understand the relation of adherence and attendance to change in weight.

### **Behavioral outcomes and Weight loss**

***Eating behaviors:*** Eating behavior, a measure of psychological aspects of eating, is likely an important factor in the prevalence of obesity (3, 58, 59) since it assesses different

aspects of behavioral control and attitude towards food (60-62). It is most commonly assessed by the self-administered 'Eating Inventory' developed by Stunkard and Messick (63) and consists of three recognized constructs: 1) restraint, defined as the conscious restriction of intake as a means of weight control, 2) disinhibition, defined as the propensity to overeat in response to various stimuli such as emotional stress or when an individual comes across a plethora of palatable foods and 3) hunger, defined as the susceptibility to eat in response to perceived physiological signals indicating the need for food (64-69). These specific eating behaviors can contribute to excess caloric intake and subsequent weight gain (3, 58, 70). Previous studies have demonstrated associations between low restraint and/or high disinhibition with a high body mass index both cross-sectionally (71-75) and longitudinally (70, 76). Longitudinal studies have investigated baseline and treatment related changes in eating behaviors as predictors of both short- and long- term weight loss over 4 to 24 months in several environments such as research studies (77-79), clinic-based diets (57, 80, 81) and community programs (82, 83). Most of the studies have shown that the amount of lost weight is associated with higher baseline restraint and lower baseline disinhibition. In addition, greater increases in restraint and/or greater decreases in disinhibition over time were typically associated with greater weight loss (57, 77, 79, 82, 84) with the exception of one report of decreases in hunger showing associations with weight loss (85).

In addition to the associations with weight loss, some investigators have assessed the associations between eating behaviors and choice of foods. In their weight loss intervention, Borg et al (29) reported that a high restraint score was associated with increased consumption of high fiber bread, vegetables and low fat dairy and a reduction

in the consumption of alcoholic drinks and high fat dairy. Similarly, in their population, low disinhibition and hunger scores were also associated with such healthier food choices. Restrained eaters have shown lower intakes of high fat snacks as compared to unrestrained eaters (86) even in a negative mood state (87). It has also been reported in the literature that the pleasure attributed to eating is an essential mediator of the association between restrained eating and psychological well-being (88, 89). Lastly, associations between eating behavior, more specifically, restraint eating and altered metabolic functions have also been reported in the literature. Martin et al (90) demonstrated an association between restraint and lower fasting plasma insulin levels, lower plasma insulin and glucose levels in the post prandial stage and better insulin sensitivity in the fasting and post-prandial stage.

Recently, subscales for each of the eating behavior traits have been proposed by Bond et al. (91). These subscales include strategic dieting behavior, attitude to self-regulation and avoidance of fattening foods under restraint, habitual, emotional and situational susceptibility under disinhibition and internal and external loci under hunger. These constructs are of particular relevance because they provide a composite understanding of the eating behaviors and currently there is very limited research on these sub-constructs (92).

***Food Cravings:*** Defined as a strong desire for a substance, cravings are known to encourage food or drug consumption (93). Food cravings are widely prevalent in the population, although there is considerable variation in estimates ranging from 21-97% (94). Further, individuals who report food cravings experience two to four episodes weekly (95). Cravings vary across gender, with women reporting higher cravings than

men, and age groups such that cravings reduce with aging (96-98). Cravings have also been reported to vary across BMI categories (99), with obese individuals reporting more frequent and stronger cravings (80, 100). One consistent finding in the literature is that sweet carbohydrates and high fat foods are the most commonly craved foods (94). The origins of food cravings remain uncertain, with several theories in the literature (101). The physiological perspective recognizes craving as a signal of nutritional and/or energy deficit whereas the psychological perspective associates craving as a reflection of negative mood states such as depression and stress (102). The biological perspective refers to craving as conditioned stimuli that develop by consumption of particular foods when hungry (103, 104). The neurological perspective for craving is attributed to increased perceptions of palatability elicited by the release of dopamine in the mid brain, particularly the nucleus accumbens or through the opioid or cannabinoid systems (105). More recently, the cognitive perspective on cravings has suggested that sensory stimulation and food cues elicit food cravings irrespective of hunger or satiation (102, 106) and these increase on repeated exposures (107).

Food cravings are suggested to play an important role in both the development of obesity (102, 107, 108) and lack of success in weight loss (99, 107, 109). Some recent studies reported increased cravings associated with dieting (98, 109-111), which supports the suggestion that cravings are a barrier to weight loss. However, several authors have reported reduction in cravings after a period of caloric restriction (112, 113) or lifestyle intervention (114, 115) whereas a few have reported a reduction in the 'giving-in' to cravings (99).

A critical challenge to obesity management efforts is the ability to help individuals manage food cravings. This can be accomplished by control based strategies such as teaching people how to cognitively restructure urge-related thoughts and cues to mentally distract them from food stimuli or acceptance based strategies aimed to increase mindfulness of internal experiences (107). However, to our knowledge, the effectiveness of these strategies and the predictive capability of cravings have never been investigated in a worksite based behavioral intervention for the treatment of obesity.

***Weight Self Efficacy (WSE):*** Adapted from Bandura's Social Learning Theory (116), self-efficacy is a cognitive construct referring to an individual's perceived ability to cope effectively in a given situation. Self efficacy is not concerned with actual skill sets to perform a task, rather with the perceptions about being able to perform that task (117, 118). Self efficacy can be general or specific to a particular task and has been linked to success across several realms of health behavior (119) including weight-control related behaviors. Weight self-efficacy (WSE), is quantified by the Weight Efficacy Lifestyle (WEL) (120) questionnaire. Associations between baseline WSE and weight loss have been mixed with some studies showing positive associations (121-127), an inverse association (128) or no association (129, 130). The associations between improvements in self-efficacy and greater weight loss following an intervention have been more consistent (55, 85, 126-128, 131, 132). Further, treatment related increases in WSE have also shown associations with prevention of weight regain (128, 133), adoption of healthier eating habits (134) and enhanced participation (135). Given that self efficacy plays a critical role in the process of behavior change and has been shown to be susceptible to intervention efforts, it is worth exploring in the worksite population.

***Quality of Life (QOL):*** In addition to the deleterious impact obesity has on morbidity and mortality (5, 6), it also has a profound, negative impact on non-physical outcomes such as the quality of life (QOL) (10, 136). The degree of obesity is proportional to the compromises in QOL and weight loss is associated with significant improvements in QOL (137-140). In addition to the primary clinical outcomes (such as blood pressure, blood glucose, lipid profile etc) that are usually measured with weight loss, the concept of measuring improvements in health also encompasses patient-reported outcomes such as the quality of life (QOL) (141). This subjective measure of physical and mental health and human function is under investigation since 1970's (142) and even modest weight loss has shown to be associated with significant improvements in QOL (137, 138). Although QOL is widely assessed in pharmaceutical trials, it is only more recently included as a routine measure in lifestyle intervention trials, and is also less commonly measured in randomized controlled lifestyle interventions (140). Knowledge on changes in QOL can greatly help to keep patients motivated and reinforce weight maintenance which is a common challenge following weight-loss interventions.

### **Attendance and Self Monitoring of Weight**

Program attendance has been recognized as critical factors in determining weight loss success (81, 83, 129, 143-147), even in worksite weight-loss interventions (39, 148-151). As noted by Glasgow et al (152), participation is an essential process measure and an outcome that deserves to be reported routinely. Further, although self-weighing has been recommended in weight-control programs (153-157), currently most programs do not emphasize frequent self-weighing (158). In particular, greater frequency of self-

weighing has been shown to be associated with greater weight loss (155, 158-161) and better weight maintenance (156, 158, 162). A more recent review pointed out the need for associations between objective measures of self-weighing and weight loss outcomes in diverse populations and different settings (163).

### **Participant feedback**

Recognition of programmatic components that encourage or hinder weight loss can provide a reliable basis for modifying intervention strategies to improve effectiveness and reduce attrition (57, 162, 164-166). While many investigators have looked at intervention effectiveness by assessing weight outcomes, only limited studies have looked at program effectiveness from participants perspective (145, 167). Since this is a pilot intervention, we believe that it is important to evaluate what components of the program were perceived as most helpful by the participants. The purpose of this component of the study is to determine which recommendations and types of assistance within the weight control program were found helpful by program participants and if those correlated with weight loss success. Feedback included participant ratings of perceived usefulness of programmatic components involving the use of specific support group opportunities, use of menus, usefulness of the provided book on the weight loss diet and self monitoring of weight.

## Summary

Obesity continues to be a major health problem across the globe (1, 2, 7, 9). Attempts to combat this multifactorial problem have been very extensive, and yet individual treatment has frequently met with limited success (168-170). Evidence for group therapy continues to grow and worksites present one such opportunity for group intervention that can utilize an already existing support system for behavior modification while reaching a large number of people in a time-efficient and cost-effective manner (53, 171)

However, inadequate information exists between the behavioral and cognitive strategies which best support weight loss especially in such work based group settings. Identifying behavioral and cognitive strategies and programmatic components for maximizing weight loss and sustaining long-term dietary adherence are crucial in obesity research. The main impetus to look at behavioral and cognitive outcomes such as eating behavior, cravings and WSE is to be able to refine the intervention to employee beliefs and needs in future large scale worksite interventions. The proposed research in this application is significant in that it has the potential to improve the health of the employees at target worksites, and perhaps more importantly, to identify effective means for disseminating a worksite health promotion program to future worksites. As an outcome of these investigations, it is expected that we will determine the behavioral and cognitive strategies best suited for weight control in a work based setting.

The aims of this thesis project will advance the understanding of behavioral and cognitive attributes in determining weight loss and in providing guidance for refinement of future worksite weight loss interventions. Ultimately, the project will aid investigators

in planning and implementing sustainable, larger scale weight loss programs in the workplace.

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## CHAPTER 3

### RESEARCH DESIGN AND METHODS

#### **Overview of the Healthy Weight for life program (HWLP)**

The HWLP was a pilot randomized, controlled trial of a worksite weight control intervention designed to inform future large scale worksite interventions. Four worksites were enrolled and randomized to either the intervention group (2 intervention sites) or the wait-listed control group (2 control sites). Worksites randomized to the intervention group began the 6-month intervention immediately following randomization, whereas worksites randomized to the wait-listed control group received no intervention during the 6-month study period and participated in outcome assessments only. To avoid drop-out after acceptance into the study, the wait-listed control sites were offered a 2-month intensive intervention which was implemented at the end of the 6-month study period.

The HWLP activities at the 2 intervention sites included two elements;

- All worksite level: employees irrespective of weight received informational resources like handouts and emails on healthy eating and monthly lunchtime seminars to facilitate healthy eating patterns for prevention of weight gain.
- Weight loss support group: Eligible and interested employees at the intervention sites received intensive support for weight loss and prevention of weight regain through weekly group meetings for the first 16 weeks followed by biweekly group meetings for the next 8 weeks. Employees in the control worksite who enrolled in the support group prior to randomization are referred to as the “intended support group participants”.

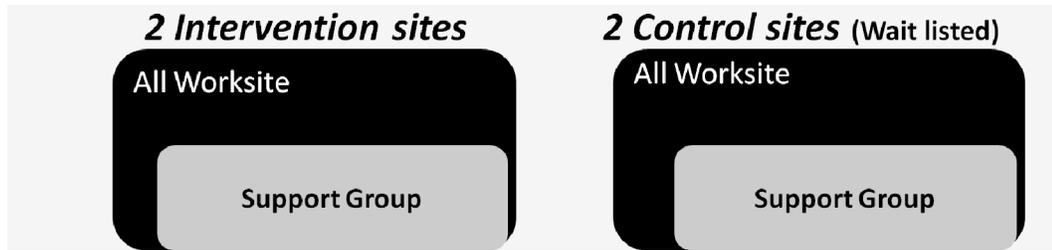


Figure 1: Levels of intervention, HWLP

Behavioral and cognitive outcomes were assessed in the support group participants and the intended support group participants at the control site. Approval of the Institutional Review Board (IRB) of Tufts Medical Center in Boston, MA was obtained. All worksites and participating employees within the worksites gave written, informed consent prior to participating.

## **Recruitment, Screening and Eligibility**

### **Wave 1: Worksites**

Worksites in the professional and government sectors in the greater Boston area were recruited through a multi-staged screening process (See Appendix A). Companies who reported 100-1200 employees (identified using Capital IQ database) were contacted by land mail with an initial information letter describing the study and highlighting the benefits of participation. 450 companies were contacted to meet our projected sample size of 4. Mailings and follow-up phone calls were made up to three times per profiled worksite if there was no response to the initial mailing. Worksites that responded to the initial study invitation were followed-up by an in-person meeting with study personnel to discuss the process of being considered for participation. The Human Resources

Department (HR) at each worksite was asked to sign a non-binding letter of understanding that confirmed the following eligibility criteria (see Appendix B):

- The worksite had 100-1200 employees within the same building, predominantly consisting of office-based employees in a for-profit, non-profit, and/or government institution.
- At the time of enrollment (or within the past 6 months) the worksite did not have an onsite formal weight loss program.
- The worksite was accessible by public transportation from the Human Nutrition Research Center on Aging located at 711 Washington Street, Boston MA.
- The HR understood that the study protocol would involve randomization to a 6-month intervention or wait-listed intervention (i.e. control group) and was willing to receive either randomization arm.
- The HR understood that employees would be asked to fill out a web-based screening survey (developed using SurveyShare.com), prior to enrollment in the study, to assess the level of company-wide interest in participating in intervention activities and willingness to complete outcome assessments.
- The HR understood that a minimum of 50% of employees were required to fill out the screening survey for their worksite to be considered for enrollment.
- The HR confirmed that space needs could be met (conference rooms for weekly weight loss support group meetings and outcome measurements as well as a central location for distribution of study materials).

- The HR was willing to either forward Tufts generated survey requests or allow employees to be contacted directly by the Tufts study team for purposes of ongoing intervention related outreach.

## **Wave 2: Employees at worksites**

Worksites that appeared to be eligible based on reported information from the HR personnel were asked to fill out a web-based screening questionnaire that captured information on level of interest in a weight loss program, previous experience with weight loss, and the key programmatic components that employees would like most in a weight loss intervention (see Appendix C). The eligibility criterion for this interest survey was set at >50% employee response rate. The final 4 worksites selected for participation in the study were required to fulfill the aforementioned eligibility criteria with priority given to worksites that had the highest response rates for the screening questionnaire.

After identification of the worksites based on the eligibility and interest survey, a ‘Health Day’ was conducted to provide employees with information about the HWLP study, encourage participation and identify and recruit employees to the weight loss support groups. Study staff members were available in-person to answer questions regarding participation and explain the process of randomization. Both height and weight measurements were obtained following a brief consent to determine whether the employees who expressed interest in the support groups met the criteria for eligibility. The eligibility criteria for participation in the support groups were –

- Willing to sign the consent form to join the group after understanding the purpose of the weight loss support groups

- BMI  $\geq$  25 kg/m<sup>2</sup> during screening (height and weight measured on Health Day)
- Age  $\geq$  21 years old
- Intention to follow recommended program and to complete outcome assessments
- Required to inform Primary Care Physician (PCP) prior to enrollment and to obtain a medical clearance letter from their PCP before beginning weight loss.
- No medical condition that would influence absorption or restrict intake of food such as gastric bypass, other bariatric surgeries, resection of small or large intestine leading to malabsorption, gastric resection for ulcers or cancer, and esophageal resection

The health day served as a baseline assessment phase following which the worksites were randomized to the control or intervention arm. The total employee size for the 2 intervention sites was 675 and for the 2 control sites were 354. After randomization a written informed consent was obtained from the eligible and interested employees in the support groups and the equivalent group in the control arm of the study.

The employees who expressed an interest and signed up for the weight loss support group are referred to as the ‘intervention support group’ at the intervention sites and ‘wait-listed support group’ at the control sites. Employees in the wait-listed control worksites were encouraged to maintain their current dietary behaviors over the 6-month study period and were assured that they would receive all of the study materials and dietary guidance given to the intervention site at the end of the 6-month period.

### **Activities at the Intervention Site**

Upon acceptance of worksites into the study, intervention activities were immediately initiated in the 2 worksites that were randomized to the intervention group.

Periodic worksite-wide activities were implemented to raise awareness of healthy eating for weight management. The purpose of the all-worksite activities was a) to create a supportive worksite-wide atmosphere for employees enrolled in the weight loss support groups and b) to provide low-level weight loss support for individuals who wished to learn more about healthy eating and lifestyle behaviors. Briefly, activities at the all-worksite level included:

- Flyers with nutrition tips and healthy recipes circulated in-person and via email as well as newsletters covering topics relevant to weight management.
- Monthly lunchtime seminars on healthy eating for weight management covering topics on cardiovascular health and nutrition, childhood nutrition, exercise and nutrition, and dietary and behavioral recommendations for weight loss and prevention of weight gain.
- Distribution of scales at intervention sites and placement in communal locations to encourage weight self-monitoring for all employees, irrespective of weight status.

### **Weight Loss Support Group Intervention Components**

A total of 19 sessions were offered during the 6-month study period (15 consecutive weekly sessions followed by bimonthly sessions).

***Dietary recommendations:*** The dietary recommendations and menus provided to employees in the HWLP support groups were based on the Instinct Diet [1] approach to weight loss and prevention of weight regain. The Instinct Diet is designed to change eating behaviors to sustainably reduce energy intake while eating a diet that provides menu-based recommended levels of macro- and micronutrients (see Appendix D).

Dietary advice was designed to facilitate the use of portion controlled meals that contained  $\geq 40$  g/day dietary fiber and were low glycemic load. Macronutrient targets were 26% protein, 26% fat, and 48% low glycemic index carbohydrate. All dietary recommendations were within Acceptable Macronutrient Distribution Ranges of the Dietary Reference Intakes [2] and dietary fiber was higher than the Recommended Daily Allowance [3, 4]. Calorie goals for each participant were based on starting weight in order to achieve the nationally recommended goal of 1-2 lb weight loss/week [5, 6]. These dietary recommendations were disseminated through a calorie controlled menu-based approach with specific information on allowable quantities of different foods. This approach has the potential to produce greater compliance due to a reduced decision-making burden on the participant [7, 8]. All support group participants were provided with a copy of the Instinct Diet book at the beginning of the intervention.

Groups were no larger than 20 employees in order to provide a standard discussion forum and social support network for participants. Food samples from the Instinct Diet manual were also distributed during weekly support group meetings to encourage participants to try new diet foods and consequently, to displace cooking old recipes with new Instinct Diet recipes. Self-monitoring of daily home weights was also encouraged and collected as a measure to increase awareness of eating patterns and to provide study staff with insight into participants' barriers to weight loss.

***Behavioral framework:*** Combined elements from 2 leading health behavior theories; Social Cognitive Theory (SCT) [9] and Cognitive Behavioral Theory (CBT) [10] were the basis of the intervention. SCT is an important paradigm in weight management interventions and explains behavior change in terms of reciprocal determinism between

the participant's behavior, personal factors and the environment. SCT also acknowledges both the importance of observational learning and raising self-efficacy for specific behavior changes through incremental mastery exercises. CBT focuses on factors such as the learning and unlearning of individual behaviors through cognitive restructuring and, thus, provides complementary intervention components to SCT. The SCT and CBT components used in the conduct of groups and presentation of education materials to support goals for changing energy intake, macronutrient intakes and energy expenditure included skill development, self-efficacy, self-monitoring, observational learning from peers and role model, problem solving including stimulus control, cognitive restructuring for food cravings, realistic goal setting, social support and reinforcement

#### **Activities at Control Worksites**

The 2 wait-listed control worksites received no intervention during the 6-month study period when they were being assessed as a control group. However, the Tufts research team held 2 meetings with the worksites to maintain contact during the 6-month study period. At the end of 6 months, employees at the wait-listed control sites received a 2-month structured intervention that aimed to provide all of the resources and materials given to the intervention worksite during the study period. For employees interested in losing weight, weight loss support groups were offered in a 2-month condensed format and included most of the material used in the support group modules at the intervention sites. Content from the nutrition newsletters, flyers, and lunch seminars carried out in the 2 intervention sites were also included in this 2-month intervention at the wait-listed control worksites. Most importantly, the 2-month intervention was designed to limit drop-out rates in the control worksites prior to completion of the 6-month study period.

## **Data Collection Procedures**

An overview of outcome assessments and the time-points are outlined in Appendix E. All questionnaires were administered online. At baseline, a demographic questionnaire was executed to collect standard information including date of birth, sex, ethnicity, race, marital status, job position, educational level, and household income (see Appendix F). The following questionnaires were administered online at baseline and at 6 months in both the intervention and control participants, with an additional time point at 2.5 months in the intervention participants.

***Eating Behavior:*** Eating behavior was measured by the 51-item Eating Inventory (previously known as the three factor eating questionnaire or TFEQ) [11]. Within this questionnaire, three sets of questions are used to calculate cognitive restraint (21 items to assess conscious attempts to monitor and regulate intake, scale 0-21); disinhibition (16 items to assess disruption of eating in response to cognitive or emotional cues, scale 0-16); and hunger (14 items to assess feeling and perception of hunger, scale 0-14). The scale consists of 36 true/false items and 15 forced-choice format questions. Higher scores reflect a proportionately greater tendency to exhibit that particular eating behavior characteristic. The Eating Inventory is a valid and reliable instrument [11] and has been successfully used online [12]. Since the development of the questionnaire, subscales for each of the three constructs have also been proposed [13]. Subscales for restraint include strategic dieting behavior (behaviors that might be used to control weight, e.g. deliberately taking small helpings), attitude to self-regulation (overarching perspective on eating and weight control) and avoidance of fattening foods (dieting behavior which limits calorie-dense foods). Disinhibition subscales include habitual susceptibility

(recurrent disinhibition triggered by routine circumstance)s, emotional susceptibility (associated with negative affective states) and situational susceptibility (disinhibition initiated by specific environmental cues e.g. social occasions). Subscales for hunger include internal locus of hunger (hunger that is interpreted and regulated internally) and external locus of hunger (hunger that is triggered by external cues). The investigation of these subscales is relevant since it may provide a more detailed understanding of eating behaviors [14], and all scales and subscales were analyzed in this study. A description and scoring of these constructs and subscales are presented in Appendix G and Appendix H respectively.

**Cravings:** Cravings were measured using the Food Craving Questionnaire (FCQ) and Food Craving Inventory (FCI). Both, FCQ [15, 16] and FCI [17] are shown to be reliable and valid instruments for food cravings. These instruments are robust and generally recognized as the best measures of food cravings currently available [18]. The FCQ assesses 9 trait (general susceptibility to craving) and 5 state (strength of craving at the moment of administration) dimensions of food craving using a 39-item and 15-item scale respectively. FCQ-T (see Appendix I) asks participants how frequently each of the 39 statements “would be true for you in general” using a 6-point scale ranging from 1 (*never or not applicable*) to 6 (*always*). The nine scales of the FCQ-T measure cravings experienced as or associated with (1) Intentions and planning to consume food, (2) Anticipation of positive reinforcement, (3) Anticipation of relief from negative state, (4) Lack of control over eating, (5) Preoccupation with food, (6) Feelings of hunger, (7) Negative-affect or emotions experienced before or during cravings, (8) Cue-dependent eating (9) Guilt from cravings. For the FCQ-S (see Appendix J), participants indicate the

extent to which they agreed with each of the 15 statements “right now, at this very moment” using a 5-point Likert-type scale ranging from 1 (*strongly agree*) to 5 (*strongly disagree*). The five factors or scales of the FCQ-S include (1) An intense desire to eat, (2) Anticipation of positive reinforcement, (3) Anticipation of relief from negative states and feelings, (4) Lack of control over eating, and (5) Feelings of hunger [15]. The FCI [19] (see Appendix K) is a 28-item self administered assessment for capturing subjective experience of specific food craving across 28 different foods. Consisting of four scales (high fats, sweets, carbohydrates/starches and fast food fats); the FCI assesses the frequency of an individual experiencing a craving for a particular food.

***Weight Self Efficacy (WSE):*** Self-efficacy related to eating behaviors and weight loss was measured with the 20-item Weight Efficacy Lifestyle Questionnaire (WEL) [20] (see Appendix L). This scale has respondents rate their confidence to resist eating in certain situations on a scale ranging from 0 (not confident) to 9 (very confident). In addition to a global WEL score, the WEL includes 5 situational subscales; availability (eating when high-calorie food is readily available), negative emotions (eating when feeling nervous, depressed or irritable), social pressure (eating when others are encouraging food consumption), physical discomfort (eating when having a headache or other bodily pain) and positive activities (eating when watching television). Each subscale consists of 4 items with higher scores indicating higher confidence levels and a possible score of 36 points with a total of up to 180 points for the global WSE score. Internal consistency of the WEL subscales has ranged from 0.70 to 0.90 and the five subscales have shown significant inter-correlations with each other ( $r$  values ranging from 0.39 to 0.66), suggesting that these components are part of a global construct of

weight self-efficacy. Further, external validity of the WEL has also been supported, as changes in WEL scores have been observed during obesity treatment [21-23].

***Quality of Life (QOL):*** QOL was assessed using WHOQOL-BREF which is a 26-item abbreviation of the WHOQOL-100 (see Appendix M). This questionnaire measures four domains – physical, psychological, social and environmental and has shown to display good validity and reliability [24-26]. Each of the 4 domains (physical, psychological, social and environmental) has a possible score ranged between 0 (poor QOL) and 20 (excellent QOL). The physical domain has questions related to daily activities such as, pain and discomfort, sleep and rest, energy and fatigue and mobility and work. In the psychological domain, there are questions of positive and negative feelings, meaning of life, self-esteem, body image and physical appearance, personal beliefs and ability to concentrate. The social relationship domain is related to personal relationships, social support and sexual activity. The environmental domain explores physical security and safety, financial resources, physical environment, home environment, health and social care and their availability, leisure activities, opportunities for acquiring new information and skills and participation in and opportunities for recreation and transport. In addition to the 4 domains, the questionnaire also consists of 2 stand alone questions on the overall perception of QOL and the overall perception of health.

***Intervention feedback survey:*** In addition to the validated questionnaires, an intervention specific feedback questionnaire requesting participant rating of the various programmatic components of our new worksite weight loss intervention was developed (see Appendix N) and administered at the end of the 6 month intervention period. The

feedback questionnaire consisted of 40 statements on a scale of 1 (strongly disagree) to 10 (strongly agree) that were broadly categorized into 4 programmatic components; book, group session, menus and self monitoring. The questionnaire also included a few open ended question on overall effectiveness of the program.

***Attendance and Adherence:*** Attendance was recorded at each support group meeting and each individual's percent attendance for the 6-month intervention period was calculated. Percent weight self monitoring (percent of weekly weight self-monitoring data sent on request to the counselor for review) was also calculated.

***Weight:*** Body weight of subjects was measured in non-fasting conditions, while wearing light clothing and no outdoor shoes (UC-321PL Precision Health Scale, A&D Medical). The same scales were used for all outcome measurements at each worksite.

***Height:*** Height was measured only at baseline, using a portable stadiometer according to the standard techniques adopted for all our previous studies (Model HM200P, Portstad Portable Stadiometer; Quick Medical, Washington) [27].

When the questionnaires were returned with some missing data we used a previously developed algorithm for calculating proportional scores of scales and subscales [28]. Specifically when <15% of the scale's questions were unanswered, proportional scales were calculated, while when >15% of the scale's questions were unanswered, a score was not calculated and data for the particular construct or subscale was set to missing. As a result of this adjustment, the sample size for subscales varied between 71 and 74 subjects for the intervention group and between 19 and 21 subjects for the control group.

## Statistical Analyses

This study is a group randomized study and comparisons are presented for participants enrolled in the weight loss program at the 2 intervention sites vs. those enrolled in the wait-listed weight loss program at the 2 control sites. Analyses were performed using SAS version 9.2 (SAS Institute, Inc., North Carolina) and statistical significance for all variables was set at a 2-sided P value of  $< .05$ . Comparisons of baseline differences between the intervention and control groups were made using Students t-test for independent samples for continuous variables and Fisher exact test for categorical variables.

*Between group analysis:* The HWLP is a group randomized study, however between group analyses presented here treat individuals and sites as fixed factors. The impact of the intervention on behavioral variables was assessed by comparing mean change in scores between the intervention and control participants by ANCOVA models controlling for age, sex and baseline values of the respective variable. The same set of models was run with an additional covariate where worksite was nested within group.

*Within group analysis:* Pearson correlation coefficients between weight change and behavioral variables were not significant for participants in the control group hence these analyses are restricted to participants in the intervention group. Pearson correlation coefficients were generated for baseline and change scores in relation to change in weight for participants in the intervention group. Fisher's z transformation was used to assess site differences in the Pearson correlation coefficients of the 2 intervention sites. We investigated association of both baseline and change scores of the behavioral variables with weight change ( $\text{Weight}_{6 \text{ months}} - \text{Weight}_{\text{baseline}}$ ) by multiple regressions. To focus on

behavioral variables as correlates of weight change beyond the contribution attributable to gender, initial weight and age, these three variables were forced into all regression models. Additionally, worksite as a covariate was also included to adjust for site to site variability in all regression models.

### **Adequacy of Protection Against Risks**

Data collected from employees throughout the study was not shared with employers and remained offsite at Tufts University's Jean Mayer Human Nutrition Research Center on Aging (HNRCA). Subjects were provided with a private ID that was only shared with the study research coordinators when filling out the web-based screening questionnaires. Paper-based study case report forms contained only study ID numbers (no names). The link between the participant's names and study ID was kept in an individual file at the HNRCA-Nutrition Center, and this information remained locked. Subjects' identity will not be revealed in any publication that may result from this study. Any participant-specific data reported to study leadership was identified only by the study ID number.

The Study Physician was responsible for monitoring study safety and serious adverse events and their likely relatedness to participation in the support group component of the study at intervention and wait-listed control sites. Subjects were asked if they had been hospitalized within the last 6 months at baseline (pre-intervention) and then at the end of the intervention. Those who were hospitalized during the study were asked to obtain their medical records for independent review by the Study Physician to assess the relationship of the study protocol to the event.

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## CHAPTER 4

### **Eating behaviors as correlates of weight loss in a 6 month worksite weight loss intervention**

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## Abstract

The eating behaviors restraint and disinhibition have been suggested to predict weight loss but there is no information on whether these predictors are valid in worksite weight loss programs, which are increasingly being recommended for reducing the obesity epidemic. This study examined associations between eating behavior constructs and weight change in a 6-month worksite weight loss intervention. A worksite group-randomized controlled trial of a group behavioral weight loss intervention versus wait-listed control was conducted at 4 worksites and comparisons were made between participants at the intervention sites versus control sites. Measures included body weight and the eating behavior constructs restraint, disinhibition, hunger and sub-constructs as determined with the Eating Inventory. In addition, rates of intervention meeting attendance and weight self-monitoring were quantified. Weight change was greater in the intervention group than controls ( $\Delta I = -8.1 \pm 6.8$ ,  $\Delta C = +0.9 \pm 3.6$ ,  $p < 0.001$ ). Between-group analyses showed that the intervention was associated with increased restraint ( $\Delta I = 5.43 \pm 4.25$ ,  $\Delta C = 0.29 \pm 3.80$ ,  $p < 0.001$ ), decreased disinhibition ( $\Delta I = -2.5 \pm 3.63$ ,  $\Delta C = 0.66 \pm 1.85$ ,  $p < 0.001$ ) and decreased hunger ( $\Delta I = -2.79 \pm 3.13$ ,  $\Delta C = 0.56 \pm 2.63$ ,  $p < 0.001$ ) and significant changes in all eating behavior subscales as compared to the control group. Within the intervention group, weight change was significantly correlated with baseline hunger ( $r = -0.25$ ,  $p = 0.03$ ), increased restraint ( $r = -0.35$ ,  $p = 0.001$ ), decreased disinhibition ( $r = 0.26$ ,  $p = 0.02$ ) and decreased hunger ( $r = 0.36$ ,  $p = 0.001$ ). However, in a multiple regression model including rates of meeting attendance and self-monitoring, hunger was the only significant eating behavior construct that associated with weight change. In conclusion, decreased hunger, rather than restraint or disinhibition, showed

significant associations with weight change in this worksite study with relatively high mean weight change. Further studies are needed to confirm the central role of hunger control in successful weight loss.

**Trial Registration** clinicaltrials.gov Identifier: [NCT01470222](https://clinicaltrials.gov/ct2/show/study/NCT01470222)

## **Introduction**

Overweight and obesity remain at epidemic levels and are associated with increased morbidity and mortality (1) as well as increased health care costs (2). Behavioral or lifestyle interventions are recommended for weight loss in obese individuals, but the widely-suggested goal of 5-10% weight loss to achieve significant health benefits (3) is not routinely achieved even in intensive weight loss intervention studies (4). Identifying individual baseline characteristics and behavior changes that correlate with more successful weight loss in different types of interventions could potentially inform the development of more effective and sustainable interventions for weight control (5, 6).

Previous studies have investigated eating behaviors and/or program adherence variables that predict short- and long- term weight loss over 4 to 24 months in several environments such as research studies (7-9), clinic-based diets (6, 10, 11) and community programs (12, 13). Most of the studies have shown that the amount of lost weight is associated with higher baseline restraint and lower baseline disinhibition. In addition, greater increases in restraint and/or greater decreases in disinhibition over time were typically associated with greater weight loss in interventions that emphasized behavior changes relating to increased restraint and decreased disinhibition (7, 9). However, to date, there have been no studies examining predictors of weight loss in worksite weight loss interventions, although worksites are increasingly being suggested for weight management interventions to reduce the national obesity epidemic (14, 15).

As part of a new weight loss intervention in worksites we examined predictors of weight change that have been reported to be significant in non-worksite trials, including baseline and change scores for eating behavior constructs and sub-constructs determined

using the Eating Inventory (16, 17), weight self-monitoring (18, 19) and rates of meeting attendance (6, 8, 13).

## **Methods and procedures**

### *Participants and procedures*

The Healthy Weight for Life (HWL) study was a 6-month randomized controlled trial of a new worksite weight loss intervention. Change in weight was the primary outcome and changes in behavioral and psychological factors were included as secondary outcomes. Four worksites in the Greater Boston area with 100-1200 employees were recruited for the study. The worksites were identified through a multi-stage screening process and eligibility of sites was defined as the absence of a formal onsite weight loss program during the previous 6 months, accessibility by public transportation, employee interest in participating in one or more program components as gauged by an online survey, and adequate infrastructure and logistical support from Human Resources. The companies enrolled in the study were broadly categorized as for-profit (2 sites) and non-profit (2 sites) office-based companies. After obtaining agreement from each of the worksites, employees were invited to enroll in a cost-free weight loss program, which would be a 6-month program beginning immediately after baseline assessments if their worksite was randomized to the intervention arm (2 sites) or a 2-month intervention starting after the main 6-month study period if their worksite was randomized to the wait-listed control arm (2 sites). The wait listed control sites completed outcome assessments during the main 6-month study period. The intervention program provided to intervention worksites was based on a published book (20). The eligibility criteria for employees to enroll in the

weight loss program were interest in participating, BMI during screening  $\geq 25$  kg/m<sup>2</sup>, age  $\geq 21$  years, and a written clearance for participation in the study from their primary care physician.

Baseline outcome assessments were obtained prior to worksite-level randomization to either intervention or control. For the randomization, one number was assigned to each worksite and a random order of the numbers was generated (SAS 9.2, SAS Institute, Inc, Cary, North Carolina). The first two numbers in the output were assigned to the intervention and the second two were assigned to the control.

Employees who enrolled in the weight loss program at the intervention sites received a lifestyle intervention program with the goal of reducing energy intake sufficient to achieve a weight loss of 0.5-1.0 kg/week. Groups of up to 20 employees met with their interventionist weekly for the first 15 weeks and then semi-monthly for the remainder of the 6 month program with a total of 19 possible group meetings that could be attended. These group meetings included an educational component as well as providing a forum for discussion and social support. Caloric restriction was based on the participant's baseline weight. Dietary advice was menu-based and designed to facilitate the preparation of portion controlled meals that were low in glycemic load and containing  $\geq 40$  g/day dietary fiber. Macronutrient targets were 26% protein, 26% fat and 48% low glycemic index carbohydrate (21). All macronutrient recommendations were within Acceptable Macronutrient Distribution Ranges of the Dietary Reference Intakes (22) and dietary fiber was higher than its Recommended Dietary Allowance (23). Hunger management and craving control were emphasized, and examples of practical behavior changes facilitated by the program included meal planning, grocery shopping, social

support, differentiating between hunger and non-hunger stimuli, promoting dietary restraint and decreasing disinhibition, hunger, cravings and practical strategies for social situations such as holiday eating and restaurant eating. Self-monitoring of daily home weights, and food intake using food logs on an as-needed basis, was also encouraged. Group meetings were led by nutritionists with experience in lifestyle approaches to weight control.

Control sites received no intervention during the 6 month study period. To facilitate participant retention, informal social events that did not involve discussions on nutrition or weight control were hosted by the study team.

### *Measures*

**Weight and Height:** Weight was measured in the non-fasting state while subjects were wearing light clothing and indoor shoes. Measurements were made at baseline and at 6 months in both groups and also at 2.5 months in the intervention group. A calibrated digital scale was used at each time-point (UC-321PL Precision Health Scale, A&D Medical; San Jose, California) at all sites and two measurements that were within 2% were obtained. Height was measured on a single occasion during the study period using a portable stadiometer (Model HM200P, Portstad Portable Stadiometer; Quick Medical, Washington).

**Online Questionnaires:** These were administered for demographics and eating behaviors at baseline and for eating behaviors also at 6 months in both the intervention and control participants, with an additional time point at 2.5 months in the intervention participants.

Eating behavior was measured by using the 51-item Eating Inventory (previously known as the three factor eating questionnaire or TFEQ) (16). Within this questionnaire, three sets of questions are used to calculate cognitive restraint (21 items to assess conscious attempts to monitor and regulate intake, scale 0-21); disinhibition (16 items to assess disruption of eating in response to cognitive or emotional cues, scale 0-16); and hunger (14 items to assess feeling and perception of hunger, scale 0-14). The scale consists of 36 true/false items and 15 forced-choice format questions. Higher scores reflect a proportionately greater tendency to exhibit that particular eating behavior characteristic. The Eating Inventory is a valid and reliable instrument (16) and has been successfully used online (24). Since the development of the questionnaire, subscales for each of the three constructs have also been proposed (17). Subscales for restraint include strategic dieting behavior (behaviors that might be used to control weight e.g. deliberately taking small helpings), attitude to self-regulation (overarching perspective on eating and weight control) and avoidance of fattening foods (dieting behavior which limits calorie-dense foods). Disinhibition subscales include habitual susceptibility (recurrent disinhibition triggered by routine circumstances, emotional susceptibility (associated with negative affective states) and situational susceptibility (disinhibition initiated by specific environmental cues e.g. social occasions). Subscales for hunger include internal locus of hunger (hunger that is interpreted and regulated internally) and external locus of hunger (hunger that is triggered by external cues). The investigation of these subscales is relevant since it may provide a more detailed understanding of eating behaviors (25), and all scales and subscales were analyzed in this study. When the Eating Inventory questionnaire was returned with some missing data we used a previously developed

algorithm for calculating proportional scores of scales and subscales (26). Specifically when <15% of the scale's questions were unanswered, proportional scales were calculated, while when >15% of the scale's questions were unanswered, a score was not calculated and data for the particular construct or subscale was set to missing. As a result of this adjustment, the sample size for subscales varied between 71 and 74 subjects for the intervention participants and between 19 and 21 between the control participants.

Attendance and Adherence: Attendance was recorded at each support group meeting and each individual's percent attendance for the 6-month intervention period was calculated. Percent weight self monitoring (percent of weekly weight self-monitoring data sent on request to the counselor for review) was also calculated.

### *Statistical Analyses*

Comparisons in this study are for participants at the intervention sites vs. those enrolled in the wait-listed weight loss program at the control sites. Although this is a group randomized trial, the analyses treated individuals and sites as fixed factors and are of an exploratory nature. Analyses were performed using SAS version 9.2 (SAS Institute, Inc., North Carolina) and statistical significance for all variables was set at a 2-sided P value of < .05. Comparisons of baseline differences between the intervention and control groups were made using Student's t-test for independent samples for continuous variables and Fisher exact test for categorical variables. The impact of the intervention on constructs measured by the Eating Inventory was assessed by comparing mean change in scores of these variables between the intervention and control participants by ANCOVA

models controlling for age, sex and baseline values. The same sets of models were run accounting for differences by worksite within each group. Pearson correlation coefficients were generated for baseline and change scores in relation to change in weight. Fisher's z transformation was used to assess site differences in the Pearson correlation coefficients. We investigated association of both baseline and change scores of the Eating Inventory variables as well as attendance and adherence with weight change ( $\text{Weight}_{6 \text{ months}} - \text{Weight}_{\text{baseline}}$ ) by multiple regressions, with overall models per construct and individual models of the sub-scales within each construct. To focus on eating behavior, attendance and adherence as correlates of weight change beyond the contribution attributable to gender, initial weight and age, these three variables were forced into all regression models. Additionally, worksite as a covariate was also included to adjust for site to site variability. "All Possible Regressions" was used to derive the best fitting overall model.

## **Results**

Baseline and 6 month measurements were completed by 89.4% of participants (84 out of 94) at the intervention sites and 87.2% (34 out of 39) at the control sites. Reasons stated for not completing the trial included time conflicts (n=7), change in job (n=3), lost to follow-up (n=3) and drop out for unrelated health issues (n=2). **Table 1** summarizes the baseline demographics for intervention participants who completed online questionnaires at all time points (n=74 intervention and n=21 controls). At baseline, there were no statistically significant differences in weight, BMI, age, or other demographic or behavioral variables between the intervention and control participants.

Please note, this study is a group randomized study and comparisons are presented for participants enrolled in the weight loss program at the 2 intervention sites vs. those enrolled in the wait-listed weight loss program at the 2 control sites. Additional analyses are also presented when accounting for the group randomized nature of the study. **Table 2** shows the eating behavior and body weight values at baseline and 6 months for intervention and control groups. Mean weight change (Mean±SD) for individuals in this study during the 6 month was  $-8.1\pm 6.8$  kg in intervention participants and  $+0.9\pm 3.6$  kg in control participants. Intervention vs. control differences analyzed by ANCOVA controlling for the baseline scores, age and sex showed that there were significant increases in dietary restraint and subscales for dietary restraint, and decreases in disinhibition, hunger and subscales for these constructs in the weight loss groups in the intervention sites compared to the wait-listed controls. When ANCOVA models included worksite within group as a variable in the model, strategic dieting behavior-restraint, attitude to self regulation-restraint, hunger and internal and external loci of hunger retained significance.

***Correlations between weight change and eating behavior constructs:***

Baseline scores for hunger and both external and internal loci of hunger, showed significant correlations with weight change such that higher scores on hunger at baseline correlated with greater subsequent weight change (**Table 3**). Change in weight was also strongly associated with increased total restraint and subscales of restraint, as well as decrease in disinhibition and habitual susceptibility to disinhibition, a decrease in hunger and subscales, and attendance and weight self monitoring. Since weight change

represents a negative change in weight, negative correlations in **Table 3** represent positive relationships between change in the variable and weight change. The significant correlations were in the range of 0.21 to 0.46 which are considered moderate to strong associations for behavioral variables (27). The correlations between eating behavior constructs and weight change were not significantly different between the 2 intervention sites. Results from within-group multiple regressions are presented below, all models were adjusted for baseline weight, gender, age and worksite.

***Models for baseline eating behaviors as predictors of weight change:*** In a model containing baseline scores of restraint, disinhibition and hunger, only baseline hunger scores predicted greater weight change ( $R^2=0.39$ ,  $p=0.0356$ ) (**Table 4**) and participants who scored lower on baseline scores of hunger ( $R^2=0.39$ ,  $p=0.01$ ), internal locus of hunger ( $R^2=0.38$ ,  $p=0.024$ ) and external locus of hunger ( $R^2=0.38$ ,  $p=0.023$ ) lost more weight subsequently over 0-6 months. When separated into early (0-3 months) and late (3-6 months) study periods, reduction in the internal locus of hunger was a significant correlate for early weight change (0-3 months) and reduction in the external locus of hunger was a significant correlate for later weight change (3-6 months) (data not shown).

***Models for association between change in eating behavior and weight change:*** In a model containing scores for changes in restraint, disinhibition and hunger, only decrease in hunger was significantly associated with weight change ( $R^2=0.43$ ,  $p=0.018$ ) (**Table 4**). Decrease in hunger ( $R^2=0.42$ ,  $p=0.002$ ), internal locus of hunger ( $R^2=0.37$ ,  $p=0.038$ ) and

external locus of hunger ( $R^2=0.40$ ,  $p=0.006$ ), were all significantly associated with weight change over six months (**Figure 1**).

***Attendance and self monitoring:*** The mean attendance at group meetings was  $83.8\pm 15.2\%$  for participants at the intervention sites during the 6-month intervention. Over the course of the intervention, participants submitted weekly weight self monitoring logs  $76.8\pm 23.7\%$  of time. As shown in Table 3, both attendance and weight self monitoring correlated with weight change and remained significant in a multiple linear regression model. Together attendance ( $p=0.003$ ) and self monitoring ( $p=0.029$ ) accounted for 51% of the variability in weight change (**Table 4**).

***Combination model:*** We ran all possible regressions starting with the changes in eating behavior and adherence measures that showed a significant correlation with weight change (Table 3). The two competing models were a 4 variable model (reduced hunger, increased restraint, % attendance and % self monitoring) and a 3 variable model (reduced hunger, % attendance and % self monitoring). In the 4 variable model, increased restraint did not have a significant coefficient and when it was dropped, there was no drop in the adjusted  $R^2$ . The final overall model, the 3 variable model, is presented in **Table 4**. As shown, reductions in hunger, high attendance and high self monitoring together accounted for 57% variability in weight change.

## **Discussion**

This study examined the effects of a 6 month worksite weight loss intervention on eating behavior and measures of program adherence, and evaluated these variables as correlates of weight change over time. As anticipated based on previous reports (6, 8, 13, 18, 19, 28, 29), a higher frequency of self-monitoring and a higher frequency of group meeting attendance were significant correlates of weight change. In addition, and in contrast to most previous studies evaluating eating behavior variables as correlates of weight change, we identified a decrease in hunger as a significant correlate of successful weight change. Specifically among the constructs captured by the Eating Inventory we found that only low hunger at baseline and a decrease in hunger during the intervention were significant predictors of the magnitude of weight change when all eating behavior variables were included in the same model. This finding that hunger is significantly associated with success both at baseline and change over time has implications for the design of interventions for weight control in worksites and potentially other settings. In particular these findings suggest that prioritization of hunger suppression during weight change may improve weight loss and further studies are needed to address this suggestion.

Changes in eating behavior variables have been shown to accompany intentional weight loss in several studies (7, 12, 29-31), but most previous investigations have shown significant associations between weight change and increased restraint and/or decreased disinhibition (7, 9, 11, 12, 30) and have not demonstrated significant associations of weight change with change in hunger. Similarly, high restraint at baseline has also been reported as a significant predictor of weight change (7, 12) and high baseline hunger has not predicted weight change. In our analysis, consistent with the previous studies we

found an increase in restraint and a decrease in disinhibition with weight change, and these changes were correlated with weight change. However, in multiple regression models including all eating behavior variables, the only eating behaviors construct that significantly correlated with weight change was change in hunger, and the change scores for disinhibition and restraint were not significant. These findings are consistent with one previous report of low baseline hunger predicting successful weight change in a research setting (32) and one report of decreases in hunger showing associations with weight change (33) but most studies have found no association between hunger and weight change (7, 9, 34-36). The reasons for why hunger was a more significant correlate of weight change in this study is not known but several possibilities may be relevant. In particular, this study achieved greater mean weight loss than is typical in weight loss interventions, which must have entailed longer periods and/or a greater magnitude of negative energy balance. Since hunger is a negative sensation typically leading to food consumption (37), participants who had the greatest decrease in hunger may well have been the ones who were able to withstand negative energy balance for a more sustained period of time. This hypothesis is consistent with previous reports of associations between low hunger scores on TFEQ and low reported energy intake (38). Alternatively, this finding could be unique to this study since the intervention had several components designed to manage hunger and enhance satiety. Factors such as dietary composition, meal timing and high fiber intake were specifically combined and translated in a practical menu based approach to manage hunger on a negative energy balance. It is also possible that the social support from fellow employees participating in the same intervention encouraged adherence to the intervention such as bringing program compatible meals to

work instead of eating out. The reasons for the relatively large weight loss in this trial is not known, but may be related to the specific features of the intervention or the use of specific types of worksites. Further trials are needed to examine both the extent to which reduced hunger is an important feature of interventions with relatively large weight loss and the relationship between hunger and weight change.

This study was also the first to examine subscales of eating behavior constructs as predictors of weight change in a worksite setting. Both the internal locus of hunger and the external locus of hunger significantly correlated with weight loss from 0-6 months, and when separated into early (0-3) and late (3-6) month study periods, reduction in internal locus of hunger was a significant correlate for early weight loss (0-3 months) and reduction in external locus of hunger was a significant correlate for later weight loss (3-6 months). These results suggest the potential importance of managing the internal locus of hunger, i.e. hunger that is interpreted and regulated internally, early on in a weight management program followed by managing hunger that is triggered by external cues for subsequent sustainability of weight loss.

There are several strengths and potential limitations in this study. A particular strength of this randomized controlled trial was that 89% of the participants were retained in the intervention through the 6 month study period. An additional strength was the considerable variation in weight change (+1.36 to -35.5 kg), providing a suitable dataset for studying correlates of weight change. One limitation of the current study is that it was a group-randomized pilot study that was not powered for weight change when a site effect was included. However, we did control for site effects in our regression analysis, to account for the fact that employees at any given site were exposed to the same

intervention, and obtained significance. Although including site as a covariate inflates our  $R^2$  as compared to similar eating inventory models by previous investigators, hunger continues to be the only significant correlate and the overall  $R^2$  higher than a similar model in the literature (9). The large number of regression models may have increased Type I error but all significant associations were strong and in the expected direction, providing additional suggestive evidence that the observed relationships are not due to chance alone.

In conclusion, this evaluation of eating behavior and adherence in a worksite weight management program provides data suggesting that hunger management is an important factor contributing to successful weight loss. The study also found that the eating behavior constructs restraint and disinhibition, which have previously been suggested to predict weight change, were not significant in this worksite weight loss intervention when included in multiple regression models with hunger. Further examination of the role of hunger control in successful weight management is warranted because these results suggest that greater focus on hunger management could lead to improved effectiveness of weight loss interventions specifically in worksites, and perhaps also in other settings.

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### **Disclosure statement**

All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and 1 author reported a disclosure.

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<b>Table 1: Baseline characteristics</b>		
	<b>Intervention</b>	<b>Control</b>
	<b>n=74</b>	<b>n=21</b>
	<b>Mean <math>\pm</math> SD</b>	<b>Mean <math>\pm</math> SD</b>
Age	49.09 $\pm$ 10.12	49.84 $\pm$ 10.98
Height (cms)	167.77 $\pm$ 9.68	163.25 $\pm$ 7.50
Weight (kg)	94.51 $\pm$ 21.93	92.91 $\pm$ 22.41
BMI (kg/m <sup>2</sup> )	33.48 $\pm$ 6.47	33.12 $\pm$ 6.61
Gender		
Male, n (%)	20 (27)	3 (14)
Female n (%)	54 (73)	18 (86)

**Table 2:** Changes in Eating Inventory constructs for control and intervention groups

	Intervention n=74				Control n=21				Between group difference for change over time  p
	Baseline		6-month		Baseline		6-month		
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Weight (kg)	94.51	± 21.93	85.93	± 19.28	91.59	± 24.41	92.54	± 26.93	<0.0001
<b>Eating Inventory</b>									
Restraint (0-21)	8.96	± 4.02	14.39	± 3.24	8.74	± 5.52	9.02	± 5.37	<0.0001 <sup>a</sup>
Strategic dieting behavior	1.27	± 1.25	2.32	± 1.32	1	± 1.45	1.44	± 1.16	0.0214
Attitude to self regulation	2.43	± 1.22	3.97	± 1.05	2.381	± 1.47	2.36	± 1.68	<0.0001 <sup>a</sup>
Avoidance of fatty foods	2.45	± 1.10	3.66	± 0.65	2.746	± 1.34	2.46	± 1.44	<0.0001
Disinhibition (0-16)	8.78	± 4.22	6.27	± 3.14	8.932	± 4.25	9.59	± 4.37	<0.0001
Habitual susceptibility	2.19	± 1.73	1.34	± 1.06	2.333	± 1.46	2.73	± 1.84	<0.0001
Emotional susceptibility	1.58	± 1.25	0.87	± 1.06	1.684	± 1.34	1.52	± 1.29	0.0039
Situational susceptibility	3.11	± 1.63	2.17	± 1.48	2.952	± 1.72	3.05	± 1.60	0.0018
Hunger (0-14)	6.35	± 3.59	3.55	± 2.75	5.667	± 3.48	6.23	± 3.68	<0.0001 <sup>b</sup>
Internal locus for hunger	2.32	± 1.94	1.04	± 1.40	2.143	± 1.82	2.44	± 2.06	<0.0001 <sup>a</sup>
External locus for hunger	2.21	± 1.42	1.15	± 1.23	1.714	± 1.42	2.33	± 1.71	<0.0001 <sup>a</sup>

Between group differences measured by GLM (general linear model) adjusting for baseline score of the variable, age and sex.

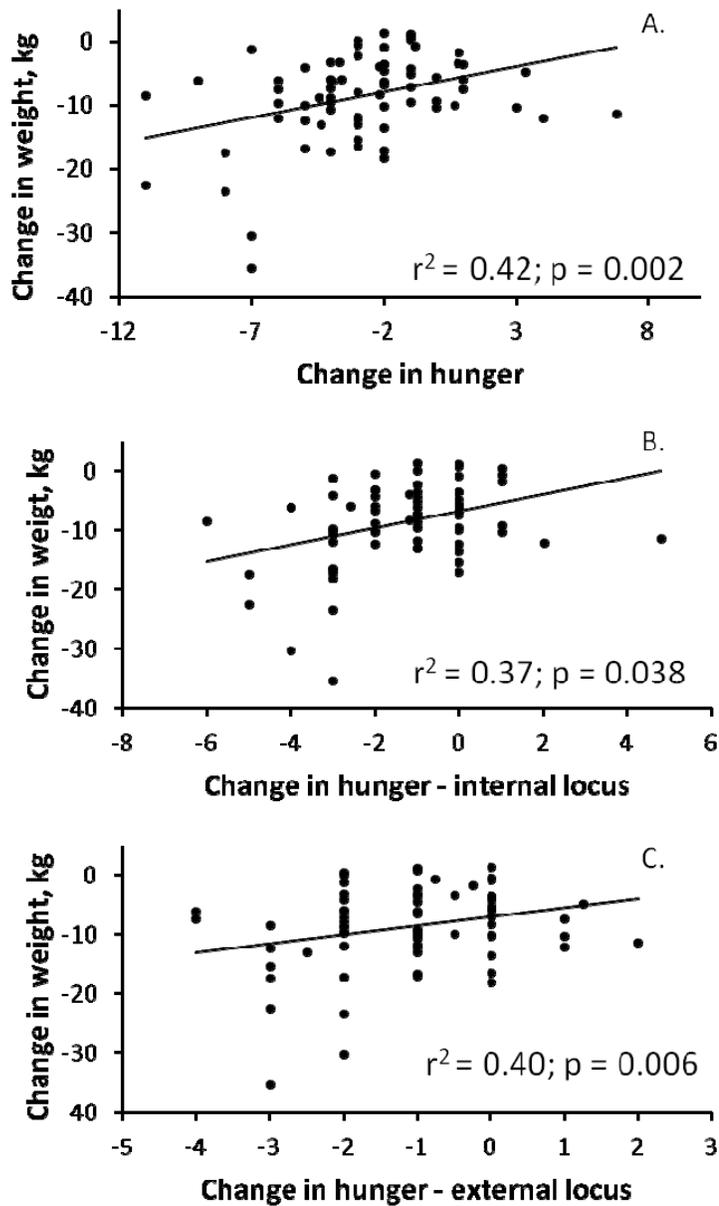
Superscripted p values are presented for models including a nested (worksite within group) covariate; <sup>a</sup> p<0.05, <sup>b</sup> p<0.01

<b>Table 3:</b> Pearson correlations between weight change and baseline and 6 month changes in Eating Inventory variables			
	Baseline		Change
	r		score
	r		r
<b>Eating Inventory</b>			
Restraint	0.146		-0.359 <sup>b</sup>
Strategic dieting behavior	0.148		-0.373 <sup>b</sup>
Attitude to self regulation	0.011		-0.235 <sup>a</sup>
Avoidance of fatty foods	0.156		-0.222
Disinhibition	-0.187		0.266 <sup>a</sup>
Habitual susceptibility	-0.157		0.235 <sup>a</sup>
Emotional susceptibility	-0.124		0.203
Situational susceptibility	-0.147		0.189
Hunger	-0.251	<sup>a</sup>	0.362 <sup>b</sup>
Internal locus for hunger	-0.237	<sup>a</sup>	0.359 <sup>b</sup>
External locus for hunger	-0.208	<sup>a</sup>	0.265 <sup>a</sup>
<b>Attendance/Adherence</b>			
% Session attendance			-0.403 <sup>c</sup>
% Self monitoring			-0.353 <sup>b</sup>
n=71-74; <sup>a</sup> p<0.05, <sup>b</sup> p<0.01, <sup>c</sup> p<0.001. Change scores for weight and Eating Inventory variables are calculated as 6 month - baseline value.			

**Table 4:** Regression models identifying predictors and correlates of weight change from 0-6 months

	Coefficients			Model Summary		
	Beta $\pm$ SE	t	p	R <sup>2</sup>	adj R <sup>2</sup>	p
<b>Baseline Eating Inventory</b>						
Restraint	-0.04 $\pm$ 0.38	-0.12	0.908	0.39	0.32	<0.0001
Disinhibition	-0.16 $\pm$ 0.42	-0.39	0.696			
Hunger	-1.03 $\pm$ 0.48	-2.14	0.035			
<b>Change in Eating Inventory</b>						
$\Delta$ Restraint	-0.30 $\pm$ 0.38	-0.77	0.443	0.43	0.36	<0.0001
$\Delta$ Disinhibition	0.18 $\pm$ 0.47	0.37	0.710			
$\Delta$ Hunger	1.32 $\pm$ 0.55	2.41	0.018			
<b>Attendance/Adherence</b>						
% Session attendance	-0.28 $\pm$ 0.09	-2.99	0.003	0.51	0.49	<0.0001
% Self monitoring	-0.15 $\pm$ 0.06	-2.22	0.029			
<b>Overall model</b>						
$\Delta$ Hunger	1.39 $\pm$ 0.45	3.05	0.0034	0.57	0.52	<0.0001
% Session attendance	-0.27 $\pm$ 0.10	-2.56	0.0129			
% Self monitoring	-0.17 $\pm$ 0.07	-2.15	0.0161			

n=71-74; all models were adjusted for baseline weight, age, sex and worksite.



**Figure 1:** Relationship between change in Hunger and Weight change; Panel A: Decreases in hunger and weight change over 0-6 months; Panel B: Decreases in internal hunger and weight change over 0-6 months; Panel C: Decreases in external hunger and weight change over 0-6 months.  $n=71-74$ ; Models adjusted for baseline weight, age, sex and site. Change scores for weight and Eating Inventory variables calculated as 6 month-baseline.

## CHAPTER 5

### **Relationship of cravings with weight loss and hunger: Results from a 6 month worksite weight loss intervention**

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## **Abstract**

We examined the association of food cravings with weight loss and eating behaviors in a 6 month worksite weight loss program. This group-randomized controlled trial of the intervention versus a wait-listed control was conducted at 4 worksites. Analyses presented here include sites and participants as fixed effects and are exploratory in nature. Assessments included non-fasting body weight, food cravings (Craving Inventory and Food Craving Questionnaire for state and trait) and eating behavior (Eating Inventory) and were completed by 95 participants at both baseline and 6 months. There were statistically significant reductions in all craving variables in the intervention group compared to the controls. Within the intervention group, changes in craving-trait were significantly associated with weight change after controlling for baseline weight, age, gender and worksite. However, in a multivariate model with craving-trait and eating behaviors (restraint, disinhibition and hunger), hunger was the only significant predictor of weight change. In contrast to several previous reports of increased food cravings with weight change, this study confirmed a broad reduction in cravings during weight change. In addition, greater reductions in craving-trait were associated with greater weight change, but craving-trait was not a significant independent correlate of weight change when hunger was included in statistical models. Hunger control may directly influence both weight change and food cravings, and studies are needed to examine the effectiveness of hunger suppressing versus craving-suppressing strategies in behavioral obesity treatment.

**Trial Registration** [clinicaltrials.gov](https://clinicaltrials.gov); Identifier: [NCT01470222](https://clinicaltrials.gov/ct2/show/study/NCT01470222)



## **Introduction**

Food cravings are defined as intense desire for specific foods [1, 2] and are experienced by 21-97% of the adult population [3]. Cravings are distinguished from hunger in that they usually focus on individual foods that are high in caloric density [3, 4] whereas the state of hunger can be relieved by a diversity of foods [5] that may differ in caloric density. Furthermore, hunger is an innate phenomenon experienced almost universally by humans and other species [6], whereas cravings are not a universal phenomenon and appear to be more prevalent in specific populations [3]. In particular, the frequency and intensity of food cravings are known to be more prevalent and intense in obese individuals [7, 8] and have been suggested to play an important role in excess energy intake and weight gain [9-11], lack of success in weight loss [10, 12-14] and early drop-out from obesity treatment programs [11, 15, 16]. Currently, however, experimental data to support a causal role for cravings in success at weight loss and weight maintenance is lacking.

The impact of food cravings on the regulation of body weight and obesity remains uncertain. Some recent studies reported increased cravings associated with dieting [12, 17], which supports the suggestion that cravings could be a barrier to weight loss. However, other research found no change in the frequency or intensity of cravings with weight loss [4] and there are also several reports of decreased cravings with weight loss [5, 12, 16, 18, 19]. The sense of deprivation may contribute to accentuation of cravings, and diet plans that restrict specific foods have been associated with increased cravings for restricted foods [2, 20]. In contrast, reduced dietary variety during weight loss has been proposed as one potential mechanism for why cravings can decline during weight loss

[5], other work has suggested the opposite association. Thus, there is no current consensus over whether weight loss is associated with increased or decreased food cravings and whether interventions that successfully decrease in cravings are associated with greater weight loss success on average.

The influence of cravings on intake, and hence on weight control, may be mediated by an intermediary factor such as hunger which is hypothesized to vary between diets based on dietary composition [21-24]. However, there is no consensus over the relationship between hunger and cravings during weight loss. Although food cravings can occur in the absence of hunger [25], several studies show a significant relationship between hunger and food cravings [9, 26, 27]. Other factors such as mood state and operant conditioning influence cravings [14], but do not necessarily invalidate a concomitant craving-hunger relationship [3].

We examined the association between changes in hunger and changes in cravings with weight change in a worksite weight loss intervention that included dietary and behavioral components that were specifically designed to control both cravings and hunger.

## **Methods and procedures**

### **Worksites and Participants**

Study information was mailed to worksites with 100-1200 employees in Greater Boston, Massachusetts. Interested worksites were interviewed to confirm eligibility which

included lack of any onsite weight loss program in the past 6 months, accessibility by public transportation, infrastructure to hold onsite group intervention sessions and a >50% employee response to an online employee interest survey. The first 4 worksites completing all screening requirements were enrolled. The selected worksites were office-based and broadly classified as for-profit (2 sites) and non-profit (2 sites) companies.

Within each site, interested participants were enrolled if age was  $\geq 21$  years, BMI was  $\geq 25.0$  kg/m<sup>2</sup>, were not pregnant, had no medical condition that could influence nutrient absorption or restrict food intake as confirmed in writing by their primary care physician. The study was approved by the Institutional Review Board at Tufts Medical Center (Boston, MA) and all participants provided written informed consent. After baseline outcome assessments, the 4 sites were randomized as intervention sites or wait listed control sites. One worksite in the intervention group was substantially larger than the other worksites resulting in a total employee size of 675 for both intervention sites and 354 for both controls sites. The wait-listed control sites completed outcome assessments during the 6 month period when the intervention sites received the weight loss program. At the end of the 6-month period, the control sites received a 2 month condensed weight loss intervention that employed the same principles as the 6 month intervention.

### **Intervention**

The weight loss intervention was group based and consisted of a lifestyle modification program based on a published book [28]. The goal of the intervention was reducing energy intake to achieve 0.5-1 kg/week weight loss facilitated by use of portion

controlled menus that were low in glycemic load, low in energy density, and contained  $\geq 40$  g/day dietary fiber. Dietary recommendations (26% protein, 26% fat and 48% low glycemic index carbohydrate) were within Acceptable Macronutrient Distribution Ranges of the Dietary Reference Intakes for all macronutrients [29] and dietary fiber were greater than its current Recommended Dietary Allowance [30]. There were a total of up to 19 group sessions (15 consecutive sessions followed by biweekly sessions), each including a 60-minute interactive educational session led by nutritionists with experience in behavior modification. The sessions addressed a variety of topics such as practical ways to reduce energy intake, hunger management and craving management by stimulus control and acceptance-based strategies [10]. Other topics included portion control, self-monitoring, self efficacy, dietary variety, holidays, eating outside the home, social support, goal setting and strategies for weight maintenance. In addition to group sessions, participants received a weekly email from their counselor for individual support.

## **Measures**

Online questionnaires were used to assess demographic data, cravings and eating behaviors. Participants in both the intervention and control sites completed these assessments at baseline and after 6 months.

Food cravings were measured using the Food Craving Questionnaire (FCQ) and Food Craving Inventory (FCI). The reliability and validity of the FCQ [11, 32] and FCI [31] have been confirmed and these instruments are generally recognized as the best measures of food cravings currently available [3]. The FCQ assesses 9 trait (T, general

susceptibility to craving) and 5 state (S, strength of craving at the moment of administration) dimensions of food craving using a 39-item and 15-item scale respectively. FCQ-T asks participants how frequently each of the 39 statements “would be true for you in general” using a 6-point scale ranging from 1 (*never or not applicable*) to 6 (*always*). The nine scales of the FCQ-T measure cravings experienced as or associated with (1) Intentions and planning to consume food, (2) Anticipation of positive reinforcement, (3) Anticipation of relief from negative state, (4) Lack of control over eating, (5) Preoccupation with food, (6) Feelings of hunger, (7) Negative-affect or emotions experienced before or during cravings, (8) Cue-dependent eating (9) Guilt from cravings. For the FCQ-S, participants indicate the extent to which they agreed with each of the 15 statements “right now, at this very moment” using a 5-point Likert-type scale ranging from 1 (*strongly agree*) to 5 (*strongly disagree*). The five factors or scales of the FCQ-S include (1) An intense desire to eat, (2) Anticipation of positive reinforcement, (3) Anticipation of relief from negative states and feelings, (4) Lack of control over eating, and (5) Feelings of hunger [32]. The FCI [8] is a 28-item self administered assessment for capturing subjective experience and frequency of specific food craving across 28 different foods, consisting of four scales (high fats, sweets, carbohydrates/starches and fast food fats).

The Eating Inventory, previously known as the three factor eating questionnaire is a validated 51 item questionnaire [33] that uses three sets of items to calculate cognitive restraint (21 items to assess conscious attempts to monitor and regulate intake); disinhibition (16 items to assess tendency to overeat in response to cognitive or emotional cues); and hunger (14 items to assess feeling and perception of hunger). The scale

consists of 36 true/false items and 15 forced-choice format questions. Higher scores reflect a proportionately greater tendency to exhibit that particular eating behavior characteristic.

Weight was measured in the non-fasting state wearing light clothing and indoor shoes. The same calibrated digital scales were used at each time-point (UC-321PL Precision Health Scale, A&D Medical; San Jose, California) at all sites and two measurements that were within 2% were obtained. Height was measured on a single occasion during the study period using a portable stadiometer (Model HM200P, Portstad Portable Stadiometer; Quick Medical, Washington).

### **Statistical Analyses**

Analyses were performed using SAS version 9.2 (SAS Institute, Inc., North Carolina) and statistical significance for all variables was set at a 2-sided P value of  $< .05$ . This is a group randomized trial however because comparisons are for participants at the intervention sites vs. those enrolled in the wait-listed weight loss program at the control sites. Comparisons of baseline differences between the intervention and control groups were made using Student's t test for independent samples for continuous variables and Fisher exact test for categorical variables. The impact of the intervention on cravings was assessed by comparing mean change in scores of the subscales and global scores on the 3 craving instruments between the intervention and control groups by ANCOVA models controlling for age, sex and baseline value of the respective variable. The same sets of models were run accounting for differences by worksite within each group. Pearson

correlation coefficients were generated for baseline and change scores on cravings in relation to changes in weight and eating behavior constructs. Fisher's z transformation was used to assess by site differences in the Pearson correlation coefficients. We investigated the association of baseline as well change in cravings with weight change over 6 months ( $\text{Weight}_{6 \text{ months}} - \text{Weight}_{\text{baseline}}$ ) by multiple regressions with and without inclusion of eating behavior variables. To focus on cravings as predictors and correlates of weight change over and above the contribution attributable to gender, initial weight, age and worksite, these variables were forced into all regression models.

## **Results**

***Subject characteristics:*** **Table 1** summarizes the subject characteristics at baseline for the intervention and control groups. The intervention was well received at the intervention sites with an 89% of intervention participants completing the 6 month program and with an 84% attendance at group sessions. Data is reported here for a subset of completers who provided all outcome measures, representing 88% of intervention participants and 62% of control participants. At baseline, there were no statistically significant differences in weight, BMI, age, or other demographic or behavioral variables between the intervention and control groups.

At baseline, 66% of the participants reported food cravings ranging from sometimes to daily in the past month and 34% reported that they rarely experienced cravings in the past month. Of the female participants, 79% reported cravings. Similarly of the male participants, 21% reported cravings. Cravers reported cravings for fatty foods

(54%), sweets (90%), carbohydrates (84%) and fast food fats (86%). There was a significant correlation between BMI at baseline and the frequency of cravings as measured by FCI ( $r=0.21$ ,  $p=0.046$ ) and the intensity of cravings as measured by FCQ-T ( $r=0.29$ ,  $p=0.006$ ) at baseline.

***Change in cravings:*** Please note, this study is a group randomized study and comparisons are presented for participants enrolled in the weight loss program at the 2 intervention sites vs. those enrolled in the wait-listed weight loss program at the 2 control sites. Additional analyses are also presented when accounting for the group randomized nature of the study. **Table 2** shows the baseline and 6-month values for body weight, craving, and eating behavior variables for intervention and control groups. Net weight change for individuals in this study during the 6 month intervention period was  $-8.1 \pm 6.8$  kg (Mean $\pm$ SD) in intervention participants and  $+0.9 \pm 3.6$  kg in control participants. There were significant decreases in all craving scores in the intervention group compared to the control group as compared by ANCOVA models controlling for the baseline scores, age and sex. When ANCOVA models included worksite within group as a variable in the model, total FCQ-S and FCQ-T scores, and several subscales remained significant as summarized in Table 2.

***Craving variables as correlates of weight change and Eating Inventory variables:*** Pearson's correlations for associations between the weight change and both baseline and change values for craving variables were not significantly different between the 2 intervention sites and are shown in **Table 3**. Neither the baseline nor the change scores of FCI and FCQ-S showed associations with weight change and were not included in further analyses. Baseline FCQ-T and most of its subscales were negatively correlated with

weight change; such that participants with greater scores on FCQ-T at baseline showed smaller subsequent weight change. Changes in FCQ-T variables were positively correlated with weight change such that greater reductions in FCQ-T were associated with greater weight change. Significant positive correlations were also observed between the baseline and change scores for hunger and disinhibition and FCQ-T variables. Decreases in all FCQ-T variables over 6 months were positively correlated with decreases in hunger susceptibility and disinhibition as shown in **Figure 1**. There was also a significant correlation between change in restraint and change in total FCQ-T score.

***Craving variables as predictors of weight change:*** Multiple regression analyses were performed on FCQ-T variables to explore predictors of weight change over 6 months of the intervention. These models were controlled for baseline weight, age, sex and worksite. Baseline scores on FCQ-T subscales or total score were not significant predictors of subsequent weight change. Using all the change scores of FCQ-T subscales in one model, decreases in ‘plans to consume food’ ( $p=0.022$ ) and ‘anticipation of relief from negative state’ ( $p=0.024$ ) associated with weight change ( $R^2=0.58$ ,  $p<0.0001$ ). Change in total FCQ-T score (Model 1, Table 4) showed a significant association with weight change from 0-6 months ( $R^2=0.39$ ,  $p=0.01$ ). However, in the presence of eating inventory constructs, restraint, disinhibition and hunger, neither total FCQ-T or the subscales of FCQ-T retained significance (Model 2, Table 4). In this overall model, change in hunger was the only significant variable ( $R^2=0.44$ ,  $p=0.0025$ ).

## **Discussion**

Food cravings are frequently suggested to be an impediment to weight loss and to promote recidivism after weight loss. [10, 11, 15]. Specific techniques for reducing food cravings are included in some behavioral programs for weight control including the present study. However, there has been limited experimental data to support a significant relationship between cravings and weight change, and thus the role of cravings in successful weight management remains uncertain. In common with most previous studies of food cravings and obesity [3, 7] we found that the majority of our population experienced food cravings, more women than men reported cravings, and cravings typically were for sweets, carbohydrates and fast food fats. In addition, higher BMI at baseline was associated with greater severity and frequency of cravings, findings which appear to support a role for cravings in the maintenance of obesity. However, the severity and frequency of cravings declined substantially during weight change in this population of adult men and women enrolled in a worksite weight loss program. Even though cravings declined during weight change, in our analyses no craving variable associated significantly with weight change independent of hunger. Combined, these findings indicate that frequent, intense cravings are associated with obesity and that these cravings are susceptible to change and are not a barrier to successful weight loss.

Potential explanations for the fact that cravings have been reported to increase [17], stay the same [4], or, as in this study, decrease [5, 16, 18] with weight change are; the different types of dietary prescriptions, different intervention components, different study duration and different instruments used to assess cravings. Several previous studies of cravings and weight loss have used liquid calorie or high protein diets with restricted

variety [5, 12, 18] thus making it difficult to separate the effects of consuming a restricted-variety diet versus weight loss on cravings. To our knowledge this is the first study that showed a decline in food cravings correlated with weight loss when a diet consisting of normally consumed foods and typical dietary patterns was recommended.

It is noteworthy that we achieved our most significant associations between weight change and the FCQ-T subscales. Although changes in FCQ-S with weight change were also highly significant, in contrast to FCQ-T these changes did not associate with weight change and did not correlate with changes in hunger and disinhibition. State-craving has been shown to respond to particular events whereas trait-craving typically manifest across times and situations (for example, chocolate craving after last meal vs. chocolate craving over the 6 month intervention period) [11], which may make it more relevant to studies relating to weight change as in this investigation. Moreover, as proposed by Vander Wal et. al., [25] overweight and obese individuals may not be sensitive to FCQ-S.

Cravings have been hypothesized to be a conditioned expression of hunger that has been acquired by repeated experience of eating the craved food in a hungry state [4, 9, 26]. Consistent with this hypothesis, cravings have been reported to decline acutely after food consumption [9, 34] and to increase acutely after food deprivation or in a hungry state [27]. However information is lacking on how this effect is sustained over the long-term or if weight change modifies this relationship. In our study, hunger and disinhibition declined significantly during the 6 months of the intervention and showed statistically significant associations with declines in FCQ-T. These associations suggest that cravings, hunger and disinhibition track each other during changes in energy balance.

However, when eating behavior variables were included in models along with FCQ-T, only hunger showed significant associations with weight change. The implication of this finding is that hunger control may be a central factor determining success or failure in weight loss, and that cravings and disinhibited eating behavior are associated with hunger levels rather than independent factors influencing weight control.

Important features of this study included the use of a randomized prospective design including features of both hunger and craving control, low attrition rates, and the use of psychometrically robust questionnaires for assessment of cravings [3, 25]. To our knowledge, this is the first study to investigate the interrelationships of cravings and hunger with weight loss and is also the first study of cravings in worksites, which are increasingly being endorsed as potentially important locations for implementing public health measures for reducing the obesity epidemic. Nevertheless, the findings should also be viewed in light of some limitations. In particular, the study findings provide associations which need to be confirmed in intervention studies designed to selectively address hunger versus craving reduction during weight change. Also, the findings have limited generalizability because of the selection bias at the worksite level and at the level of employees [35]. Although we accounted for differences in worksite in regression models, it was a pilot group-randomized study and lacked statistical power to conduct cluster-randomized analyzes. Hence, we could not assess why several significant between group differences attenuated when we accounted for worksite as a covariate in our models. Further, there was a difference in the number of participants who enrolled and completed the study in intervention group compared to the wait-listed control which could be attributable to the differences in company size. Lastly, analyses are presented

for participants who completed all outcome assessments which is a subset of participants who completed the intervention. The completers of all outcome assessments can potentially be significantly different from those who completed the intervention however the mean weight change between the completers and non-completers was not statistically different.

In conclusion, this 6 month study provides the first data on cravings from a worksite weight loss program and confirms that food cravings are widespread in obese and overweight adults. Although the intensity and frequency of cravings decreased with weight change, neither baseline nor change in scores for cravings showed associations with weight change when included in models with hunger. These results suggest that a reduction in hunger may be more important for successful weight control than reduction in cravings. Behavioral programs for weight control can be improved with evidence for the primary or secondary effect of different potential components, and intervention studies are needed to compare the relative importance of reducing hunger versus reducing cravings in long-term weight control.

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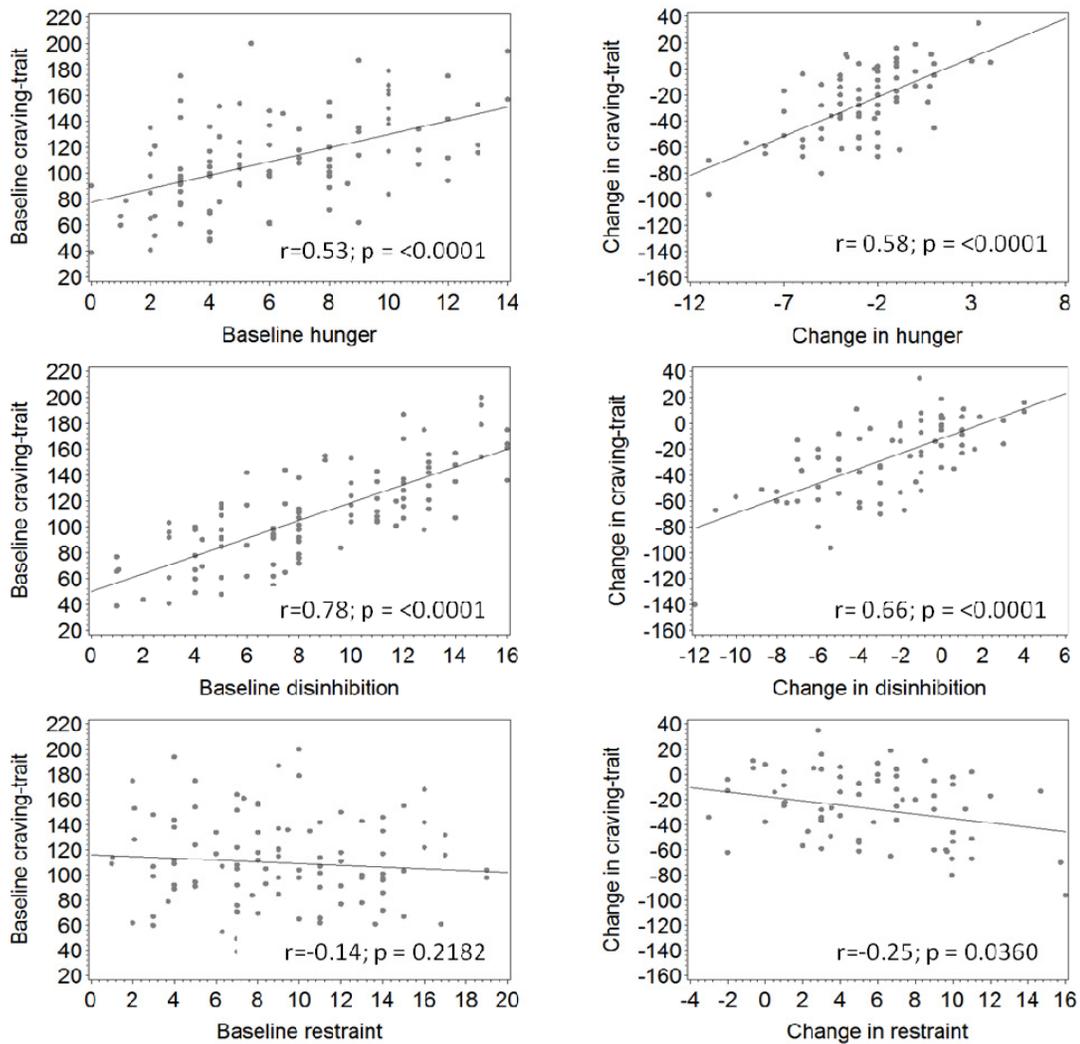
<b>Table 1: Baseline characteristics</b>		
	<b>Intervention n=74</b>	<b>Control n=21</b>
	Mean $\pm$ SD	Mean $\pm$ SD
Age	49.1 $\pm$ 10.1	49.8 $\pm$ 10.9
Height (cms)	167.8 $\pm$ 9.7	163.2 $\pm$ 7.5
Weight (kg)	94.5 $\pm$ 21.9	91.6 $\pm$ 24.4
BMI (kg/m <sup>2</sup> )	33.5 $\pm$ 6.5	33.1 $\pm$ 6.6
Gender		
Male, n (%)	20 (27)	3 (14)
Female n (%)	54 (73)	18 (86)

**Table 2:** Changes in cravings and eating inventory for intervention and control groups

	<b>Intervention n=74</b>		<b>Control n=21</b>		Between group difference for change over time  p
	Baseline	6-month	Baseline	6-month	
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	
Weight (kg)	94.5 $\pm$ 21.9	85.9 $\pm$ 19.2	91.6 $\pm$ 24.4	92.5 $\pm$ 26.9	<0.0001
<b>Craving Inventory</b>					
Fats	1.92 $\pm$ 0.60	1.44 $\pm$ 0.45	1.88 $\pm$ 0.72	1.77 $\pm$ 0.60	0.0020
Sweets	2.48 $\pm$ 0.75	1.68 $\pm$ 0.60	2.56 $\pm$ 0.99	2.30 $\pm$ 0.95	<0.0001
Carbohydrates	2.26 $\pm$ 0.69	1.69 $\pm$ 0.55	2.11 $\pm$ 0.78	2.01 $\pm$ 0.65	0.0033
Fast food fats	2.51 $\pm$ 0.78	1.95 $\pm$ 0.77	2.46 $\pm$ 0.78	2.40 $\pm$ 0.82	0.0027
Total Craving Inventory Score	2.25 $\pm$ 0.56	1.66 $\pm$ 0.47	2.22 $\pm$ 0.59	2.07 $\pm$ 0.48	<0.0001
<b>Craving - State</b>					
Intense desire to eat	8.53 $\pm$ 3.32	6.45 $\pm$ 2.95	9.04 $\pm$ 3.47	9.76 $\pm$ 3.66	<0.0001 <sup>a</sup>
Anticipation of positive reinforcement	7.91 $\pm$ 3.15	5.92 $\pm$ 2.61	7.61 $\pm$ 2.36	8.10 $\pm$ 3.79	0.0016
Anticipation of relief from negative state	7.50 $\pm$ 2.84	5.92 $\pm$ 2.60	6.47 $\pm$ 2.73	7.52 $\pm$ 2.79	0.0021 <sup>b</sup>
Lack of control over eating	7.81 $\pm$ 3.14	5.82 $\pm$ 2.58	8.42 $\pm$ 3.08	8.52 $\pm$ 4.00	0.0004 <sup>a</sup>
Hunger	7.89 $\pm$ 3.02	5.63 $\pm$ 2.41	7.57 $\pm$ 2.83	7.38 $\pm$ 3.01	0.0035 <sup>a</sup>
Total Craving-state score	39.60 $\pm$ 11.8	29.7 $\pm$ 10.9	39.1 $\pm$ 7.3	41.3 $\pm$ 11.6	<0.0001 <sup>b</sup>
<b>Craving - Trait</b>					
Plans to consume food	9.20 $\pm$ 3.68	6.62 $\pm$ 3.06	9.52 $\pm$ 4.37	9.90 $\pm$ 4.64	<0.0001 <sup>b</sup>
Anticipation of positive reinforcement	13.49 $\pm$ 4.94	10.57 $\pm$ 4.02	14.1 $\pm$ 5.66	14.6 1 $\pm$ 6.34	0.0002
Anticipation of relief from	7.71 $\pm$ 3.03	5.83 $\pm$ 2.38	7.62 $\pm$ 3.77	8.10 $\pm$ 4.64	0.0009

negative state									
Lack of control over eating	17.23	± 7.53	13.12	± 5.68	18.19	± 8.86	18.4	± 9.9	0.0007
Preoccupation with food	16.25	± 8.05	12.38	± 4.82	16.68	± 7.95	18.7	± 9.3	<0.0001
Hunger	11.91	± 4.07	9.24	± 3.69	11.68	± 4.47	12.3	± 4.3	<0.0001
Emotions experienced before or during food cravings	11.91	± 5.76	8.98	± 3.87	12.71	± 7.34	13.7	± 7.09	<0.0001
Cues that trigger craving	13.82	± 4.75	10.52	± 4.17	13.57	± 4.80	12.9	± 4.92	0.0038
Guilt from cravings	9.66	± 4.36	7.51	± 3.25	10.14	± 3.81	9.64	± 3.82	0.0091 <sup>a</sup>
Total Craving-trait score	111.2	± 38.8	84.30	± 29.4	114.3	± 41.5	118.	± 46.3	<0.0001 <sup>a</sup>
<b>Eating Inventory</b>									
Hunger	6.35	± 3.59	3.55	± 2.75	5.66	± 3.48	6.23	± 3.68	<0.0001 <sup>b</sup>
Disinhibition	8.78	± 4.22	6.27	± 3.14	8.93	± 4.25	9.59	± 4.37	<0.0001
Restraint	8.96	± 4.02	14.39	± 3.24	8.74	± 5.52	9.02	± 5.37	<0.0001
Between group differences measured by GLM (general linear model) adjusting for baseline score of the variable, age and sex. Superscripted p values are presented for models including a nested (worksite within group) covariate; <sup>a</sup> p<0.05, <sup>b</sup> p<0.01									

<b>Table 3: Pearson correlations between weight change and craving variables</b>			
	Weight change and baseline craving score		Weight change and craving change score
	r		r
<b>Craving Inventory</b>			
Fats	0.048		-0.008
Sweets	0.101		0.186
Carbohydrates	0.085		-0.029
Fast food fats	-0.157		0.198
Total Craving Inventory Score	-0.022		0.087
<b>Craving - State</b>			
Intense desire to eat	-0.113		0.137
Anticipation of positive reinforcement	-0.135		0.051
Anticipation of relief from negative state	0.009		0.117
Lack of control over eating	-0.003		-0.039
Hunger	0.021		0.003
Total Craving-state score	-0.048		0.061
<b>Craving - Trait</b>			
Plans to consume food	-0.301	<sup>b</sup>	0.365 <sup>b</sup>
Anticipation of positive reinforcement	-0.215		0.169
Anticipation of relief from negative state	-0.328	<sup>b</sup>	0.462 <sup>c</sup>
Lack of control over eating	-0.238	<sup>a</sup>	0.344 <sup>b</sup>
Preoccupation with food	-0.256	<sup>a</sup>	0.284 <sup>a</sup>
Hunger	-0.194		0.271 <sup>a</sup>
Emotions experienced before or during food cravings	-0.126		0.146
Cues that trigger craving	-0.105		0.158
Guilt from cravings	-0.075		0.047
Total Craving-trait score	-0.241	<sup>a</sup>	0.334 <sup>a</sup>
<sup>a</sup> p<0.05, <sup>b</sup> p<0.01, <sup>c</sup> p<0.001			
Change scores for weight and craving variables are calculated as 6 month - baseline value			



**Figure 1: Relationship between Craving-Trait and Hunger, Disinhibition and Restraint.**

Pearson's correlation coefficients shown for relationships between weight (kgs), hunger, restraint and disinhibition from the Eating Inventory and total craving-traits at baseline and after 6 months of intervention.

<b>Table 4: Regression models identifying predictors of weight loss from 0-6 months</b>							
	Coefficients			Model Summary			
	Beta ± SE	t	p	r <sup>2</sup>	adj r <sup>2</sup>	p	
<b>Model 1: Craving - Trait total score</b>							
Δ Total Craving-trait score	0.12 + 0.05	2.5	0.0150	0.39	0.33	<0.0001	
<b>Model 2: Craving - Trait and Eating Inventory</b>							
Δ Hunger	1.45 + 0.62	2.34	0.0225	0.44	0.36	<0.0001	
Δ Restraint	-0.30 + 0.39	-0.76	0.4480				
Δ Disinhibition	0.10 + 0.57	0.18	0.8597				
Δ Total Craving-trait score	0.03 + 0.07	0.43	0.6715				
n=71; the models were adjusted for baseline weight, age, sex and site.							

## CHAPTER 6

### **Self efficacy, QOL and participant evaluation in a worksite weight loss intervention.**

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## **Abstract**

**Objective:** Changes in weight self efficacy (WSE) and quality of life (QOL) as a result of weight loss have been examined. However, information on these variables in the context of worksite weight control interventions is limited. The purpose of this study was to examine changes in WSE and QOL in a worksite weight loss intervention and assess if these changes correlated with the magnitude of weight change.

**Design:** A 6-month randomized controlled trial was conducted at 4 worksites (2 intervention, 2 control) in the Boston metropolitan area.

**Subjects:** 94 participants enrolled at the intervention sites and 39 enrolled at the control sites. Outcome assessments were obtained from 74 participants at the intervention sites and 21 participants at the control sites.

**Measurements:** Measures included fasting body weight, Weight Efficacy Lifestyle (WEL) questionnaire and WHO-BREF quality of life questionnaire at baseline and 6 months for both the intervention and control groups, with an additional time point of 2.5 months in the intervention group. A participant feedback survey was collected at 6 months and included self reported ratings of various program components.

**Results:** This study is a group randomized study and comparisons are presented for participants enrolled in the weight loss program at the 2 intervention sites vs. those enrolled in the wait-listed weight loss program at the 2 control sites. Significant improvements in both overall scores and in all 5 dimensions of WSE and all 4 domains of QOL were observed in the intervention group compared to the control group. Within the intervention group, increases in overall WSE (adj  $R^2=0.35$ ,  $p<0.007$ ) and all 5 dimensions of WSE were significantly correlated with weight change after controlling for baseline weight, age, gender and worksite. Change in the overall perception of health was significantly correlated with weight change (adj  $R^2=0.35$ ,  $p<0.005$ ). Participant feedback on the intervention was positive overall and ratings on group sessions, menus, book and self monitoring were favorably correlated with weight change.

**Conclusion:** In conclusion, our worksite weight loss intervention resulted in significant improvements in WSE and QOL. Additionally, the increases in WSE were correlated with greater weight change.

**Trial Registration** [clinicaltrials.gov](https://clinicaltrials.gov); Identifier: [NCT01470222](https://clinicaltrials.gov/ct2/show/study/NCT01470222)

## **Introduction**

There has been considerable clinical interest in examining the role of subjective and behavioral attributes in relation to obesity and weight loss treatment. While some candidates have been studied over the years, other newer candidates have emerged as the obesity epidemic continues. One such variable of interest is Weight Self Efficacy (WSE). Self efficacy, adapted from Bandura's Social Learning Theory (1), refers to an individual's perceived ability to successfully perform a behavior. Self efficacy can be general or specific to a particular task and has been linked to success across several realms of health behavior (2) including weight control related behaviors. Associations between baseline WSE and subsequent weight loss have been mixed with some studies showing positive associations (3-8), an inverse association (9) or no association (10, 11). The associations between improvements in self-efficacy with greater weight change during a weight loss intervention have been more consistent (7-9, 12-15). However, most of these studies have examined the role of WSE in tightly controlled research settings or following individual therapy and information regarding the role of WSE in community and group based weight loss settings is lacking. It is unclear if effects of group based sessions affect WSE differently because although individual therapy is more intensive, group sessions can provide opportunities for observational learning and social support.

In addition to the deleterious impact obesity has on morbidity and mortality (16, 17), it also has a profound, negative impact on non-physical outcomes such as the quality of life (QOL)(18, 19). The degree of obesity is proportional to the compromises in QOL and weight loss is associated with significant improvements in QOL (20-23). Although QOL is widely assessed in pharmaceutical trials, it is only more recently included as a

routine measure in lifestyle intervention trials, and is also less commonly measured in randomized controlled lifestyle interventions (23). Knowledge on changes in QOL can greatly help to keep patients motivated and reinforce weight maintenance which is a common challenge following weight loss interventions.

Since both weight-self efficacy and QOL have been shown to be susceptible to intervention efforts (24) and are associated with positive weight loss outcomes, we aimed to examine the relationship of these outcomes in a 6 month group delivered worksite weight loss intervention program. Additionally we explored the predictive role of WSE and QOL on weight loss. Finally, we were interested in understanding which programmatic components of our new worksite weight loss intervention were most useful to participants to be able to better inform future efforts in worksites and for this, we developed an intervention specific feedback questionnaire that was administered at the end of the 6 month period.

## **Methods**

### *Study design*

The Healthy Weight for Life (HWL) study was a randomized controlled trial where worksites were assigned to either the intervention group or to the wait-list control group. The worksites were enrolled through a multi-stage screening and recruitment process. Worksites with 100-1200 employees in Greater Boston, Massachusetts were approached with study information and interested worksites were followed by an in person meeting with the study personnel to confirm eligibility. The eligibility criteria included absence of any onsite weight loss program in the past 6 months, accessible by public transportation,

infrastructure to hold onsite meetings and >50% employees response to an online employee interest survey. Based on this selection criteria, 4 worksites (2 non-profit and 2 for-profit) were enrolled in the study.

### *Participants*

After worksite enrollment, employees at each of these worksites were invited to sign-up for a no cost weight loss program. The inclusion criteria for eligibility into the weight loss program were age  $\geq 21$  years, BMI  $\geq 25.0$  kg/m<sup>2</sup> and a letter from the primary care physician approving participation in a weight loss program. Employees were excluded if they had any medical condition that could influence nutrient absorption or restrict food intake or were pregnant at the time of enrollment. The study was approved by the Institutional Review Board at Tufts Medical Center and all participants provided written informed consent. After collecting individual employee consents, baseline assessments were carried out following which the 4 worksites were randomized to either the intervention or the wait-listed control (2 Intervention and 2 Wait-listed control).

### *Intervention*

The 6-month, group based weight loss intervention was based on a published book (25) and participants were provided with the diet book and menu samples. Low glycemic load and portion controlled menus that contained  $\geq 40$  g/day dietary fiber were the core of this lifestyle modification program and were designed to reduce energy intake such that it facilitated a 0.5-1.0 kg/week weight loss. Dietary recommendations were within Acceptable Macronutrient Distribution Ranges of the Dietary Reference Intakes for all macronutrients (26) and dietary fiber was prescribed at greater than its current Recommended Dietary Allowance (RDA) (27). There were 15 weekly sessions followed

by 4 biweekly sessions, each including 60-minute didactic group meetings led by nutritionists with experience in behavior modification. These sessions addressed a variety of topics such as dietary composition recommendations, portion control, self-monitoring, self-efficacy, dietary variety, holidays, eating out, social support, goals and weight maintenance. In addition to group sessions, participants received a weekly email for individual support.

### *Outcomes*

Outcomes included weight and online questionnaires for weight self efficacy and quality of life. These measures were collected at baseline and at 6-months for both the intervention and wait-listed control groups. Height and demographics information were collected at baseline. Additionally, a feedback survey was collected at the end of 6 months for the participants in the intervention group.

Weight Self-efficacy (WSE): Self-efficacy related to eating behaviors and weight loss was measured with the 20-item Weight Efficacy Lifestyle Questionnaire (WEL) (28). This scale has respondents rate their confidence to resist eating in certain situations on a scale ranging from 0 (not confident) to 9 (very confident). In addition to a global WEL score, the WEL includes 5 subscales; availability (eating when high-calorie food is readily available), negative emotions (eating when feeling nervous, depressed or irritable), social pressure (eating when others are encouraging food consumption), physical discomfort (eating when having a headache or other bodily pain) and positive activities (eating when watching television). Each sub scale consists of 4 items with higher scores indicating higher confidence levels and a possible score of 36 points with a total of 180 points possible for the global WSE score.

Quality of life (QOL): QOL was assessed using WHOQOL-BREF which is a 26-item abbreviation of the WHOQOL-100. This questionnaire measures four domains – physical, psychological, social and environmental and has shown to display good validity and reliability (29-31). Each of the 4 domains has a possible score ranging between 0 (poor QOL) and 20 (excellent QOL). In addition to the 4 domains, the questionnaire also consists of 2 stand alone questions on the overall perception of QOL and the overall perception of health.

Intervention feedback survey: We developed an intervention specific feedback questionnaire requesting participant rating on the various programmatic components of our new worksite weight loss intervention and was administered at the end of the 6 month intervention period. This survey consisted of 40 statements on a scale of 1 (strongly disagree) to 10 (strongly agree). The questions were broadly categorized into 4 programmatic components; book, group session, menus and self monitoring. Each of these categories was weighted and a mean score was calculated with a final score on the scale of 1-10. The questionnaire also included a few open ended question on overall effectiveness of the program and extent of family support

#### *Statistical analysis*

Analyses were performed using SAS version 9.2 (SAS Institute, Inc., North Carolina) and statistical significance for all variables was set at a 2-sided P value of < 0.05. This is a group randomized trial however comparisons are made for participants at the intervention sites vs. those enrolled in the wait-listed weight loss program at the control sites because of the exploratory nature of this investigation. Comparisons of baseline differences between the intervention and control groups were made using Student's t test for

independent samples for continuous variables and Fisher's exact test for categorical variables. The impact of the intervention on WSE and QOL was assessed by comparing mean change in scores of these variables between the intervention and control participants by ANCOVA models controlling for age, sex and baseline value of the respective variable. Pearson correlation coefficients were generated for baseline and change scores in relation to change in weight. The correlations are for only the intervention group since correlations of weight change and behavioral variables for the control sites were not significant. Fisher's z transformation was used to assess differences in the Pearson correlation coefficients between the 2 intervention sites. We investigated association of both baseline and change scores of the WSE and QOL variables as well as participant feedback with weight change ( $\text{Weight}_{6 \text{ months}} - \text{Weight}_{\text{baseline}}$ ) by multiple regressions. Additionally, correlations between participant feedback on perceived usefulness of self monitoring and actual frequency of self monitoring (77%) ( $r=0.44$ ,  $p<0.001$ ) and perceived usefulness of sessions to % attendance (84%) ( $r=0.44$ ,  $p<0.001$ ) were examined. Gender, initial weight and age were included as covariates in all models. Additionally, worksite as a covariate was also included to adjust for variability between sites.

## **Results**

Baseline demographics and scores on weight self efficacy (WSE) and quality of life (QOL) are summarized in **Table 1** for participants who completed assessments at all time points ( $n=74$  intervention and  $n=21$  controls). There were no statistically significant

differences in weight, height, age, gender, total WSE, and overall QOL scores between the intervention and control participants.

### **Treatment effects**

Please note, this study is a group randomized study and comparisons are presented for participants enrolled in the weight loss program at the 2 intervention sites vs. those enrolled in the wait-listed weight loss program at the 2 control sites. Additional analyses are also presented when accounting for the group randomized nature of the study. Mean weight change for individuals in this study during the 6 month was  $-8.1 \pm 6.8$  kg in intervention participants and  $+0.9 \pm 3.6$  kg in control participants. Mean changes for WSE and QOL during the 6 months are summarized in **Figure 1**. After controlling for baseline score, age and sex, change over time in the intervention group was significantly different from that of the control group for WSE and its 5 subscales (Panel A) and for all domains of QOL (Panel B) with the exception of ‘overall perception of quality of life’. When accounting for differences by worksite within each group in the model, the effects were attenuated for some variables. Total WSE and negative emotions and the psychological relationship domain of QOL retained significance.

### **Correlates of weight change within the intervention group**

There were no statistically significant differences in the correlations between weight change and change in WSE and QOL scores between the 2 intervention sites. Weight change was not correlated with baseline scores of WSE subscales or with QOL domains. Correlations between the change in WSE and QOL with weight change in the intervention group are shown in **Table 2**. Change in weight was significantly associated with increases in WSE and its subscales and increases in QOL relating to overall

perception of health with increase in scores of these variables correlated with greater weight change. Results from multiple regression models looking at weight change within the intervention group are discussed below.

*Weight self efficacy:* WSE variables that were significantly correlated with weight change were entered in a multiple regression model with baseline weight, age, sex and worksite as covariates. Weight change was associated with increases in perceived ability to cope with eating when experiencing negative emotions (adj  $R^2= 0.36$ ,  $p=0.003$ ), social pressure (adj  $R^2= 0.32$ ,  $p=0.033$ ), physical discomfort (adj  $R^2= 0.34$ ,  $p=0.010$ ) and while doing positive activities (adj  $R^2= 0.33$ ,  $p=0.022$ ) associated with weight change. With the exception of the ‘availability’ dimension (adj  $R^2= 0.31$ ,  $p=0.056$ ), change in all dimensions of WSE and total WSE were significantly associated with weight change. The association between change in total WSE score and weight change is presented in **Figure 2**.

*QOL:* Although there were significant changes in all dimensions of QOL, only change in overall perception of health showed significant associations with weight (adj  $R^2= 0.35$ ,  $p=0.005$ ) (Figure 2).

### **Participant feedback**

Overall participant feedback on all components of the intervention as indicated by perceived usefulness (of the provided book, provision of menus, weight loss support groups and self monitoring of weight) were positive, with 97% participants agreeing that it was advantageous to have our intervention at their worksite; 21% ( $n=14$ ) indicated that their family was supportive and followed the healthier choices with them, 46% ( $n=31$ )

indicated receiving family support throughout the 6 month period, 9% (n=6) indicated lack of consistent support from their families and 25% (n=17) reported that they lived alone. Mean score of participant feedback on each of the 4 programmatic components was book ( $8.1 \pm 1.8$ ), group session ( $8.4 \pm 1.5$ ), menu ( $8.6 \pm 1.6$ ) and self monitoring ( $8.5 \pm 2.2$ ). In regression models, these scores were significantly associated with weight change; book (adj  $R^2=0.38$ ,  $p<0.038$ ), group session (adj  $R^2=0.36$ ,  $p<0.014$ ); menu (adj  $R^2=0.42$ ,  $p<0.002$ ) and self monitoring (adj  $R^2=0.40$ ,  $p<0.001$ ). Correlations between participant feedback on perceived usefulness of self monitoring and actual frequency of self monitoring (77%) ( $r=0.44$ ,  $p<0.001$ ) and perceived usefulness of sessions to % attendance (84%) ( $r=0.44$ ,  $p<0.001$ ) were examined to assess the relationship between practice and perceived feedback.

## **Discussion**

There has been a growing interest in understanding the role of subjective and behavioral attributes in weight management due to their substantial potential to influence weight change. Our study examined the impact of a worksite weight loss intervention on WSE and QOL. Worksites are increasingly popular as locations for targeting weight loss interventions and information on behavioral factors in worksite settings is lacking. As previously published in non-worksite weight loss trials, improvements in WSE (7-9, 12-15, 32) were significant in the intervention group compared to the control group. While most investigators report improvements in the overall WSE score and some but not all dimensions of WSE, our results show a significant improvement in overall as well as the 5 dimensions of WSE in the intervention group. We attribute this to Social Cognitive

Theory (SCT), which recognizes the importance of raising self efficacy and was the basis of this intervention. It is also possible that opportunities of observational learning, social support and reinforcement from fellow employees participating in the same intervention further helped raise WSE. This finding is of significance since intervention programs may be incomplete if they change only a subset of the dimensions of WSE (28). Although associations between pre-treatment WSE and weight change have been mixed, investigators have consistently reported treatment related improvements in WSE and greater weight change (7-9, 12-15). Results from our study highlight the importance of interventions including approaches to strengthen WSE and support the notion that lifestyle interventions for weight loss can improve participant WSE as demonstrated for the first time in a worksite setting.

Changes in QOL following weight change in lifestyle interventions have been examined by a few investigators. Our findings of significant improvements in all dimensions of quality of life in the intervention group compared to the control group is similar to those reported by Young et al. in the PREMIER trial (23) and Barham et al. (33) in the Diabetes Prevention Program (DPP) in worksites and a few others that reported change over time and did not include a control group (34-37). Our results confirm the finding that QOL is improved with weight change and that our worksite intervention was effective in improving all dimensions of QOL. Participant feedback indicated that the HWLP program was generally well received and that all programmatic components were perceived as useful and were highly correlated with weight change.

Important features of this study include a randomized prospective design and low attrition rates. Previous worksite weight loss trials have reported typical attrition rates of

about 20% (38) and in our working sample, only 10% of participants who began the study had dropped out at the end of the intervention period. Our study is the first to show that in a worksite weight loss program, improvements in WSE is a significant correlate of weight change. These findings as well as the results of participant feedback provide a sound basis for designing future worksite weight loss interventions.

This study was a group randomized trial and the outcomes assessed here were secondary outcomes which were not included in power calculations. Due to the pilot nature of this study and the limited power, we could not assess why several significant between group differences attenuated when we accounted for worksite as a covariate in our models. Findings from this study may have limited external validity because of the selection bias at the worksite level and at the level of employees (11, 39, 40). We included only worksites that responded to our study invitation and within each worksite employees opted to be a part of the weight loss support group. The worksites and employees who signed up may not have been representative of the average worksite and employees, in that they probably showed a higher interest in health promotion and health than worksites and employees who did not express an interest to participate. Finally, we showed a significant association between change in WSE and weight change, but it remains unclear if the increase in WSE predicted weight change or whether weight change predicted increases in WSE. In other words, successful weight change may be responsible for improvements in WSE. Nevertheless, increases in WSE have shown to be a predictor of subsequent weight maintenance emphasizing the importance of interventions including approaches to strengthen WSE (7, 8, 24).

Despite these limitations, this investigation highlights the importance of WSE and QOL in a worksite weight loss intervention. To our knowledge, no other studies have investigated the predictive role of WSE with respect to weight loss in a work environment. Further studies are warranted to confirm the role of WSE and QOL in weight loss at worksites and to investigate the influence of these variables in weight maintenance.

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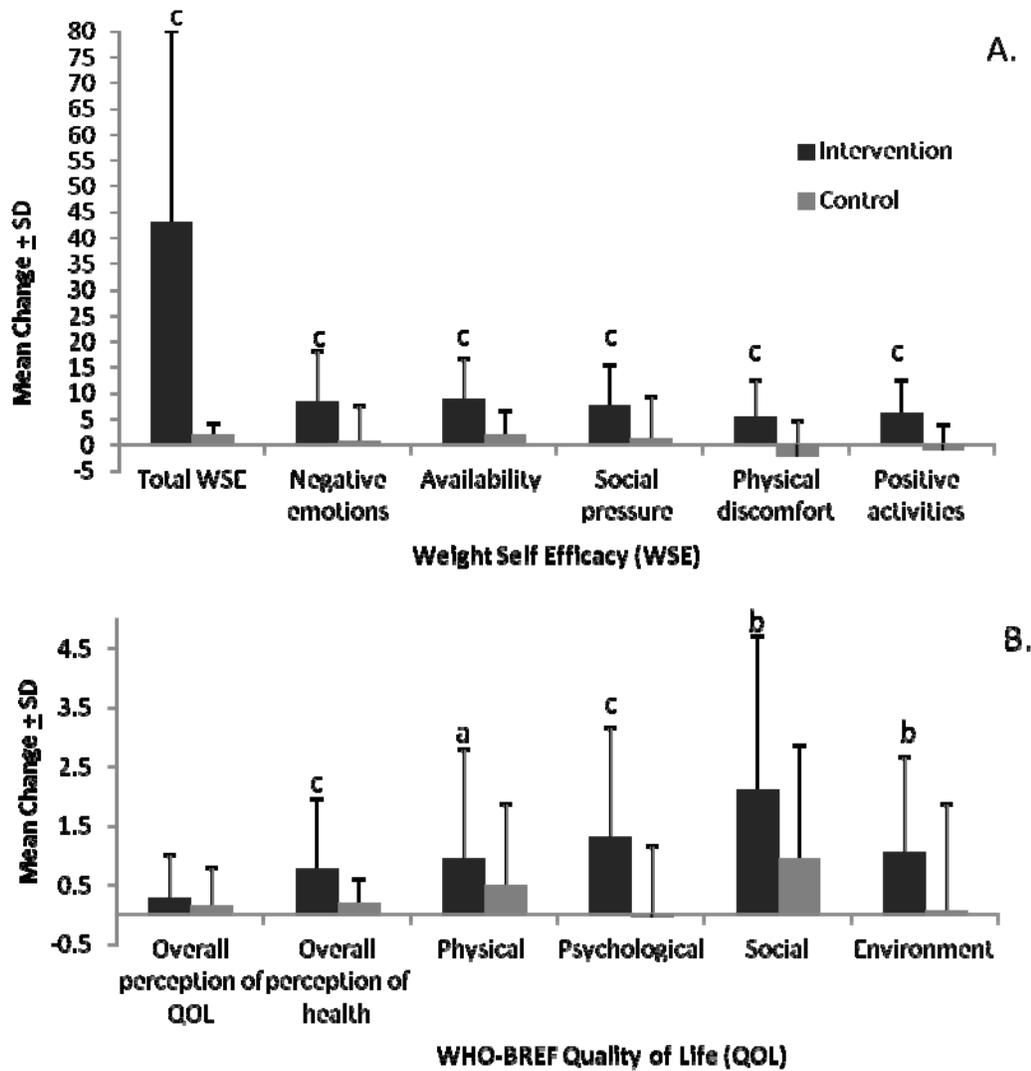
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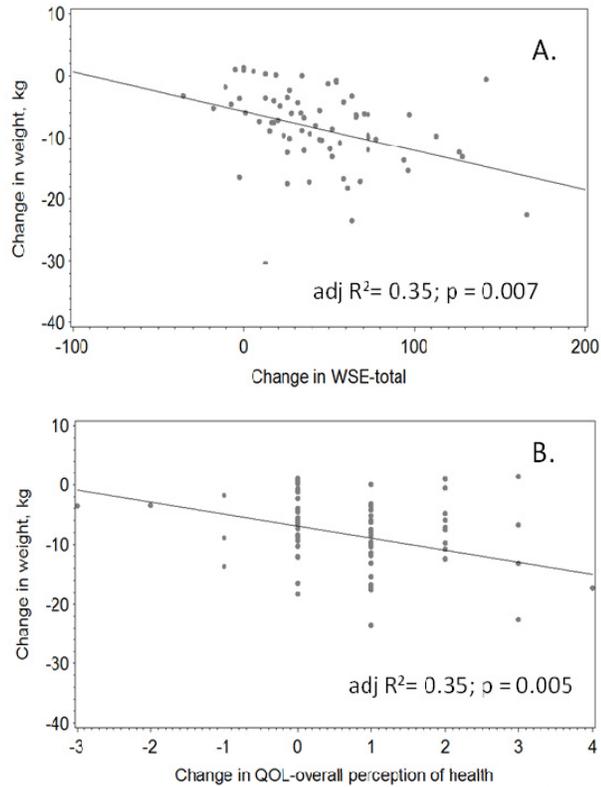
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<b>Table 1: Baseline characteristics and scores on Weight Self Efficacy and Quality of Life for intervention and control groups</b>		
	<b>Intervention n=74</b>	<b>Control n=21</b>
	<u>Baseline</u>	<u>Baseline</u>
	Mean $\pm$ SD	Mean $\pm$ SD
Age	49.09 $\pm$ 10.12	49.84 $\pm$ 10.98
Height (cm)	167.77 $\pm$ 9.68	163.25 $\pm$ 7.50
Weight (kg)	94.51 $\pm$ 21.93	91.59 $\pm$ 24.41
Gender		
Male, n (%)	20 (27)	3 (14)
Female n (%)	54 (73)	18 (86)
<b>WSE</b>		
Negative emotions	18.68 $\pm$ 10.11	17.381 $\pm$ 11.62
Availability	16.62 $\pm$ 7.08	15.09 $\pm$ 10.08
Social pressure	21.15 $\pm$ 8.14	21.317 $\pm$ 10.23
Physical discomfort	23.76 $\pm$ 8.15	25.476 $\pm$ 8.53
Positive activities	23.93 $\pm$ 7.07	22.714 $\pm$ 8.92
Total WEL Score	122.54 $\pm$ 40.59	120.05 $\pm$ 47.07
<b>WHO - BREF QOL</b>		
Overall perception of QOL	4.12 $\pm$ 0.70	4.05 $\pm$ 0.59
Overall perception of health	3.14 $\pm$ 1.05	2.76 $\pm$ 1.04
Physical health	12.62 $\pm$ 1.75	12.44 $\pm$ 1.53
Psychological	13.50 $\pm$ 1.97	12.98 $\pm$ 1.68
Social Relationships	13.93 $\pm$ 3.12	13.33 $\pm$ 3.24
Environment	15.51 $\pm$ 2.04	15.57 $\pm$ 2.00



**Figure 1: Between group differences on Weight Self Efficacy and Quality of life.** Bar graph showing the mean changes (final-baseline) in WSE (Panel A) and QOL (Panel B) variables for intervention and control groups. Error bars represent  $\pm 1$  SD (<sup>a</sup> $p < 0.05$ ; <sup>b</sup> $< 0.01$ ; <sup>c</sup> $< 0.001$  treatment vs control group)

<b>Table 2:</b> Pearson correlations between weight change and change in WSE and QOL	
	Weight change and change in variable
	r
<b>WSE</b>	
Negative emotions	-0.345 <sup>b</sup>
Availability	-0.278 <sup>a</sup>
Social pressure	-0.321 <sup>b</sup>
Physical discomfort	-0.314 <sup>a</sup>
Positive activities	-0.238 <sup>a</sup>
Total WEL Score	-0.338 <sup>b</sup>
<b>WHO - BREF QOL</b>	
Overall perception of QOL	-0.074
Overall perception of health	-0.332 <sup>b</sup>
Physical health	-0.041
Psychological	0.016
Social Relationships	-0.037
Environment	0.123
<sup>a</sup> p<0.05, <sup>b</sup> p<0.01, <sup>c</sup> p<0.001; Change scores for weight and behavioral variables calculated as 6 month - baseline value	



**Figure 2: Relationship between change in weight and change in WSE and overall perception of QOL**  
 Multiple linear regression equations for change in weight and Total WSE (Panel A) and QOL-overall perception of health (Panel B); models adjusted for baseline weight, sex, age and worksite.

## CHAPTER 7

### SUMMARY AND DISCUSSION

#### **Introduction**

Obesity is a worldwide epidemic (1-4) affecting an estimated 300 million people. It has a profound, negative impact on health and quality of life among adults, adolescents, and even children (5-8). Obesity has received a lot of attention both nationally and internationally due to its detrimental health consequences, the huge economic burden it entails, and its increasing prevalence (5, 9-13). Since the 1970's when efforts on treating obesity started in its earnest, the field has seen an explosion of weight loss programs and treatment modalities (12). Each year an estimated 24% men and 38% women attempt to lose weight in the United States (14). Despite the explosion of weight loss treatments paralleling this epidemic (15, 16), individual treatment of obesity has shown modest success in many individuals and weight regain or relapse continues to be common (5, 9, 17-22). Information on the behavioral strategies that best support successful weight loss is limited (12, 23, 24) and is essential to the development of improved programs for obesity treatment.

Recent evidence suggests that comprehensive approaches that target groups of population such as schools, worksites, health care organizations etc could be more effective than individual treatment of obesity since they offer an existing social support network that may potentially facilitate behavior change (11, 25). Worksites present one such important community model to reach a large number of people in a time-efficient and cost-effective manner (11, 26-29). It serves as an environment where a large number of people spend considerable amounts of time on a regular basis, and therefore holds

promise as an ideal forum in which to implement an intervention encouraging healthier lifestyle behaviors (25, 27, 30-34). However, the development and testing of new worksite weight control programs with strong behavioral components is needed to identify approaches that are most effective and sustainable. The identification of behavioral and cognitive factors associated with successful weight loss will aid in improving and replicating worksite weight loss programs. Therefore, this study investigated behavioral and cognitive variables in a new multi-component intervention for weight loss in worksites that focused on changing both dietary intake and eating behavior patterns in overweight and obese employees.

### **Overview of results from the Healthy Weight for Life Program**

This group-randomized, controlled trial was well received at the intervention worksites as judged by the 89% retention of weight loss program participants through 6 months and an 84% session attendance. The HWLP demonstrated that a multi component, group-based weight loss intervention can result in significant weight loss at worksites. In the current study, mean weight loss and standard deviation in intervention participants was  $-8.1 \pm 6.8\text{kg}$  as compared to wait-listed controls,  $+0.9 \pm 3.6\text{kg}$  over the 6 month intervention period.

The intervention resulted in significant improvements in behavioral and cognitive variables. Specifically, the intervention was associated with increase in restraint ( $\Delta I=5.43\pm 4.25$ ,  $\Delta C=0.29\pm 3.80$ ,  $p<0.001$ ) including all of the subscales of restraint, decreased overall disinhibition ( $\Delta I=-2.5\pm 3.63$ ,  $\Delta C=0.66\pm 1.85$ ,  $p<0.001$ ) and in the subscales of disinhibition and decreased hunger ( $\Delta I=-2.79\pm 3.13$ ,  $\Delta C=0.56\pm 2.63$ ,

$p < 0.001$ ) and the subscales of hunger. The intervention also showed significant reductions in all aspects of craving including craving frequency and intensity as measured by a battery of robust craving questionnaires [Food Craving Inventory (FCI), Food Craving Questionnaire-State (FCQ-S) and Food Craving Questionnaire-Trait (FCQ-T)]. Similarly, an increase in weight self efficacy and its 5 situational dimensions as well as significant improvements in the 4 domains of quality of life were also observed. Together, these findings provide evidence that our multi-component worksite weight loss intervention resulted in positive changes in behavioral and cognitive attributes of the participants in addition to weight loss.

Through the investigations presented in this thesis, we examined the relationship between behavioral attributes and weight change within the intervention group. Of the eating inventory constructs, increased restraint ( $r = -0.35$ ,  $p = 0.001$ ), decreased disinhibition ( $r = 0.26$ ,  $p = 0.02$ ) and decreased hunger ( $r = 0.36$ ,  $p = 0.001$ ) showed significant associations with weight change. In a multiple regression model controlling for age, sex, worksite and baseline weight, decreased hunger was the only variable that was significantly associated with change in weight. Changes in eating behavior variables have been shown to accompany intentional weight loss in several studies (35-39), but most previous investigations have shown significant associations between weight loss and increased restraint and/or decreased disinhibition (35-37, 40, 41) and have not demonstrated significant associations of weight loss with change in hunger. Several possibilities can be considered for why hunger showed significant associations with weight change in this study. Since hunger is a negative sensation typically leading to food consumption (42), participants who had the greatest decrease in hunger may well have

been the ones who were able to withstand negative energy balance for a more sustained period of time. Alternatively, this finding could be unique to this study since the intervention had several components designed to manage hunger and enhance satiety. Factors such as dietary composition, meal timing and high fiber intake were specifically combined and translated in a practical menu based approach to manage hunger on a negative energy balance. It is also possible that the social support from fellow employees participating in the same intervention encouraged adherence to the intervention such as bringing program compatible meals to work instead of eating out. Identification of hunger as a significant correlate of weight loss success has implications for the design of interventions for weight control in worksites and, potentially, other settings. Further trials are needed to address if the nature of the dietary intervention, the worksite environment or other factors contributed to the observed relationship between hunger and weight loss.

Of the craving variables, decreased FCQ-trait ( $r=-0.24$ ,  $p=0.04$ ) showed significant correlation with weight change. To our knowledge this is the first study that showed a decline in food cravings specifically correlated with weight change when a diet consisting only of regular foods and typical dietary patterns was recommended. This could be attributable to the design of the intervention that included strategies to help participants manage cravings. Specifically, the program included a combination of control based strategies (such as teaching people how to cognitively restructure urge related thoughts and cues to mentally distract them from food stimuli) and acceptance based strategies aimed to increase mindfulness of internal experiences (43). Further, cravings have been hypothesized to be a conditioned expression of hunger that has been acquired by repeated experience of eating the craved food in a hungry state (44-46).

Based on this, we also examined change in craving-trait as a correlate of weight change in the presence of change in hunger scores. Our analysis provides empirical evidence to support this hypothesis suggesting that a reduction in hunger may be more important for successful weight control than reduction in cravings and changes in cravings maybe secondary to changes in hunger.

Similarly, increased total WSE ( $r=-0.34$ ,  $p=0.01$ ) and in all situational dimensions of WSE showed significant associations with weight change such that greater increases in WSE were associated with greater weight change. This finding along with reports in the literature that intervention related increases in WSE are predictors of subsequent weight maintenance highlight the importance of interventions including approaches to strengthen WSE (47-49). Social Cognitive Theory (SCT), which recognizes the importance of raising self efficacy, was the basis of this intervention.

We also investigated attendance and adherence measures as correlates of weight loss success. The mean attendance at group meetings was 84% for participants at the intervention sites during the 6-month intervention. Over the course of the intervention, participants submitted weekly weight self monitoring logs 77% of time. Both attendance ( $r=-0.4$ ,  $p=0.003$ ) and weight self-monitoring ( $r=-0.3$ ,  $p=0.029$ ) correlated with weight change and remained significant in a multiple linear regression model. Thus in line with previous reports (39, 50-55), a higher frequency of self-monitoring and a higher frequency of group meeting attendance were significant correlates of weight change. Finally, program evaluations were positive, with 97% participants agreeing that overall it was advantageous to have this intervention at the worksite. Participant feedback indicated

that all programmatic components were perceived as useful and were highly correlated with weight change.

To our knowledge, this study achieved greater mean weight loss than is typical in weight loss interventions in worksites. We attribute the success of this worksite intervention to the multidimensionality and practicality of the intervention components. The intervention incorporated an innovative dietary prescription, which emphasized the importance of dietary composition (i.e. high fiber, low-glycemic) (56, 57) and meal timings for hunger regulation. Some of the practical topics covered were portion control, self monitoring, dietary variety, holidays, eating out, goal setting and weight maintenance. Additionally, the support groups served as a favorable medium to deliver the mastery exercises and provide opportunities for observational learning, social support and reinforcement. It is also possible that the dietary composition and the behavioral framework of the intervention, a combination of Social Cognitive Theory and Cognitive Behavioral Theory, were particularly effective in the group setting of worksites.

### **Study Strengths and Limitations**

A particular strength of this randomized controlled trial was that 89% of the participants were retained in the intervention through the 6 month study period. Previous worksite weight loss trials have reported typical attrition rates of about 20% (38) and in our working sample, about 10% of participants who began the study had dropped out by the end of the intervention. This study was also the first to examine cognitive and behavioral correlates of weight loss such as eating behaviors, cravings and weight self-efficacy in a worksite setting. Further, we used comprehensive and previously validated

questionnaires to measure these behavioral and cognitive attributes (58, 59). An additional strength was the considerable variation in weight loss (+1.36 to -35.5 kg), providing a suitable dataset for studying correlates of weight loss. Use of in-person delivery of the group based program (60, 61), weekly correspondence with study staff for accountability and self-monitoring (54, 55, 62-65), and the incorporation of both weight loss and weight maintenance components into our curriculum were additional strengths of our intervention (66, 67).

In spite of the substantial implications of these findings, some limitations need to be acknowledged. One limitation of the current study is that it was a group-randomized pilot study and because of the exploratory nature of the outcomes presented here, individuals and sites were treated as fixed effects. We did control for worksite as a covariate in our regression analysis, to account for the fact that employees at any given site were exposed to the same intervention. However, the limited power and small sample size may explain why several significant between group differences attenuated when we accounted for worksite as a covariate in our models. The worksites might differ in some ways that would affect the intervention or outcomes but these differences could not be assessed. Also, the sample size between the intervention and control groups was substantially different. Perhaps more participants completed the outcome assessments in the intervention group but the number of enrollees before randomization was greater in one study arm. Of the worksites, 3 averaged in the range of 150-200 employees whereas 1 worksite had 525 employees which was randomized to the intervention group. Further, the large number of regression models may have increased Type I error but all associations were in the expected direction, suggesting that the observed relationships are

not due to chance alone. Findings from this study may also have limited generalizability due to the type of worksites recruited for this study. We recruited worksites with office-based employees for this study and although we did not test this they may have been particularly receptive to on-site weight management programs as compared to other types of worksites. In addition, the self sign-up at the employee level may have resulted in a selective population at each worksite. The non-responders may have been different from responders and these differences could not be assessed. Similarly, differences in behavioral variables between completers of behavioral outcome assessments and non-completers could not be assessed, although there were no significant differences in their weight loss. Additionally, while both intervention sites lost significant weight and showed significant improvements in behavioral and cognitive aspects, the magnitude of these improvements was different between the two sites suggesting that other factors specific to worksite may have played a role and need to be assessed in future studies. We did not have the statistical power to fully account for this variability between worksites. Despite these limitations, this study provides novel evidence for associations between aspects of eating behavior; primarily decreases in hunger and generalized susceptibility to cravings, improvements in weight self efficacy and higher attendance and self monitoring as correlates of weight loss in a work environment.

### **Future Implications and Recommendations**

Despite the substantial implications of results from our worksite weight loss intervention, there is certainly a need for replication of these findings with larger randomized, controlled worksite trials and longer follow-up periods. Studies are also

needed to define which of the specific components of our intervention contributed most to the results obtained. Further examination of these behavioral and cognitive components in successful weight management is warranted because these could lead to improved effectiveness of weight loss interventions specifically in worksites, and perhaps also in other settings. Behavioral programs for weight control can be improved with evidence for the primary or secondary effect of different potential components, such as comparisons of the relative importance of reducing hunger versus reducing cravings in long-term weight control. Further studies are also needed to confirm the role of weight self-efficacy and quality of life in weight loss at worksites and to investigate the influence of these variables in weight maintenance. Understanding the variability to response among sites and establishing the generalizability and sustainability of these findings is important to inform future interventions and public policy regarding worksite health promotion programs. Further, considering the extensive health-care costs associated with obesity and related health problems (13, 68), future studies are needed to assess the cost-effectiveness of such weight management programs at worksites.

From an implementation perspective soliciting upper level management support and co-operation is critical to enhance employee participation and minimize implementation barriers (69). Meeting infrastructure needs such as scheduling space for meetings, evaluating company turnover and prioritizing program-related events and group meetings during work hours (70) is essential for enhancing delivery of group sessions. Similarly, forming an Employee Advisory Board (EAB), consisting of both upper level management, interested employees and study personnel can facilitate the execution of such programs, and maximize alignment of worksite culture and participant

needs; this will in turn enhance participation and encourage adherence (71, 72). Future interventions should also evaluate the efficacy of incorporating dietary and exercise programmatic components in combination as recent meta-analyses have shown that this approach may be most promising for success in worksite weight loss interventions (29). Lastly, socioeconomic and cultural food preferences among support group participants also need to be addressed in such interventions as it may enhance effectiveness, dietary adherence, and subsequently result in greater improvements in weight loss success (73).

## **Conclusion**

In conclusion, these results support the growing evidence for worksite weight loss programs to approach the burgeoning obesity epidemic. Our intervention demonstrates that by combining a multi-component group-based program, positive changes in behavioral and cognitive attributes can be achieved in the context of a worksite setting and complements the substantial weight loss achieved. This 6 month study provides the first data on behavioral correlates of weight loss from a worksite weight loss program. Together, results from our study advance the understanding of behavioral and cognitive attributes as determinants of weight loss and provide guidance for refinement of future worksite weight-loss interventions. Future studies are needed to replicate and corroborate these findings and identify the primary or secondary effects of different components for successful weight loss and long-term weight maintenance.

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## **APPENDICES**

### **APPENDIX A: Recruitment, Screening and Eligibility Flowchart**

## APPENDIX B: Company Eligibility and Interest Survey

Please complete the questions below and fax to 617-556-3122. Alternatively you can complete the same survey online at (url)

I, \_\_\_\_\_, representing \_\_\_\_\_ (company name), confirm that my participation in this survey is voluntary.

Please give the number of individuals currently employed at this worksite \_\_\_\_\_

Your company is not currently (or within past 6 months) employing any comprehensive weight, exercise or wellness program at work.

Yes  No

Most or all employees at your worksite are not highly active as part of their work.

Yes  No

Your company has a low turnover rate.

Yes  No

Your company has a 3 year or greater history of being in business.

Yes  No

You anticipate that >10% of your company employees may wish to participate in this intervention.

Yes  No

You understand that the next phase of screening will involve employees completing a 5 minute web-based screening questionnaire, and that at least 50% of employees will need to complete the

survey for your company to be eligible. (This survey only charts willingness to be part of the study and does not require 50% of employees to participate in the weight loss elements of the program.)

Yes  No

You confirm that space needs can be met (room for weekly group support if meetings are to be conducted on site, bulletin board available for study flyers, central location for distribution of study handouts and setting up periodic booth for information).

Yes  No

Tufts personnel, or individuals designated by you at your worksite, will be able to disseminate study information across your worksite including posting study flyers and setting up occasional informational booths. You are willing to either send out emails and study informational on behalf of the Tufts team or will provide us with emails that allow us to periodically contact employees (up to 12 contacts per study).

Yes  No

## APPENDIX C: Web Employee interest survey

### Employee Consent

I understand that all employees at my worksite are being asked to complete this brief anonymous survey with the approval of Human Resources. I am completing this survey to determine the eligibility of my worksite to participate in a research study organized by scientists from Tufts University. The study is evaluating a worksite program for helping employees with weight issues, and all enrolling worksites will be provided with cost-free weight control help by leading weight control experts. I understand that even if I do not wish to participate in a weight control program, my completion of this survey is requested.

By checking this box, I consent to voluntarily providing the information below.

### Personal

1. **Gender**                      Male    Female
  
2. **Age**                              21-30              31-40              41-50              51-60              >60
  
3. **Company Name:** \_\_\_\_\_
  
4. **Job Title/Job Description:** \_\_\_\_\_
  
5. **Weight** \_\_\_\_\_ lbs.
  
6. **Height** \_\_\_ Ft \_\_\_ Inches

7. Do you currently feel the need to eat healthier?

Yes

No

8. Are you currently:

- Happy with your weight
- Want to lose weight
- Want to gain weight
- Want to avoid weight gain.

9. Has there been a change in your weight over the last one year    Yes            No

10. If yes, please list the change here:            Gained   lb            or   Lost   lb

11. Does your company provide any resources to employees for weight management  
(i.e. Weight watchers, Jenny Craig)?

Yes

No

12. Does your company have any on-site exercise facilities or does it provide free or  
discounted gym membership?

13. If you were offered a weight management program through your company, would  
you potentially be interested in participating?

Definitely Yes

Very Likely

Possibly

No

14. If you were to partake in a weight loss program through your company, what facilities would you be most interested in (Please check which aspects of a weight loss program you would be most enthusiastic about):

- 12-week program of group support for weight loss
- 3-month program of group support for preventing weight regain after weight loss
- Good foods for weight control available at on-site cafeteria
- List of weigh control foods available at restaurants close to your work
- Occasional seminars on specific topics to encourage healthy eating and prevent weight gain (Holiday eating, vacation eating, healthier snack options, breakfast on the go, etc).
- Electronic Newsletters/Email
- Food samples for foods suitable for healthy weight control
- Others \_\_\_\_\_

15. If others, please note your suggestions here.

## APPENDIX D: Sample Menu from the Instinct diet

Sample Menu: 1600 Calories

- Breakfast:** 2 slices of low-carb toast, 1 Tbsp peanut butter, ½ grapefruit
- Snack:** apple and 2 Tbsp peanuts
- Lunch:** Soup & Sandwich: 1 cup broth vegetable soup; 1 ½ ham sandwich made with 3 slices low-carb bread, 2 slices ham, optional 1 slice fat-free cheese, 1 tsp low-cal mayo, mustard, lettuce, tomato, onion, hot peppers  ¼ cup frozen grapes  Coffee/tea/water
- Snack:** 2 low-fat cheese sticks
- Dinner:** 5 oz. grilled fish, 1 ½ cups green beans, 1 tomato w/ oil & vinegar
- Dessert:** Ginger-pecan crunch (ginger, Fiber One cereal, yogurt, & 7 pecans)

**APPENDIX E: Overview of outcome measures**

		Support group at Intervention Worksites	Support group at Control Worksites
<b>Questionnaires</b>			
<b>All Aims</b>	<b>Demographics &amp; Brief Medical History</b>	<b>0</b>	<b>0</b>
<b>Specific Aim 1</b>	<b>Three Factor Eating Questionnaire</b>	<b>0, 10, 24</b>	<b>0, 24</b>
	<b>Weight Self-Efficacy</b>	<b>0, 10, 24</b>	<b>0, 24</b>
	<b>Cravings Questionnaire (FCQ- State, FCQ-Trait and Craving Inventory)</b>	<b>0, 10, 24</b>	<b>0, 24</b>
	<b>The WHO-BREF Quality of Life</b>	<b>0, 10, 24</b>	<b>0, 24</b>
<b>Specific Aim 2</b>	<b>Attendance and Email Support</b>	<b>Weekly</b>	
<b>Specific Aim 3</b>	<b>Intervention Feedback Survey</b>	<b>24</b>	
<b>Measurements</b>			
<b>All Aims</b>	<b>Weight</b>	<b>0, 10, 24</b>	<b>0, 24, 28</b>

## APPENDIX F: Employee Demographics Survey

**Employee Consent:** I understand that I am completing this survey for the Human Nutrition Center at Tufts University as part of their Healthy Weight for Life Program and that my answers will be kept confidential except as required by law. I understand I am being asked to complete the survey even if I do not participate in the weight program and that it will take about 10-15 minutes. I will place my completion slip generated at the end of the survey in the Healthy Weight for Life Program box at my worksite to receive a thank you gift (pedometer).

By checking this box, I consent to voluntarily providing the information below.

### 1. Demographics Questionnaire

1. Date of birth: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_  
Day month year

2. Sex (circle): M F

3. Ethnicity (check only one):

- Hispanic or Latino
- Not Hispanic or Latino
- Unknown (not reporting ethnicity)

4. Race (check only one):

- American Indian or Alaska Native
- Asian
- Native Hawaiian or other Pacific Islander
- Black or African American
- White
- More than one race
- Unknown

5. Marital Status (check only one):

- Married
- Divorced
- Single, never married
- Widowed
- Separated
- Not married, but living with partner

6. Job position/department \_\_\_\_\_

7. Education: What is the highest level of formal education you have completed (check only one)?

- 12<sup>th</sup> grade or GED
- Some college/Associates degree
- College (includes multiple degrees)
- Non-doctoral graduate degree
- Doctoral degree (M.D., J.D., Ph.D., etc.)

8. Family Income: what is the total annual income of your household (check only one)

- \$0-\$19,999
- \$20,000-\$39,999
- \$40,000-\$59,999
- \$60,000-\$79,999
- \$80,000-\$99,999
- Greater than \$100,000

9. Have you been hospitalized in the last year?    Yes    No

## APPENDIX G: Description of Eating Inventory constructs and subscales

Eating Inventory Constructs	
Restraint	Conscious restriction of energy intake to prevent weight gain or promote weight loss by, for example, counting calories and purchasing low calorie food items
Disinhibition	Tendency to overeat in response to different stimuli and triggers
Hunger	Susceptibility to eat in response to perceived physiological symptoms that signal the need for food
Eating Inventory Subscales of Bond et al.	
Restraint	
Strategic Dieting Behavior	Behaviors that might be used to control weight (e.g. deliberately taking small helpings)
Attitude to Self-Regulation	Overarching perspective on eating and weight control (e.g. feeling that life is too short to worry about dieting)
Avoidance of Fattening Foods	Dieting behavior which limits calorie-dense foods
Disinhibition	
Habitual Susceptibility	Recurrent disinhibition triggered by routine circumstances
Emotional Susceptibility	Disinhibition associated with negative affective states
Situational Susceptibility	Disinhibition initiated by specific environmental cues (e.g. social occasions)
Hunger	
Internal Locus for Hunger	Hunger that is interpreted and regulated internally
External Locus for Hunger	Hunger that is triggered by external cues

## **APPENDIX H: Eating Inventory and Scoring Summary**

### **Eating Inventory Scoring**

#### **Summary**

The Eating Inventory consisted of 51 questions that contributed to the scoring of eating behavior constructs and subscales. Each question contributed to the score of one of the three original Eating Inventory constructs (restraint, disinhibition, and hunger), and most questions contributed to the score of one or more Eating Inventory subscales, as shown in the following table and questionnaire. Questions were each worth one point; questionnaire answers in bold type accrued one point and answers in regular type accrued zero points. Higher scores indicate greater levels of the eating behavior. If answers were missing, proportional scales were calculated when less than 15% of the scale's questions were unanswered. The proportional scale was calculated as:

$$\frac{\text{raw score}}{\text{total number of possible answers} - \text{number of missing answers}} \times \text{total number of possible answers}$$

When greater than 15% of the scale's questions were unanswered, a score could not be calculated and was considered missing data.

---

**Eating Inventory Constructs**

Restraint	0-21	4, 6, 10, 14, 18, 21, 23, 28, 30, 32, 33, 35, 37, 38, 40, 42, 43, 44, 46, 48, 50
Disinhibition	0-16	1, 2, 7, 9, 11, 13, 15, 16, 20, 25, 27, 31, 36, 45, 49, 51
Hunger	0-14	3, 5, 8, 12, 17, 19, 22, 24, 26, 29, 34, 39, 41, 47

---

**Eating Inventory Subscales of Bond et al.**

## Restraint

Strategic Dieting Behavior	0-4	6, 23, 28, 48
Attitude to Self-Regulation	0-5	10, 21, 30, 32, 37
Avoidance of Fattening Foods	0-4	33, 42, 43, 44

## Disinhibition

Habitual Susceptibility	0-5	11, 36, 45, 49, 51
Emotional Susceptibility	0-3	9, 20, 27
Situational Susceptibility	0-5	2, 7, 13, 15, 16

## Hunger

Internal Locus for Hunger	0-6	3, 5, 12, 24, 34, 39, 8,
External Locus for Hunger	0-6	19, 22, 26, 41, 47

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## Eating Inventory

Construct	Subscale	Question	
D	none	1. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal.	T F
D	D-S	2. I usually eat too much at social occasions, like parties and picnics.	T F
H	H-I	3. I am usually so hungry that I eat more than three times a day.	T F
R	R-F	4. When I have eaten my quota of calories, I am usually good about not eating any	T F
H	H-I	5. Dieting is so hard for me because I just get too hungry.	T F
R	R-D, R-F	6. I deliberately take small helpings as a means of controlling my weight.	T F
D	D-S	7. Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	TF
H	H-E	8. Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat.	TF
D	D-E	9. When I feel anxious, I find myself eating.	TF
R	R-S	10. Life is too short to worry about dieting.	TF
D	D-H	11. Since my weight goes up and down, I have gone on reducing diets more than once.	T F
H	H-I	12. I often feel so hungry that I just have to eat something.	T F
D	D-S	13. When I am with someone who is overeating, I usually overeat too.	T F
R	R-R	14. I have a pretty good idea of the number of calories of common food.	T F
D	D-S	15. Sometimes when I start eating, I just can't seem to stop.	T F
D	D-S	16. It is not difficult for me to leave something on my plate.	T F
H	none	17. At certain times of the day, I get hungry because I have gotten used to eating then.	T F
R	R-F	18. While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	T F

H	H-E	19. Being with someone who is eating often makes me hungry enough to eat also.	T F
D	D-E	20. When I feel blue, I often overeat.	T F
R	R-S	21. I enjoy eating too much to spoil it by counting calories or watching my weight.	T F
H	H-E	22. When I see a real delicacy, I often get so hungry that I have to eat right away.	T F
R	R-D	23. I often stop eating when I am not really full as a conscious means of limiting the amount that I eat.	T F
H	H-I	24. I get so hungry that my stomach often seems like a bottomless pit.	T F
D	none	25. My weight has hardly changed at all in the last ten years.	T F
H	H-E	26. I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	T F
D	D-E	27. When I feel lonely, I console myself by eating.	T F
R	R-D, R-F	28. I consciously hold back at meals in order not to gain weight.	T F
H	none	29. I sometimes get very hungry late in the evening or at night.	T F
R	R-S	30. I eat anything I want, any time I want.	T F
D	none	31. Without even thinking about it, I take a long time to eat.	T F
R	R-S, R-R	32. I count calories as a conscious means of controlling my weight.	T F
R	R-A	33. I do not eat some foods because they make me fat.	T F
H	H-I	34. I am always hungry enough to eat at any time.	T F
R	R-F	35. I pay a great deal of attention to changes in my figure.	T F
D	D-H	36. While on a diet, if I eat a food that is not allowed, I often then splurge and eat other high calorie foods.	T F

**Construct, Subscale**            **Question**

---

R, R-S, R-R 37. How often are you dieting in a conscious effort to control your weight?

(1) rarely (2) sometimes **(3) usually (4) always**

R, R-R 38. Would a weight fluctuation of 5 pounds affect the way you live your life?

(1) not at all (2) slightly **(3) moderately (4) very much**

H, H-I 39. How often do you feel hungry?

(1) only at mealtimes (2) sometimes between meals **(3) often between meals (4) almost always**

R, R-R 40. Do your feelings of guilt about overeating help you to control your food intake?

(1) never (2) rarely **(3) often (4) always**

H, H-E 41. How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?

(1) easy (2) slightly difficult **(3) moderately difficult (4) very difficult**

R, R-A, R-F 42. How conscious are you of what you are eating?

(1) not at all (2) slightly **(3) moderately (4) extremely**

R, R-A, R-R 43. How frequently do you avoid 'stocking up' on tempting foods?

(1) almost never (2) seldom **(3) usually (4) almost always**

R, R-A, R-R 44. How likely are you to shop for low calorie foods?

(1) unlikely (2) slightly unlikely **(3) moderately likely (4) very likely**

D, D-H 45. Do you eat sensibly in front of others and splurge alone?

(1) never (2) rarely **(3) often (4) always**

R, none 46. How likely are you to consciously eat slowly in order to cut down on how much you

(1) unlikely (2) slightly likely **(3) moderately likely (4) very likely**

H,H-E 47. How frequently do you skip dessert because you are no longer hungry?

**(1) almost never (2) seldom** (3) at least once a week (4) almost every day

R, R-D, R-F 48. How likely are you to consciously eat less than you want?

(1) unlikely (2) slightly likely **(3) moderately likely (4) very likely**

D, D-H 49. Do you go on eating binges though you are not hungry?

(1) never (2) rarely **(3) sometimes (4) at least once a week**

R, none 50. On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never 'giving in'), what number would you give yourself? (Check one.)

(0) eat whatever you want, whenever you want it

(1) usually eat whatever you want, whenever you want it

(2) often eat whatever you want, whenever you want it

**(3) often limit food intake, but often 'give in'**

**(4) usually limit food intake, rarely 'give in'**

**(5) constantly limiting food intake, never 'give in'**

D, D-H 51. To what extent does this statement describe your eating behavior? 'I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow.'

(1) not like me (2) little like me **(3) pretty good description of me (4) describes me**

**perfectly**

---

Eating Inventory Constructs: R = restraint, D = disinhibition, H= hunger

Restraint Subscales: R-D = strategic dieting behavior, R-S = attitude to self-regulation, R-A = avoidance of fattening foods, R-F = flexible restraint, R-R = rigid restraint

Disinhibition Subscales: D-H = habitual susceptibility, D-E = emotional susceptibility, D-S = situational susceptibility

Hunger Subscales: H-I = internal locus for hunger, H-E=external locus for hunger

Answers in bold type accrue 1 point. Answers in regular type accrue 0 points.

## APPENDIX I: Food Craving Questionnaire – Trait

Please indicate the extent which you agreed with each statement below, in general, by checking the appropriate box.

	Never or NA	Rarely	Some- times	Often	Usually	Always
1. Being with someone who is eating often makes me hungry.	<input type="checkbox"/>					
2. When I crave something, I know I won't be able to stop eating once I start.	<input type="checkbox"/>					
3. If I eat what I am craving, I often lose control and eat too much.	<input type="checkbox"/>					
4. I hate it when I give into cravings.	<input type="checkbox"/>					
5. Food cravings invariably make me think of ways to get what I want to eat.	<input type="checkbox"/>					
6. I feel like I have food on my mind all the time	<input type="checkbox"/>					
7. I often feel guilty for craving certain foods.	<input type="checkbox"/>					
8. I find myself preoccupied with food.	<input type="checkbox"/>					
9. I eat to feel better.	<input type="checkbox"/>					
10. Sometimes, eating makes things seem just perfect.	<input type="checkbox"/>					
11. Thinking about my favorite foods makes me mouth water.	<input type="checkbox"/>					
12. I crave foods when my stomach is empty.	<input type="checkbox"/>					
13. I feel as if my body asks for certain foods.	<input type="checkbox"/>					
14. I get so hungry that my stomach seems like a bottomless pit.	<input type="checkbox"/>					
15. Eating what I crave makes me feel better.	<input type="checkbox"/>					

## Food Craving Questionnaire-Trait (continued)

	Never or NA	Rarely	Some- times	Often	Usually	Always
16. When I satisfy a craving, I feel less depressed.	<input type="checkbox"/>					
17. When I eat what I am craving, I feel less guilt.	<input type="checkbox"/>					
18. Whenever I have cravings, I find myself making plans to eat.	<input type="checkbox"/>					
19. Eating calms me down.	<input type="checkbox"/>					
20. I crave foods when I am bored, angry, or sad.	<input type="checkbox"/>					
21. I feel less anxious after I eat.	<input type="checkbox"/>					
22. If I get what I am craving, I cannot stop myself from eating it.	<input type="checkbox"/>					
23. When I crave certain foods, I usually try to eat them as soon as I can.	<input type="checkbox"/>					
24. When I start eating, I have trouble stopping.	<input type="checkbox"/>					
25. I have no will power to resist my food crave.	<input type="checkbox"/>					
26. Once I start eating, I have trouble stopping.	<input type="checkbox"/>					
27. I can't stop thinking about eating, no matter how hard I try.	<input type="checkbox"/>					
28. I spend a lot of time thinking about whatever it is I will eat next.	<input type="checkbox"/>					
29. If I give into a good craving, all control is lost.	<input type="checkbox"/>					
30. When I'm stressed out, I crave food.	<input type="checkbox"/>					
31. I day dream about food.	<input type="checkbox"/>					
32. Whenever I have a food craving, I keep on thinking about eating until I actually eat the food.	<input type="checkbox"/>					
33. If I am craving something, thoughts of eating it consume me.	<input type="checkbox"/>					
34. My emotions often make me want to eat	<input type="checkbox"/>					

**Food Craving Questionnaire-Trait** (continued)

	<b>Never or NA</b>	<b>Rarely</b>	<b>Some- times</b>	<b>Often</b>	<b>Usually</b>	<b>Always</b>
<b>35.</b> Whenever I go to a buffet, I end up eating more than what I needed.	<input type="checkbox"/>					
<b>36.</b> It is hard for me to resist the temptation to eat appetizing foods that are in my reach.	<input type="checkbox"/>					
<b>37.</b> When I am with something that is overeating, I usually overeat too.	<input type="checkbox"/>					
<b>38.</b> When I eat food, I feel comforted.	<input type="checkbox"/>					
<b>39.</b> I crave foods when I'm upset.	<input type="checkbox"/>					

## APPENDIX J: Food Craving Questionnaire – State

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment **right now, at this very moment**. Notice that some questions refer to foods in general while others refer to one of more specific foods. Please respond to each item as honestly as possible.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I have an intense desire to eat [one or more specific foods].	<input type="checkbox"/>				
2. I'm craving [one or more specific foods].	<input type="checkbox"/>				
3. I have an urge for [one or more specific foods].	<input type="checkbox"/>				
4. Eating [one or more specific foods] would make things seem just perfect.	<input type="checkbox"/>				
5. If I were to eat what I am craving, I am sure my mood would improve.	<input type="checkbox"/>				
6. Eating [one or more specific foods] would feel wonderful.	<input type="checkbox"/>				
7. If I ate something, I wouldn't feel so sluggish and lethargic.	<input type="checkbox"/>				
8. Satisfying my craving would make me feel less grouchy and irritable.	<input type="checkbox"/>				
9. I would feel more alert if I could satisfy my craving.	<input type="checkbox"/>				
10. If I had [one or more specific foods], I could not stop eating it.	<input type="checkbox"/>				
11. My desire to eat [one or more specific foods] seems overpowering.	<input type="checkbox"/>				
12. I know I'm going to keep thinking about [one or more specific foods] until I actually have it.	<input type="checkbox"/>				
13. I am hungry.	<input type="checkbox"/>				
14. If I ate right now, my stomach wouldn't feel as empty	<input type="checkbox"/>				
15. I feel weak because of not eating anything	<input type="checkbox"/>				

## APPENDIX K: Food Craving Inventory

For each of the foods listed below, please check the appropriate box.

Note: A craving is defined as an intense desire to consume a particular food or food type that is difficult to resist.

Over the past months, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always / Almost Every Day
1. Coke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Pizza	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Fried Chicken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Gravy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Sandwich bread	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Sausage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. French Fries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Cinnamon Rolls	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Rice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Hot dog	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Hamburger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Biscuits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Ice cream	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Pasta	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Fried fish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Cookies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Chocolate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Pancakes or waffles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Corn bread	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Chips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Food Cravings Inventory (FCI-II) (continued)

Over the past months, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always / Almost Every Day
21. Rolls	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Cereal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Donuts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Candy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Brownies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Bacon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Steak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Baked potato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## APPENDIX L: Weight Self Efficacy

This form describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat. Write this number next to each item.

Not confident at all that you can resist the desire to eat

Very confident that you can resist the desire to eat

0    1    2    3    4    5    6    7    8    9

### EXAMPLES

I am confident that:

Confidence

Number

1. I can control my eating on weekends.

\_\_\_\_\_

2. I can say “no” to snacks.

\_\_\_\_\_

---

### I am confident that:

1. I can resist eating when I am anxious (nervous).

\_\_\_\_\_

2. I can control my eating on the weekends.

\_\_\_\_\_

3. I can resist eating even when I have to say “no” to others.

\_\_\_\_\_

4. I can resist eating when I feel physically run down.

\_\_\_\_\_

5. I can resist eating when I am watching TV. \_\_\_\_\_
6. I can resist eating when I am depressed (or down). \_\_\_\_\_
7. I can resist eating when there are many different kinds  
of food available. \_\_\_\_\_
8. I can resist eating even when I feel it is impolite to refuse a  
second helping. \_\_\_\_\_
9. I can resist eating even when I have a headache. \_\_\_\_\_
10. I can resist eating when I am reading. \_\_\_\_\_
11. I can resist eating even when I am angry (or irritable). \_\_\_\_\_
12. I can resist eating when I am at a party. \_\_\_\_\_
13. I can resist eating even when others are pressuring me to eat. \_\_\_\_\_
14. I can resist eating when I am in pain. \_\_\_\_\_
15. I can resist eating just before going to bed. \_\_\_\_\_
16. I can resist eating when I have experienced failure. \_\_\_\_\_
17. I can resist eating when high-calorie foods are available. \_\_\_\_\_
18. I can resist eating even when I think others will be upset if I  
don't eat. \_\_\_\_\_
19. I can resist eating when I feel uncomfortable. \_\_\_\_\_
20. I can resist eating when I am happy. \_\_\_\_\_

## APPENDIX M: WHO-BREF Quality of Life

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		<b>Very poor</b>	<b>Poor</b>	<b>Neither poor nor good</b>	<b>Good</b>	<b>Very good</b>
<b>1.</b>	<b>How would you rate your quality of life?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

		<b>Very dissatisfied</b>	<b>Dissatisfied</b>	<b>Neither satisfied nor dissatisfied</b>	<b>Satisfied</b>	<b>Very Satisfied</b>
<b>2.</b>	<b>How satisfied are you with your health?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		<b>Not at all</b>	<b>A little</b>	<b>A moderate</b>	<b>Very much</b>	<b>An extreme</b>

				<b>amount</b>		<b>amount</b>
<b>3.</b>	<b>To what extent do you feel that physical pain prevents you from doing what you need to do?</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>
<b>4.</b>	<b>How much do you need any medical treatment to function in your daily life?</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>
<b>5.</b>	<b>How much do you enjoy life?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>6.</b>	<b>To what extent do you feel your life to be meaningful?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

		<b>Not at all</b>	<b>A little</b>	<b>A moderate amount</b>	<b>Very much</b>	<b>Extremely</b>
<b>7.</b>	<b>How well are you able to concentrate?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>8.</b>	<b>How safe do you feel in your daily life?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>9.</b>	<b>How healthy is your physical environment?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		<b>Not at all</b>	<b>A little</b>	<b>Moderately</b>	<b>Mostly</b>	<b>Completely</b>
<b>10.</b>	<b>Do you have enough energy for everyday life?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>11.</b>	<b>Are you able to accept your bodily appearance?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>12.</b>	<b>Have you enough money to meet your needs?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>13.</b>	<b>How available to you is the information that you need in your day-to-day life?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>14.</b>	<b>To what extent do you have the opportunity for leisure activities?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

		<b>Very poor</b>	<b>Poor</b>	<b>Neither poor nor good</b>	<b>Good</b>	<b>Very good</b>
<b>15.</b>	<b>How well are you able to get around?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

		<b>Very dissatisfied</b>	<b>Dissatisfied</b>	<b>Neither satisfied nor dissatisfied</b>	<b>Satisfied</b>	<b>Very Satisfied</b>

16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5
20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of	1	2	3	4	5

	<b>your living place?</b>					
<b>24.</b>	<b>How satisfied are you with your access to health services?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>25.</b>	<b>How satisfied are you with your transport?</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		<b>Never</b>	<b>Seldom</b>	<b>Quite often</b>	<b>Very often</b>	<b>Always</b>
<b>26.</b>	<b>How often do you have negative feelings such as blue mood, despair, anxiety, depression?</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>

**Do you have any comments about the assessment?**

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**APPENDIX N: Intervention feedback survey**

1) The ‘Healthy Weight for Life Program’ used several approaches to help with weight loss and maintenance. Based on your experiences, please select a number on the scale of 1 to 10 as described below, to reflect your level of agreement for each of the following questions indicating how much that given approach helped you to follow the program. **For statements that do not apply, mark the choice on the far right, “not applicable”.**

1   2   3   4   5   6   7   8   9   10   NA

Strongly disagree

Strongly agree

1.	I read some or all of the The “T” Diet book	Book
2.	The I diet menus were easy to follow	Menu
3.	I was given enough information to help me follow the menus	Menu
4.	I found it useful to have menus with both recipes and meals that required no cooking in the program	Menu
5.	During the first month of the program I mostly followed the menus	Menu
6.	Some of the meals recommended by the program have become regular things that I eat	Menu
7.	The information on planning meals and shopping helped me follow the meal plan	Group
8.	I enjoyed getting the food samples provided by the team	Group
9.	The recipes in the book motivated me to cook more often as compared to before starting the program	Book
10.	I enjoyed some or all of the recipes I tried from the book	Book
11.	I will continue to use recipes from the book even after I finish losing weight	Book
12.	Talking about recipes in the groups motivated me to cook more often as compared to before starting the program	Group
13.	The additional recipes given by the team in handouts contributed to my enjoyment of the program	Group
14.	The education units were helpful in keeping my weight on track	Group
15.	The support I felt from the counselor was helpful and encouraged me to attend meetings	Group
16.	When I did not lose weight during the week I was reluctant to attend weekly meetings	Group
17.	The support I felt from other group members was helpful and encouraged me to attend meetings	Group

18.	The education units were interesting and encouraged me to attend meetings	Group
19.	Daily weights helped keep me on track	Self weighing
20.	Sending my excel spreadsheet weekly to the team helped keep me on track	Self weighing
21.	Having a scale at the office helped me stay on track	Self weighing
22.	Feedback from my counselors on weight excel trackers helped me stay on track	Self weighing
23.	The weekly meetings helped me stay on track	Group
24.	Written materials and handouts that I received at group sessions were helpful	Group
25.	The information on how to avoid weight gain over 'holidays' was helpful	Group
26.	The list of suggested foods to eat at different restaurants when eating out was useful	Group
27.	The information on how to get back on track quickly after falling off the wagon was helpful	Group
28.	The information on how to avoid weight gain when traveling was helpful	Group
29.	The information on how to get through a plateau was helpful	Group
30.	The information on how to avoid overeating on weekends was useful	Group
31.	It was possible to incorporate the menus into my family meals	Menu
32.	I ate out less frequently while on the program	Menu
33.	With the information covered at groups, I now make healthier choices when eating out	Group
34.	I now eat more fiber than previously, to help control my hunger	Menu
35.	The program was successful in decreasing fat in my diet	Menu
36.	It was possible to adapt the menu recommendations for my family traditions and cultural habits	Menu
37.	I will continue to use some aspects of program even after the end of the study	Book
38.	The topics covered in group sessions were relevant to my lifestyle	Group
39.	The program helped me overcome my weekend challenges	Group
40.	The frequency of the group meetings was helpful (1/weekly for the first 16 weeks followed by 1/biweekly for 8 weeks)	Group

2) How did the adults you are living with react to the program.

- Supportive – they joined in!
- Supportive but they did not join in
- Not supportive throughout

- Not supportive at first but became more supportive over time
- Supportive at first but became less so over time
- N/A I live alone

3) Did you feel overall it was an advantage or disadvantage to do the program at your worksite? Please explain why you feel this way.

4) Overall, how did this program compare to other diets you have tried?

- More Effective: I lost more weight on it and/or the diet was easier to follow
- About the same: I have lost a similar amount of weight on other diets and felt it was equivalently effective
- Less Effective: I lost less weight on it and/or was harder to follow