IMPROVING MEN'S HEALTH THROUGH WEIGHT CONTROL: RANDOMIZED TRIALS TESTING RECRUITMENT MESSAGING AND A NOVEL WEIGHT LOSS INTERVENTION

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ABSTRACT

Melissa M. Crane: Improving Men's Health through Weight Control: Randomized Trials Testing Recruitment Messaging and a Novel Weight Loss Intervention (Under the direction of Deborah F. Tate)

The combined prevalence of overweight and obesity is greater among men than women in the United States but men are less likely to participate in behavioral weight control interventions. This dissertation tested ways to increase men's involvement with such programs so that they can improve their health through weight management. Aim One tested targeted recruitment messages to increase men's recruitment to a study of weight gain prevention. Young-adult households (n=30,000) were randomized to receive either a generic or a male-targeted recruitment postcard. The number of male respondents was similar across mailings (p=0.30); however a greater proportion of the total respondents to the targeted card were men (36.8% versus 19.1%; p=0.07). In Aim Two, a novel weight loss intervention was developed that incorporated men's preferences for weight loss with evidenced-based strategies. The program was designed to appeal to men by increasing autonomy and using a unique approach to calorie reduction. Men (N=107) were randomized to an immediate intervention group or a wait list control: 90.6% of those randomized provided data at the sixmonth assessment. The intervention was delivered via two face-to-face sessions followed by weekly Internet contact (tailored feedback and participant lesson selection) through three months, followed by monthly Internet contacts through six months. The intervention group

lost significantly more weight than the waitlist group (5.6 kg vs. 0.6 kg, p<0.001) at six months. Greater reductions in percent weight loss, waist circumference, and body fat were also observed in the intervention group compared to the control group (all p's<0.001). Participants completed an average of 11.2 (SD=2.7) of 13 online contacts. Aim Three tested whether changes in theoretical constructs and behaviors mediated the intervention effect on weight loss at six months. Changes in autonomous motivation, self-efficacy, and selfregulation for diet; caloric intake; and frequency of daily self-weighing mediated the intervention effect on weight loss. This collection of studies contributes to the growing literature focused on men's weight loss by providing evidence for using targeted messages to recruit men and by testing a novel approach to weight control that holds promise as an alternative to traditional behavioral therapy for men.

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LIST OF ABBREVIATIONS

ASA-24	Automated Self-Administered 24-Hour Recall
BMI	Body mass index
CI	Confidence interval
ELM	Elaboration likelihood model
KG	kilogram
KG/M ²	kilograms per meter-squared
MVPA	Moderate to vigorous physical activity
SCT	Social cognitive theory
SDT	Self-determination theory
SE	Standard error
SHED-IT	Self-Help, Exercise, and Diet using Technology
SMART	Specific, measurable, attainable, reward, and time-bound
SNAP	Study of Novel Approaches to Prevention
REFIT	Rethinking Eating and FITness

CHAPTER 1: INTRODUCTION

Overview

Obesity is one of the greatest threats to modern public health. It is associated with negative physical and mental health outcomes as well as increased healthcare expenditures. In the United States, men have consistently been more likely than women to be overweight and, conversely, women have been more likely to be obese. However, this situation is changing: over the past decade, the prevalence of obesity has increased among men while it has stabilized among women. For the first time, men and women have near equal rates of obesity; approximately 35.7% of American adults are classified as obese. Meanwhile, the prevalence of overweight continues to be higher among men than among women.

Behavioral interventions for obesity have reliably produced weight losses of approximately 5-10% of initial body weight. Weight losses of this magnitude have been associated with decreased risk for type 2 diabetes, reduced blood pressure, and improvement in mental health outcomes among other benefits. Unfortunately, men do not take advantage of such programs. Across multiple reviews, men make up approximately 27% of study samples. This has led to accrual of little information about how to enroll men in weight loss programs and how to create programs that appeal to men while still being effective. In order to combat increased obesity in men and help them to reduce or avoid the negative consequences of obesity, it is important to help overweight and obese men change their eating and physical activity habits with the goal of losing weight.

There are two major hypotheses for why men are not participating in weight control programs. The first is that the messages recruiting or advertising for weight control programs are not being received and processed by men. A second hypothesis is that the programs that are currently available are not aligned with their preferences for weight control. Therefore, the purpose of this research project is to test how modifying the messages used for recruitment and the type of program can be used to help more men benefit from behavioral weight control.

Dissertation Aims

This was a two-phase project with the following specific aims:

Phase One: Randomized comparison of recruitment messages conducted during recruitment for the Study of Novel Approaches to Prevention (SNAP) randomized controlled trial.

Aim One: Determine whether modifying recruitment materials will influence recruitment of men for a study of weight gain prevention.

1a. Test whether using recruitment postcards or brochures will yield the greatest response to recruitment materials.

1b. Test whether using targeted recruitment messages will increase men's response to recruitment materials.

Phase Two: Randomized controlled trial to determine the efficacy of a novel behavioral weight loss intervention for men delivered primarily online that focused on increasing autonomy and achieving weight loss through diet and exercise modification with minimal lifestyle disruption.

Aim Two: Determine the effects of an autonomy focused behavioral weight loss intervention on objectively measured weight loss and secondary outcomes (change in waist

circumference, percent body fat, percent weight change, caloric intake, and leisure time physical activity) as compared to a waitlist control group at six months.

Aim Three: Test whether proposed theoretical and behavioral intervention targets mediate the relationship between intervention group and weight loss assessed at six months.

CHAPTER 2: BACKGROUND AND LITERATURE REVIEW

Obesity as a Public Health Problem

In the United States, 68.8% of adults are overweight (body mass index (BMI) 25-29.9 kg/m²) or obese (BMI \geq 30 kg/m²; Flegal, Carroll, Kit, & Ogden, 2012)). The prevalence of overweight and obesity have increased dramatically since 1960 when approximately 43.3% of adults were overweight or obese (Flegal, Carroll, Kuczmarski, & Johnson, 1998). In the past decade, the prevalence of obesity in men has continued to rise (from 27.5% in 1999 to 35.5% in 2010) while the prevalence in women has generally remained the same (33.4% in 1999 and 35.8 in 2010; Flegal, et al., 2012). The impact of obesity on public health is farreaching with effects seen on physical health, mental health, disability, and mortality.

Obesity is associated with increased risk for a variety of cardiovascular problems including hypertension, hyperlipidemia, and stroke (Field et al., 2001). Additionally, type 2 diabetes is comorbid with overweight and obesity and as average body weights have increased in the U.S., so has the prevalence of diabetes (Wilson et al., 2007). It is estimated that the number of Americans with diabetes will increase from the current 11 million cases to 29 million by 2050, should obesity rates continue to increase as projected (Boyle et al., 2001). Excess body weight has also been associated with increased risk for cancers including colon and rectal cancers, kidney cancer, and post-menopausal breast cancer (Calle, Rodriguez, Walker-Thurmond, & Thun, 2003; Renehan, Tyson, Egger, Heller, & Zwahlen, 2008). Like type 2 diabetes, the incidence of these cancers has increased as the prevalence of overweight has increased (Eheman et al., 2012). Because of its association with numerous health outcomes, medical costs associated with overweight and obesity totaled an estimated \$147 billion in 2008 (Finkelstein, Trogdon, Cohen, & Dietz, 2009).

Obesity is also related to negative psychological outcomes and poorer daily functioning outcomes. Individuals who are overweight and obese face weight related stigma which has been associated with lower pay and increased risk of depression (Puhl & Heuer, 2009). Obesity also affects quality of life across multiple domains, ranging from physical functioning to emotional functioning (Kushner & Foster, 2000). Overweight and obesity is associated with increased functional disability, especially among the elderly (Alley & Chang, 2007). The strong connection between body weight and disability causes individuals with obesity to have a significantly lower disability-free life expectancy than normal weight adults (Al Snih et al., 2007). Finally, obesity is associated with an increased risk of all-cause mortality (Allison, Fontaine, Manson, Stevens, & VanItallie, 1999; Flegal, Graubard, Williamson, & Gail, 2005). Most of the deaths associated with obesity are caused by coronary heart disease, other forms of cardiovascular disease, and cancers associated with obesity (Flegal, Graubard, Williamson, & Gail, 2007).

With the numerous negative outcomes associated with obesity, it is important for public health researchers to focus on finding ways to slow or reverse the trend of the continuing obesity epidemic. Although surgical and pharmacological approaches to obesity treatment are possible, these are costly and may not be appropriate for many people. Behavioral interventions for obesity hold promise for reducing the negative effects of obesity on a scale that could potentially offset the rise of the obesity epidemic.

Behavioral Treatment for Obesity

Behavioral weight loss programs focus on using diet, exercise, and cognitive behavior therapy to promote weight loss. These changes to habits are presented as a way to maintain a healthier lifestyle that can be continued beyond the treatment phase of the weight loss program, increasing the impact of the interventions. The behavior therapy focuses on using techniques from cognitive behavior therapy to change behaviors related to diet and physical activity. Techniques often used include focus on self-regulation and stimulus control (Wadden, Butryn, & Byrne, 2004; Wadden, Webb, Moran, & Bailer, 2012). Generally, these programs encourage a reduction of caloric intake by 500 to 1000 calories per day in order to produce weight losses of approximately one to two pounds per week. Participants are also encouraged to increase their physical activity to approximately 200 minutes per week during weight loss and 300 minutes per week for weight loss maintenance (Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Wadden, et al., 2012). The intervention is typically delivered in-person to groups of 10-30 adults that occur weekly and last between 60-90 minutes per session. Most behavioral weight loss programs are short (6-12 months) with limited long-term follow-up (18-24 months).

Behavioral treatment for obesity has proven to be an effective option for weight loss. In meta-analyses, behavioral weight loss programs produce average weight losses between 5-10% of the initial body weight during the first year of treatment (Franz et al., 2007; Wadden & Butryn, 2003). This magnitude of weight loss is associated with reductions in risk for developing type 2 diabetes (Diabetes Prevention Program Research Group, 2004), reduction in blood pressure, improvements in lipid profiles, and reduction in cardiovascular disease medication use (The Look AHEAD Research Group, 2007). In addition to physical health

improvements, behavioral treatments are also associated with improvements in depression and self-esteem (e.g., Blaine, Rodman, & Newman, 2007). Although weight losses achieved during the intensive treatment phase are often regained without continuing intervention (MacLean et al., 2015; Ross Middleton, Patidar, & Perri, 2011) there is evidence that even with regain, behavioral interventions for weight loss produce long-lasting health benefits.

The Diabetes Prevention Program compared the effects of a behavioral weight loss intervention, a diabetes medication, and usual care for preventing the onset of type 2 diabetes among participants who entered the program with insulin resistance. Participants who were randomized to take part in the intensive lifestyle intervention for weight loss reduced their risk for developing type 2 diabetes during a 10-year follow-up period as compared to both the mediation and usual care groups. This effect was seen despite poor weight loss maintenance during this time (Diabetes Prevention Program Research Group, 2009). Similarly, improvements of cardiovascular risk factors were found among lifestyle intervention participants in the Look AHEAD trial three years after the intervention period ended. These effects again were seen despite significant weight regain (The Look AHEAD Research Group, 2010).

Although these programs have led to encouraging results, face-to-face behavioral treatment for obesity has several limitations. First, the behavioral weight loss treatments discussed above are costly to implement. A recent intervention that used 60-minute group meetings, once per week, for six months estimated the cost of implementation to be \$113,738 for 130 individuals (Krukowski, Tilford, Harvey-Berino, & West, 2011). Additionally, behavioral weight loss programs have been critiqued because of their limited geographical reach. These programs are typically delivered in university settings, attracting largely

homogenous sample of participants—generally middle-aged, college-educated, white women (Pagoto et al., 2011). Both of these factors severely limit the potential for disseminating these programs on a large enough scale to combat the obesity epidemic as well as limiting the generalizability of the results of the studies to other populations.

In order create behavioral weight loss programs that have a larger reach, is it first necessary to understand which recommendations are most effective for producing weight loss. To advance this understanding, three major aspects of the interventions have been tested to better understand their influence on subsequent weight loss. These include the composition of the recommended diets, the recommendations for physical activity, and the role of selfmonitoring in weight loss. First, the macronutrient composition of the diets recommended for weight loss has been extensively tested. Two major types of diet compositions that have been tested are high versus low carbohydrate recommendations (e.g., Foster et al., 2010) and high versus low glycemic index diets (e.g., Fabricatore et al., 2007). Taken as a whole, this body of research appears to indicate that the composition of the diet recommended does not have strong effects on weight loss over a period of 12 months. Rather, it is the reduction of *total calories* that is associated with weight loss. Thus, Wadden and colleagues recommend that diet compositions should be guided by the presence of comorbid conditions and by participant preference rather than making generalized recommendations supporting any particular macronutrient diet content (Wadden, et al., 2012).

The role of physical activity in weight loss has also been tested. Dietary changes alone do not produce weight losses that are as great as through the combination of changes in diet and physical activity (Swift, Johannsen, Lavie, Earnest, & Church, 2014). This finding has been demonstrated using samples of women and men (Franz, et al., 2007). Meanwhile,

physical activity alone does not seem to produce weight loss among women but there is some evidence that high levels of moderate physical activity (200-300 minutes per week) has been associated with weight loss in men (Donnelly et al., 2003). Physical activity is more important during weight loss maintenance. Observational data suggest that high levels of moderate to vigorous activity (MVPA) are associated with improved weight loss maintenance (i.e., weight loss after 12 or more months after initial weight loss initiation). In a study of successful weight losers, participants report an average of 60 minutes of exercise, most days per week (Wing & Phelan, 2005). This level of activity has been confirmed to be effective for weight loss maintenance in randomized trials (Jakicic et al., 2011; Jeffery, Wing, Sherwood, & Tate, 2003). Thus, a combination of diet and physical activity is recommended for weight loss maintenance.

Finally, self-monitoring is an important behavior for successful weight loss. Selfmonitoring serves multiple purposes including feedback on progress towards goals and identifying problematic habitual behaviors. A recent meta-analysis concluded that selfmonitoring of diet and physical activity was associated with total weight loss (Burke, Wang, & Sevick, 2011). However, as noted in the review, there is still uncertainty concerning the detail of the self-monitoring that is needed for weight loss. It is hypothesized that detailed self-monitoring of diet (including recording the calories and fat in every food eaten) is necessary to maximize weight loss (Burke et al., 2008). Unfortunately, monitoring at this level is taxing and generally decreases over time. Other research suggests that the detail of the monitoring recording is not as important as the process of self-monitoring itself (Burke, et al., 2008; Helsel, Jakicic, & Otto, 2007; Peterson et al., 2014). There is evidence from both

observational (Linde, Jeffery, French, Pronk, & Boyle, 2005) and experimental studies (Steinberg et al., 2013; Wing, Tate, Gorin, Raynor, & Fava, 2006) that only monitoring daily body weight and responding to changes in weight with appropriate behavior changes is sufficient to produce weight loss, at least in the short term.

Behavioral Interventions Delivered via Technology

In order to overcome some of the limitations of face-to-face behavioral weight loss interventions, delivery of interventions using technology has been explored. Although some studies have been conducted that use telephones (e.g., Perri et al., 2008) or text-messages (e.g., Haapala, Barengo, Biggs, Surakka, & Manninen, 2009), use of the Internet and email to deliver interventions has received the most attention. Internet delivery of behavioral interventions has the potential to reach many people simultaneously while maintaining the core tenants of face-to-face programs.

The majority of American adults (87%) use the Internet at least occasionally (Pew Research Center, 2014). Although Internet use remains lower among those who have less education (76% for individuals with less than a high school education) or among those with lower household incomes (77% for those making < \$30,000 per year), these groups are still well represented online (Pew Research Center, 2014). Thus, delivery of behavioral interventions over the Internet may be able to reach many individuals, with detailed information and on their schedule, making it an ideal delivery system for health promotion programs.

Internet-delivered behavioral weight loss programs have been tested over the past decade. Several reviews have concluded that Internet-delivered programs produce weight losses that are greater than minimal treatment- or no treatment-control groups (Arem &

Irwin, 2011; Neve, Morgan, Jones, & Collins, 2009; Wieland et al., 2012). A recent Cochrane review attempted a meta-analysis of seven studies of interactive, Internet-delivered interventions and found that weight losses were 1.5 kg greater in the computer delivered intervention groups than minimal contact control groups at six months (Wieland, et al., 2012). However, as noted in this review and others, the overall effectiveness and cost effectiveness of behavioral interventions delivered online is difficult to determine due to the heterogeneity of the programs (Tate, Finkelstein, Khavjou, & Gustafson, 2009).

In order to better understand the comparisons in efficacy as well as cost effectiveness between face-to-face and Internet-delivered weight loss, a study compared delivery of the same weight loss program in-person, online, or using a hybrid approach (Harvey-Berino et al., 2010). As might be expected, the weight losses were greatest among those in the inperson intervention with no differences between the Internet and hybrid groups (-7.6 kg vs. -5.5 and -6.0, respectively; Harvey-Berino, et al., 2010). In contrast to the absolute weight losses, a similar percentage of individuals in each group (approximately 59%) lost a clinically significant weight loss of at least five percent of their initial weight. The in-person group, in contrast, was more likely to achieve a 7% weight loss compared to the two other treatment groups. The cost-effectiveness analysis of this program found that while the inperson program was most effective, it was also much more costly per person (in-person: \$706 vs. Internet: \$373; Krukowski, et al., 2011). The authors conclude that the differences in weight loss may not be as important as the reduced cost as well as the potential dissemination of the program offered by the online program. This finding suggests that using the Internet to deliver weight loss programs has the potential to be more cost-effective than similar face-to-face programs.

Despite the increased flexibility and cost effectiveness, Internet-delivered weight loss programs still attract a limited segment of the overweight and obese population. The participants in both face-to-face and technology delivered programs tend to be collegeeducated, non-Hispanic white women (Wieland, et al., 2012), similar to face-to-face programs. Therefore, regardless of mode of treatment delivery, there is a need to involve a broader representation of the population in behavioral weight loss treatment.

Gender in Behavioral Treatment of Obesity

Men represent one segment of the population that is largely missing from behavioral weight control programs. Several reviews of weight loss programs—including programs delivered both in-person and online, those with a minimum of one year follow-up, and those exclusively delivered online—have found that only about 27% of participants are men (Franz, et al., 2007; Pagoto, et al., 2011; Wieland, et al., 2012). A closer examination of both of the Franz, et al. and Pagoto, et al., reviews suggest that the percentage of men participating studies testing *behavioral* interventions may be even lower than these estimates. For example, some of the studies that were reviewed that were exclusively comprised of men were testing the effect of the addition of a specific food to a diet on weight loss in the short term (e.g., guar gum in Kovacs et al., 2001) rather than testing a lifestyle intervention.

Although men are underrepresented in behavioral weight loss trials, they are not entirely absent and there is limited research that has been conducted to understand how men perform in these programs. A recent review and meta-analysis examined whether there were differences in weight loss, percent weight loss, and BMI change during weight loss programs by gender (R. L. Williams, Wood, Collins, & Callister, 2015). The articles reviewed that included results from 58 interventions that reported weight loss by gender, although not all of

these studies tested for differences by gender. Men lost more weight, measured in absolute kilograms and percent of initial weight, than women, regardless of type intervention (diet only, exercise alone, or combination). On the other hand, there appeared to be no difference in change in BMI by gender, although the sample for this analysis was limited (R. L. Williams, et al., 2015). This evidence suggests that men perform as well as women when they join a weight loss program.

Despite these findings however, results from the review must be extrapolated with caution. The men who join weight loss programs, despite being in the minority, may not be representative of men in general. For example, these participants may be more highly motivated or have more obesity-related health concerns than men who choose not to join a weight loss program. Additionally, there may be personality factors that lead these men to seek help with weight loss when perhaps a more typical response is avoiding help seeking for health concerns (Galdas, Cheater, & Marshall, 2005).

Men's health researchers suggest that men's lack of participation in weight loss programs is part of a larger trend where men avoid healthcare and health promotion behaviors as a demonstration of masculinity (Addis & Mahalik, 2003; Galdas, et al., 2005; Hammond, Matthews, Mohottige, Agyemang, & Corbie-Smith, 2010). Masculinity has been widely studied from a constructivist approach where gender is viewed as a socially created construct and is something that is "performed" on a daily basis. These behaviors are selected subconsciously rather than as part of a more conscious decision-making process. The predominant form of masculinity in Western societies is characterized by the "denial of weakness or vulnerability, emotional and physical control, the appearance of being strong and robust, dismissal of any need for help..." (Courtenay, 2000, p. 1389). Other features that

define masculine behaviors, affect, and cognition are: a focusing on winning, emotional control, risk-taking, violence, power over women, dominance, primacy of work, disdain for homosexuality, and pursuit of status (Mahalik et al., 2003). While not all men, or subgroups of men, endorse all of these characteristics, these descriptors form the basis of hegemonic masculinity that is defined by the dominant group in the United States; that is, by Caucasian, middle or upper-class heterosexuals (Mahalik, et al., 2003). Theorists believe that hegemonic masculinity affects all other subgroups in the population who in turn, act out masculinity in ways appropriate for their cultural subgroup. This creates a multitude of masculinities that vary based on the age, sexual orientation, and racial group of the man (Courtenay, 2000; Evans, Frank, Oliffe, & Gregory, 2011).

It is hypothesized that because of the central focus on self-reliance in masculinity, men are more likely than women to avoid seeking medical attention even during emergencies because it would demonstrate weakness (Addis & Mahalik, 2003; Galdas, et al., 2005). Further, men often avoid situations where they are low in the social hierarchy, for example as a patient in a healthcare situation because can be seen as an act of submission (Addis & Mahalik, 2003). Finally, because of the focus in masculinity on control over physical conditions, preventative health behaviors are seen as more feminine than masculine (Courtenay, 2000).

While broad theorizing has been used to explain differences between men and women, a more useful approach to studying the effect of masculinity on health has been to compare men who highly endorse traditional masculinity to those lower on this trait (Galdas, et al., 2005). Mahalik and colleagues have conducted a series of studies where endorsement of traditional masculinity was used to predict either self-report health behaviors or self-

reported perception of risk for disease. In two studies of self-reported health behaviors, samples of men in the United States and Australia who reported higher levels of endorsement of masculinity also reported fewer health promotion behaviors (Mahalik, Burns, & Syzdek, 2007; Mahalik, Levi-Minzi, & Walker, 2007). Among the health behaviors measured, masculinity endorsement was associated with eating fewer servings of fruit and lower intake of fiber. In another study, masculinity moderated the effect of perceived barriers on health promoting behaviors. For men higher on masculinity, perceived barriers to health promoting behaviors were more strongly and negatively associated with their behaviors than men who reported lower levels of masculinity (Mahalik & Burns, 2011).

It is not surprising, given that even general health promotion can be seen as feminine, that participating in weight loss programs and dieting have both been reported as "feminine" activities in qualitative studies of men's perceptions of weight loss (de Souza & Ciclitira, 2005). Gough's discourse analysis of mainstream media's discussion of weight loss for men suggested that men are expected to express their masculinity through their selection of masculine foods such as red meat. Further, Gough notes that men are often talked down to in articles discussing weight loss, implying that men are not aware of what is needed for weight loss (Gough, 2007). An analysis of *Men's Health* magazine found that in reference to diet, men are frequently encouraged to increase their consumption of protein rich foods in order to increase muscle mass and rarely encouraged to reduce intake to manage weight (Cook, Russell, & Barker, 2014). In light of the growing obesity epidemic, this advice is concerning and there is a need to involve men in weight loss programs and overcome the perception that weight loss itself is feminine and the diets required of weight loss are feminine, programs

need to emphasize how men can continue to express their masculinity while participating in the program in order to appeal to men.

Gender Differences in Weight Related Beliefs and Behaviors

Masculinity intersects men's weight through influencing their perceptions of their bodies, how they eat, and how they approach weight loss. Men typically consider an ideal body to be one that is large and muscular (Frederick et al., 2007). This view is mirrored in popular media which presents messages to men that they should focus on "bulking up" by gaining muscle rather than focusing on losing weight (Cook, et al., 2014; Gough, 2007). The impact of this message in a society where most men are overweight or obese is troubling. This message of the ideal male body that is bulky due to muscle may lead to men who are overweight not due to muscle, but instead due to excess fat, to overlook excess body weight as a health concern.

There is evidence that this misclassification of body weight due to these societal ideals is taking place. In contrast to men, women strive for a body type that is smaller than their own (Cohn & Adler, 2006). These differences in ideal body weight translate directly onto overweight men and women's classification of their own body weight. Overweight women are more likely than overweight men to correctly identify themselves as overweight (Gregory, Blanck, Gillespie, Maynard, & Serdula, 2008a). Similarly, obese women are more likely to report themselves as "very overweight" than obese men. This misclassification likely explains why overweight men are less likely to view their weight as a health risk than overweight women, which is an important viewpoint because the perception of weight as a health risk in turn is associated with reporting a current attempt to lose weight (Chang & Christakis, 2003; Gregory, Blanck, Gillespie, Maynard, & Serdula, 2008b). Finally,

overweight and obese men are more satisfied with their current weight than women and are less likely than similarly sized women to report a desire to change their current eating or physical activity habits (Kuk et al., 2009). This increased satisfaction with current weight status may indicate that overweight men may have less motivation to change the behaviors needed for weight loss than women.

Similar to perceptions of bodies, men have concerning perceptions about diet. In qualitative analyses, men report that food is something that is necessary to sustain life and is likened to fuel rather than something to be enjoyed (Sellaeg & Chapman, 2008) and report that they eat a "masculine" diet including meat, potatoes, alcohol, and few fruits or vegetables (Jensen & Holm, 1999; Sellaeg & Chapman, 2008; Sobal, 2005). Foods that are lower in calories and fat that are often prescribed in weight loss programs—including fruits, vegetables, and low-fat dairy products—are all perceived by men to be feminine (Gough & Conner, 2006), insufficient to curb hunger (Roos, Prattala, & Koski, 2001), and too time consuming to prepare on a regular basis (Sellaeg & Chapman, 2008; Welsh, Sherwood, VanWormer, Hotop, & Jeffery, 2009).

The reports of men's views of food are confirmed in analyses of consumption patterns between men and women. Using data from the National Health and Nutrition Examination Survey, gendered displays of consumption are found across multiple food groups and eating patterns. Men report eating more calories per day, (approximately 2,507 calories per day) compared to women (1,760 calories; Sebastian, Wilkinson Enns, & Goldman, 2011), however it is unclear if these estimates adjust for men's larger stature and higher caloric needs. Men are less likely than women to report eating breakfast (Deshmukh-Taskar, Radcliffe, Liu, & Nicklas, 2010). Men and women also tend to eat different types of

foods. Men in the United States eat approximately the same number of servings of fruits and vegetables per day as women but men are more likely to get their servings from juice (Demydas, 2011). Not surprisingly, men tend to eat more meat, particularly red meat, a food strongly associated with masculinity (Daniel, Cross, Koebnick, & Sinha, 2011). Finally, men are also more likely than women to drink sugar-sweetened beverages on a daily basis (Rehm, Matte, Van Wye, Young, & Frieden, 2008). These eating habits found in the United States are also found in studies of European populations indicating consistent gender differences in eating across western cultures (Jensen & Holm, 1999) and worldwide men consume diets that are less health promoting than women (Imamura et al., 2015).

In addition to differences in eating patterns and food selections, men and women also differ in their cognitive and emotional reactions to foods. These differing reactions to food begin appearing between boys and girls during adolescence and are maintained as they age (Rolls, Fedoroff, & Guthrie, 1991). This suggests that these gender differences are well established by the time individuals reach adulthood. For example, studies suggest that men do not consider food choices with the same level of cognition as women, who spend more time weighing pros and cons of each food choice (Levi, Chan, & Pence, 2006). Additionally, men and women have differing neural responses to food cues. Using functional magnetic resonance imaging, women demonstrate greater overall reactions to food cues than men when compared to nonfood cues in both fasting and fed states (Uher, Treasure, Heining, Brammer, & Campbell, 2006). Women are also more likely than men to show reactions in the reward pathways of the brain when shown high-calorie foods while in a fasting state (Frank et al., 2010). This difference may have significant implications for weight loss and suggest that men may fare better than women in their attempts to lose weight, if and when,

they try. A recent study found that strong reactions to high-calorie foods within the reward pathway was predictive of poorer weight loss in a 12-week behavioral weight loss intervention (Murdaugh, Cox, Cook, & Weller, 2012).

Taken as a sum, this evidence suggests that the weight loss programs that have been developed using samples primarily composed of women may not be the most effective or efficient programs for men, despite men's past success. Men and women enter into weight loss programs with differing concerns that need to be addressed as part of the weight loss program. Whereas men's selections of foods and their patterns of intake are problematic, women typically have more emotional and cognitive concerns related to eating and their bodies that need to be addressed. For example, women are more likely to express barriers to weight loss related to emotional eating than men whereas men report barriers such as food knowledge and other practical barriers (French, Jeffery, & Wing, 1994). At enrollment into a weight loss program woman are more likely to report being depressed than men and also more likely to report binge eating (Linde et al., 2004). Lessons focused on overcoming emotional barriers to weight loss are often featured in standard behavioral weight loss programs.

The additional time that is spent in a weight loss program on addressing emotional eating with women may be better served by focusing on appropriate portion control and selection of diet with men. Some of the gender differences in food consumption described above suggest that men on average consume diets that are associated with increased body weight or poorer weight loss. For example, men report drinking more sweetened drinks and more juice than women. The consumption of sugar-sweetened beverages is associated with greater body weight (Malik, Schulze, & Hu, 2006) and drinking fruit juice is less filling than

consuming whole fruit (Flood-Obbagy & Rolls, 2009). Further, reducing caloric drinks is associated with greater weight losses in behavioral weight loss trials (Chen et al., 2009; Tate et al., 2012). Another example is that men are less likely than women to report eating breakfast. Breakfast consumption is associated with longterm weight loss success (Wyatt et al., 2002). Addressing these issues directly may be beneficial to men's weight loss progress.

The development of a weight loss program that focuses on men's eating styles may lead to greater weight losses among men. Programs to date do not consider the differences in men and women's habitual food patterns prior to the weight loss program. Because men are resistant to diets high in fruits and vegetables, typical weight loss programs ask men to make larger changes in their diet and to eat more foods that they initially avoid than women. Maintaining these large changes may be especially challenging for men, which may in part, explain why although men lose more weight during treatment programs, these larger loses are not always maintained into the weight loss maintenance phase (e.g., Svetkey et al., 2011).

Men's Perceptions of Weight Loss and Preferences for Treatment

In order to better understand how to reconcile the conflicting pressures men face between how masculinity suggests they should behave and their need for weight loss, researchers have begun studying how men perceive weight loss programs and what they want from these programs. Three qualitative studies and one quantitative study have been published that investigated these questions from different perspectives and with different samples. The results of these studies support what might be hypothesized using masculinity theory and can provide insight when developing weight loss interventions for men.

To study men's perceptions and preferences for weight loss, two qualitative studies used samples of men from blue-collar worksites from the Netherlands (Sabinsky, Toft,

Raben, & Holm, 2007) and Australia (Egger & Mowbray, 1993) while the third study recruited men from slimming clubs (commercial weight loss programs) in the United Kingdom (de Souza & Ciclitira, 2005). A quantitative study was identified that included men who had never participated in an organized weight loss program who were recruited at a primary care clinic (Wolfe & Smith, 2002). In these studies, nearly all men reported that they had attempted to lose weight in the past. Many men reported using "crash-diets" and most reported attempting to lose weight on their own. The finding that men are unlikely to have experience with formal weight loss programs has also been found in quantitative analyses of men in weight loss research studies (Crane & Tate, 2013; Forster & Jeffery, 1986).

When asked about their barriers to joining a weight loss program, many men indicated that formal weight loss programs are seen as aimed at women, which supports the masculinity theory's supposition that dieting is seen as feminine. Interestingly, when de Souza and Ciclitira interviewed men participating in a sliming club, five of the six men joined the club with their wives. These men reported that they would not have joined without their wives because their wives instigated the weight loss attempt. For many men, language represented another barrier to joining a weight loss program. Perhaps in an attempt to masculinize weight loss, men in the qualitative studies preferred to avoid the phrase "weight loss". Instead, men preferred to frame messages about weight loss as improving health, increasing fitness, or getting fit. This finding encouraged Egger and colleagues to focus their program (described below) as focusing on "waist loss" rather than weight loss. This finding supports what is found in the masculinity literature in that "weight loss" is perceived as feminine therefore changing the focus to general health would reduce some of the perception of femininity.

Another barrier to joining a weight loss program the men identified were differences in reasons for weight loss between themselves and women. De Souza and Ciclitira found that men who were interested in losing weight drew strong distinctions between men's and women's motivations for weight loss. The men in this study reported that women wanted to lose weight for reasons of vanity while men are motivated by "legitimate" health concerns and the desire to feel better (de Souza & Ciclitira, 2005). When asked about their reasons for weight loss, improved health, improved quality of life, and improved fitness were found across both qualitative (Egger & Mowbray, 1993; Sabinsky, et al., 2007) and quantitative studies (Hankey, Leslie, & Lean, 2002; Wolfe & Smith, 2002). In the two studies conducted at worksites, the men also reported that they were motivated to lose weight to improve their work performance.

Interestingly, changing intake was reported as one of the strongest deterrents from joining weight loss programs despite correctly identify changing diet change as one of the major components of an effective weight loss program. Men in the three qualitative studies reported they felt that changing their diet was the best way to lose weight (de Souza & Ciclitira, 2005; Egger & Mowbray, 1993; Sabinsky, et al., 2007). On the other hand, men reported that the diets needed to lose weight were unappealing because they were too restrictive and would not be sufficient to fuel them in their daily lives (Egger & Mowbray, 1993). Another study of men and eating found that "healthy eating" was reported by men to seem boring, time consuming, and would lead to feelings of deprivation (Gough & Conner, 2006).

When researchers investigated what features of a weight loss program would appeal to men, individualization was a crucial issue. In the three qualitative studies as well as the

survey, men reported that they were not interested in a "one-size fits all" approach. In both the qualitative and quantitative studies, men reported wanting individually focused programs that would not include strict meal plans (Sabinsky, et al., 2007). Instead, men wanted to be able to tailor the diet to their preferences, including eating meat and drinking alcohol. Further, participants reported that while they had followed their own approach, if they were going to join a program they would want valid information presented in a clear manner but that they would also appreciate humor (Sabinsky, et al., 2007). Another common preference was for a program that would not disrupt their daily routine. Specifically, men reported being interested in programs would take place either in a worksite or at a fitness facility (Wolfe & Smith, 2002). Finally, across the studies, men reported that they were not interested in attending group sessions for the treatment intervention and instead wanted personal intervention delivery.

One significant drawback to the qualitative studies discussed above is that they were all conducted outside the United States. The prevalence of obesity has been significantly higher among men than women in these countries for a longer period than in the United States, which may influence the men's perceptions of weight loss. However, there is also reason to believe that the results of these studies can be generalized to men living in the United States. As evidence of this, a survey conducted by Wolfe and Smith in the United States (Wolfe & Smith, 2002) concluded that men would prefer individually focused programs conducted either in fitness centers or in the home. This result confirms findings from the qualitative literature reviewed above.

In summary, men in these studies reported many barriers to joining weight loss programs, primarily related to a desire to avoid feminine activities. The program features that

men describe as appealing lend themselves well to delivery of the intervention over the Internet. This mode of delivery would allow for a program that is individualized and is less disruptive to men's lifestyles than a standard weight loss program, delivered face-to-face in group settings. Researchers have begun to use these studies as formative research for weight loss programs designed to meet men's needs and have created programs that have generally been perceived positively by men.

Weight Loss Programs for Men

In response to men's preferences for weight loss, researchers have begun developing weight loss treatments that focus on men and incorporating their program preferences. A systematic review found that 23 studies have been published that tested behavioral interventions for weight loss or weight loss maintenance using samples of only men (Young, Morgan, Plotnikoff, Callister, & Collins, 2012). Of note, not all of these interventions were developed to target men: some tested the effects of generic weight loss programs using samples of men. The five studies that focused on weight loss, used randomized trials, and featured a no-treatment control were combined in a meta-analysis. The resulting difference between groups indicated a 5.6 kg greater weight loss in the intervention groups as compared to the no-intervention control groups. However, this analysis combined studies with significant heterogeneity in the studies' interventions (diet only vs. diet plus physical activity vs. comprehensive behavioral weight loss) and length of intervention (3 months to 12 months). Nevertheless, the studies included in this review represent attempts to date to target men with weight loss interventions. Of the studies conducted evaluating weight loss programs for men, novel approaches to recruitment, calorie reduction, and delivery have been used, a selection of which is described below.

Some researchers have attempted to better involve men in weight control by changing recruitment messages and framing of the intervention to be more appealing to men. One novel approach used in this area was to recruit men by emphasizing their role as a father and role model for their children. The intervention, developed and evaluated in Australia, was delivered during eight face-to-face group sessions and used a standard approach to weight control but stressed the importance of fathers changing weight-related behaviors in order to be a healthy role model for their children. At the six-month follow up, men in the treatment group had lost more weight (-6.7 kg) than men in the control group (-0.4 kg; Morgan, Lubans, et al., 2011). Another novel approach that has been tested was to develop a weight loss program that was affiliated with professional football teams (Wyke et al., 2015). For this program, recruitment and intervention delivery took place at the stadium, capitalizing on the affiliation with the team. This approach was tested in the United Kingdom, and was compared to a waitlist control group during a six-month randomized trial. The program used a gender-sensitized behavioral approach to weight control, including 12 weekly group sessions delivered at the football stadiums and exercise sessions conducted on the stadium field. The program was successful in producing a 5.8 kg weight loss within the intervention group at 12 weeks, which was largely sustained until the 12-month assessment (intervention: 5.6 kg vs. control: 0.58 kg).

Another unique approach to recruitment and program delivery was tested where a weight loss program was delivered directly to men or through their wives (Matsuo et al., 2009). The authors suggest that by influencing the social network of the target man, their behavior would be changed. Although not stated in the article, this approach may be of interest because wives are more likely to be responsible for food preparation than husbands

(Sobal, 2005). The results suggest that the direct delivery of the intervention to the male participant was more effective than the indirect intervention (-6.2 kg vs. -4.4 kg) but both were better than the no intervention group (-0.7 kg; Matsuo, et al., 2009).

Finally, the majority of studies have focused on changing the approach of the intervention in order to make it more appealing to men. Several of these studies have been conducted in Australia, including the early "Gut Busters" program. This program developed by Egger and colleagues focused on "waist loss" and incorporated aspects of the male diet into the weight loss program, including drinking alcohol and eating red meat. The group delivered, face-to-face intervention focused on the science of weight loss, tracking fat (not calories), increasing fiber, increasing walking, and on making "tradeoffs" of increased exercise to allow for consumption of alcohol. Unfortunately, this program has only been evaluated using a one-group pre-/post- design, limiting the conclusions that can be reached about its effectiveness. Nevertheless, Egger reported that men enjoyed the program and lost an average of approximately 15 kg after six weeks, although the exact weight losses were not reported (Egger, Bolton, O'Neill, & Freeman, 1996). This magnitude of weight loss has not been reported by other behavioral interventions for weight loss among men or women and may have resulted from unique characteristics of the sample used in this study rather than the program itself.

More recently, a series of studies have been conducted that have tested similar interventions in varying contexts in Australia. The core intervention, Self-Help, Exercise, and Diet using Technology (SHED-IT), was delivered via one group session and weekly electronic feedback for 12 weeks. Educational intervention content was provided via a booklet with nine keys to weight loss strategies plus access to an online calorie tracking

system. The nine keys to weight loss were simple, easy to communicate strategies for weight loss including "keep a health lifestyle diary," "reduce your junk food," and "tilt the balance with physical activity." Men in the intervention were asked to track their intake using an online calorie tracker and to submit diaries to the study on a weekly basis. In the first study, this intervention was compared to the booklet alone and no differences were observed between groups at any time point (12-months: -3.0 kg control, -4.8 kg intervention; Morgan, Lubans, Collins, Warren, & Callister, 2011). Men from both treatment arms significantly reduced their total intake, portion sizes, energy from fat and saturated fat, and intake of energy-dense foods between baseline and the six-month assessment, suggesting that the keys to weight loss provided during the intervention were effective in changing men's diet patterns (Collins, Morgan, Warren, Lubans, & Callister, 2011). Men in both groups also increased their average steps per day from 8,500 steps per day at baseline to 9,625 at month six (Morgan, Lubans, Collins, Warren, & Callister, 2009). The results of semi-structured interviews conducted after the final assessment indicated that men enjoyed participating in the program and that the program was appealing because of the low time commitment required and because it allowed for "treat" foods. The interviews also revealed that the presentation of the information (which balanced science and education about weight loss with humor) was appealing (Morgan, Warren, Lubans, Collins, & Callister, 2011).

The intervention developed for the SHED-IT trial was then used as the basis of a program to promote weight loss among employees at an aluminum production facility. The intervention was compared to an assessment only control group. Similar to the initial trial, the group that received the intervention lost more weight (4.0 kg) than the control group (0.3 kg) at four months (Morgan, Collins, et al., 2011). Men in the intervention group increased

their physical activity more than the control group but few significant changes were found for diet. Most recently, this intervention was tested without the face-to-face meetings (Morgan et al., 2012). In this trial, the booklet developed for the SHED-IT intervention was given along with an introductory DVD to men randomized to use paper self-monitoring or online monitoring plus periodic feedback from study staff. These groups were compared to a waitlist control. Men were encouraged to follow the program for three months, followed by three months of no treatment. At the end of the six-month period, men in both treatment groups had lost more weight (3.7 and 4.7 kg) than men in the comparison group (0.5 kg).

Patrick and colleagues conducted the only randomized trial that evaluated a weight loss program developed specifically for men in the United States. This study tested the effect of an online weight loss program delivered over one year as compared to a delayed intervention group (Patrick et al., 2011). Similar to the SHED-IT trial, this intervention focused on a limited number of strategies that could be used to produce weight loss. Additionally, the intervention focused on improving the healthfulness of the diet rather than on restriction and did not provide a suggested calorie intake or suggest that participants selfmonitor their diet. The intervention was delivered via a study website and focused on goal setting to involve the participants with the weight loss program. At the end of one year, weight losses from both groups were minimal; however, there was a trend toward the intervention group losing more weight (0.9 kg vs. 0.2 kg) although this difference was not statistically significant.

Taken in summary, there is still a great need for the development and evaluation of weight loss interventions for men. First, there is a need for more research to be conducted in the United States. Of the studies reviewed above, only one study was conducted in the US

(the remainder of which were in Australia, the United Kingdom, and Japan). It is unclear if men in these other countries are similar to men in the US but with high obesity rates, the US is greatly in need of programs that will appeal to men. Secondly, these studies indicate that using specific weight loss recommendations, rather than focusing on using a full standard behavioral approach may be fruitful for weight loss in men; however, more research is needed on this topic.

Summary

Obesity represents a major threat to public health and needs to be addressed through interventions that will help the nearly 68% of American adults who are overweight or obese to lose weight. As reviewed above, behavioral weight loss interventions demonstrate effectiveness in helping individuals to lose weight and improve their health. Unfortunately, these programs are generally tested using samples of women. To overcome this disparity, research is needed that focuses on men's weight loss needs. This dissertation addresses this need through randomized trials focusing on two aspects of men's weight loss. First, in Aim One, recruitment messages that are targeted toward men were tested for their effectiveness as compared to general recruitment messages. Secondly, in Aim Two, a new approach to behavioral weight loss was tested that integrated the formative research on men's perceptions of weight loss programs with health behavior theories in an innovative weight loss intervention developed specifically for men. Finally, in Aim Three, the effects of theoretical and behavioral mediators were examined to understand the mechanisms through which the program led to weight loss.

CHAPTER 3: THEORETICAL FRAMEWORK, RATIONALE, AND METHODS OF THE REFIT STUDY

Theoretical Framework and Conceptual Model

Social cognitive theory (SCT) and self-determination theory (SDT) are two of the most commonly used theories in health behavior research. These theories were used in tandem to guide the development of the Rethinking Eating and FITness (REFIT) program due to their complimentary views on sustainable behavior change. SCT focuses on the learning and environmental factors that influence changing behaviors while SDT focuses on the motivation for the behavior change. Understanding how to help individuals change behavior while addressing the motivation underlying these changes is vital to creating a health behavior program that will produce sustainable behavior change and, in turn, prolonged positive effects on health. Figure 3.1 shows the conceptual model of the intervention that integrates constructs from these two theories.

Social cognitive theory. Social cognitive theory (SCT) describes five categories of influence that determine how an individual behaves: psychological determinants, results from observational learning, environmental determinants, self-regulation, and moral disengagement (McAlister, Perry, & Parcel, 2008). Additionally, SCT posits that through reciprocal determinism the social and physical environment in which individuals and groups live influences their behaviors. Simultaneously, individuals and groups also influence their environment (McAlister, et al., 2008). Although SCT offers a comprehensive theory to describe the influences on behavior, this project will utilize a selection of constructs from SCT. Self-efficacy, self-regulation, and outcome expectations will be used as intervention targets because these constructs have each been associated with weight loss or behaviors needed for weight loss in previous behavioral weight loss interventions.

Self-efficacy. Self-efficacy is the belief held by an individual that he or she can control his or her behaviors and that these behaviors will then lead to a desired outcome (McAlister, et al., 2008). Bandura has suggested that self-efficacy is central to behavior change because it influences directly the individual's perceptions of attainable behavior change (outcome expectancy) as well as the goals an individual creates for him or herself (Bandura, 2004). Within the arena of weight control, self-efficacy is generally operationalized as feelings of control over eating and physical activity behaviors in socially, emotionally, and structurally challenging situations (Clark, Abrams, Niaura, Eaton, & Rossi, 1991; Sallis, Pinski, Grossman, Patterson, & Nader, 1988). In a recent systematic review, increases in self-efficacy during a weight loss program were associated with increased weight losses (Stubbs et al., 2011). Although only one study was found that specifically reported the relationship between self-efficacy and weight loss among men, the association supports the theory that self-efficacy is positively associated with weight loss (Jeffery et al., 1984); however, other studies have found that baseline self-efficacy predicts weight loss among men but not among women (French, et al., 1994; Presnell, Pells, Stout, & Musante, 2007).

The REFIT intervention was designed to increase self-efficacy in several ways. First, self-efficacy can be enhanced through mastery experience (McAlister, et al., 2008). In traditional weight loss programs, calorie reduction is typically achieved through providing participants with a structured meal plan that requires immediate and dramatic changes in behavior early in the weight loss program. This may lead to feelings of frustration rather than

mastery due to the large behavioral changes that are required. Instead of using this standard approach, behavior shaping was used in this study. Shaping is used in cognitive behavioral therapy to successively change behavior in small increments in order to increase feelings of mastery while moving closer to the ultimate goal (Ferguson & Christiansen, 2008). In the REFIT intervention, shaping was used by asking participants to change one significant weight loss behavior at a time. The REFIT program also encouraged participants to increase their physical activity incrementally during program. Additionally, self-efficacy was enhanced through integrating goal setting into the intervention. Goal setting can increase feelings of mastery by focusing on small but realistic goals in order to reach an ultimate goal (Bandura, 2004). Finally, self-efficacy was enhanced in this program through written encouragement included in the weekly tailored feedback (McAlister, et al., 2008).

Self-regulation. Self-regulation is a process of monitoring progress through systematic self-monitoring, goal-setting, receiving feedback, self-reward, self-instruction, and enlistment of social support (McAlister, et al., 2008). Self-monitoring has been associated with weight loss in behavioral weight loss studies when operationalized as both detailed self-monitoring of diet and activity (Burke, Wang, et al., 2011) and as daily selfweighing (Steinberg, et al., 2013). Using an intervention based on self-regulation, participants in a face-to-face intervention group were able to maintain greater weight losses than participants in the self-guided group (Wing, et al., 2006). Self-regulation is generally cited as a core component in successful weight loss programs (e.g., Wadden, et al., 2012).

Self-regulation was integrated centrally into the REFIT program. First, all participants were encouraged to self-monitor their weight loss behaviors, physical activity, and their weight on a daily basis. Secondly, participants were encouraged to develop weekly goals that

would allow them regular opportunities to evaluate their progress. These goals were structured using the SMART technique which specifies that goals should be: Specific, Measurable, Attainable, Reward, and Time-bound (Doran, 1981). Although, participants received regular feedback on their progress from the study, they were also encouraged to evaluate their own progress relative to their own goals.

Outcome expectancies. Outcome expectancies are the beliefs a person holds about a behavior. These can include the feelings of what would happen if a behavior is completed and also if it is not completed. Bandura includes in the conceptualization that outcome expectancies include any social outcomes—both the positive or negative reactions—within a person's social environment as well as the direct effects of the behavior (Bandura, 2004). Addressing and managing these expectations can help individuals understand why behaviors are important and what to expect if negative behaviors continue. During interviews with men, qualitative researchers found that men generally have negative expectances related to eating a healthy diet, including concerns about hunger (Egger & Mowbray, 1993; Gough & Conner, 2006). Because of the presence of such expectancies, the REFIT program focused on changing the outcome expectancies for both the outcomes of specific behaviors as well as for weight loss in general.

Self-determination theory. Self-determination theory (SDT) focuses on describing human motivation and posits that humans have an innate desire to grow and improve (Ryan & Deci, 2000). SDT suggests that humans will be happiest, most effective, and most likely to maintain behaviors when they feel that they are competent in the behavior, when they feel related to those around them, and when they are acting out of their own desires, rather than in response to external pressures (Deci & Ryan, 1985). When tasks are interesting and are

carried out for the sole purpose of doing the task, participants are motivated by internal motivation (Ryan & Deci, 2000). In contrast, many behaviors are completed in order to gain something other than the enjoyment of the task: this is external motivation. Many behaviors related to health are driven by external motivation because it is the result and not the behavior that is motivating the behavior. As an illustration, eating a healthy diet is often undertaken with the goal being healthy or losing weight, thus the behavior is externally motivated. However, external motivation is not a singular construct but falls on a continuum ranging from autonomous motivation—that is, coming from within the self—or controlled motivation—responding to external pressures. Again, in a weight-related example, a person may be motivated to eat a healthy diet to improve their own self-image or they could be motivated to eat a healthy diet due to advice given by their physician. Respectively, these would be considered autonomous and controlled motivation. The goal for most health-related behavior change interventions is to encourage the development of autonomous motivation for the behaviors.

Several authors have discussed the importance of autonomous motivation for weight loss (e.g., Silva et al., 2010; Teixeira, Silva, Mata, Palmeira, & Markland, 2012; G. C. Williams, Grow, Freedman, Ryan, & Deci, 1996). In all cases, autonomous motivation for participating in a weight loss program measured during, but not prior, to a weight loss program is associated with weight losses in both short term (Webber, Tate, Ward, & Bowling, 2010) and longer term studies (G. C. Williams, et al., 1996). Increases in internal motivation for exercise has also been associated with greater longer-term weight loss (Teixeira et al., 2006). Using this information, Silva and colleagues developed and tested a weight loss intervention based on SDT for overweight women. In their program, women

experienced meaningful weight losses of 6.6% compared to 1.3% in the control group (Silva, et al., 2010). These weight losses were well maintained over time where after two years of no treatment participants where 3.9% and 1.9% below their initial weights. Autonomous motivation for exercise was a significant predictor of weight loss maintenance throughout this trial (Silva et al., 2011).

Based on results from laboratory studies as well as intervention studies, Ryan and Deci have developed recommendations for aiding others in increasing autonomous motivation. First, they suggest that clinicians and behavior change programs focus on providing autonomy support. Autonomy support includes providing participants with choices in behaviors, encouraging them to set their own goals, and encouraging participants to focus on what is personally relevant and important to them (Deci & Ryan, 2008). Providing rationale for why the behavior of focus is important can also increase the autonomous motivation (Ryan & Deci, 2000). The REFIT program focused on providing information about weight loss and behavior change in a manner that was autonomy supportive. For instance, participants were encouraged to select their own behavior goals and to decide which target behaviors they wanted to focus on each week. Moreover, the lessons provided during this program included why each behavior is important for weight loss. This was hypothesized as a way to increase the internalization of motivation for the behavior while also fulfilling men's desire for clear and evidenced based weight loss information (Gough & Conner, 2006; Sabinsky, et al., 2007).

The integration of behavioral theories described above was guided by two factors. First, theoretical constructs were selected because of their association with weight loss in prior behavioral weight loss interventions. Of equal importance, they have also been selected

because they fit together with the theories of masculinity described previously. For example, while SDT has not yet been used to address weight loss with men, it may be more especially relevant for men. Descriptions of the masculine ideal focus on being independent and self-reliant. Courtenay suggests that expressing this self-reliance is one of the keys ways men express their masculinity (2000). Therefore, for a weight loss program to be effective with men, there is a need to help them increase their feelings of self-reliance, even within a structured program. Additionally, focusing on shaping behaviors may also be especially relevant to men. Compared to women, men have less experience with weight loss behaviors within organized weight loss programs (Crane & Tate, 2013; Forster & Jeffery, 1986). This suggests that they may not have the behavioral repertoire needed to make major changes to diet and physical activity from the start of the program. Using shaping to more slowly change their behavior may be more effective and provide the mastery experiences needed to increase self-efficacy for weight loss.

One shortcoming of the literature discussed above is that many studies that tested the association between theoretical constructs and weight loss have done so construct by construct. This stands in opposition to the theories these constructs originate from, which suggest that the constructs function together to create behavior change. To address this shortcoming, Aim Three of this dissertation tested not only whether the individual constructs mediate the relationship between the intervention and weight loss, it also tested whether the constructs continued to mediate the relationship taking into account the other constructs in the model. This more closely tests the conceptual model that underlies the REFIT intervention.

Rationale for Intervention Components

The REFIT intervention focused on encouraging changes in eating and activity through increasing self-efficacy, autonomous motivation, outcome expectancies, and selfregulation for weight loss behaviors. The development of this intervention was guided by qualitative research focused on what men want and need from weight loss programs as well as previous research focused on weight loss among both men and women. The approach used in the REFIT intervention was innovative as a combination of the "small changes" approach that has been used in weight gain prevention (Gokee LaRose, Tate, Gorin, & Wing, 2010) as well as the client centered deficit approaches used by Lutes and colleagues and Sbrocco and colleagues in weight loss programs (Damschroder, Lutes, Goodrich, Gillon, & Lowery, 2010; Damschroder et al., 2014; Lutes et al., 2012; Lutes et al., 2008; Sbrocco, Nedegaard, Stone, & Lewis, 1999). The major unique facets of the REFIT program are described below.

Novel approach to calorie reduction. In the qualitative studies of men's views on healthy eating and weight loss, despite the empirical evidence in support counting calories, however this behavior is in conflict with men's desire for weight loss programs that are not excessively time consuming (e.g., Egger & Mowbray, 1993). To address this finding, an alternative approach to producing weight loss was selected for this trial. In the REFIT program, participants were encouraged to make small but numerous changes to their diet behavior each day, described as making "six 100-calorie changes per day". This was selected as the goal because it was hypothesized to be a large enough deficit to produce approximately one pound of weight loss each week while still making changes small enough that they could be sustained over time.

In order to help participants find ways to make these changes each day, lessons were developed that focused on specific eating behaviors and food groups that could be targeted to make 100-calorie changes. Several studies have been conducted which provide participants with booklets or informational sheets with simple to communitcate "key" strategies for weight loss. While some of these studies have produced nonsignificant (Patrick, et al., 2011) or minimal (Bennett et al., 2012; Leslie, Lean, Baillie, & Hankey, 2002) weight losses others have been more successful. The SHED-IT trial used a booklet featuring nine key weight loss behaviors which produced significant decreases in weight both with and without detailed self-monitoring (Morgan, Lubans, Collins, et al., 2011). The approach used in SHED-IT has demonstrated effectiveness in worksite and community samples as well (Morgan, et al., 2012; Morgan, Collins, et al., 2011).

The REFIT trial combined the "key-behaviors" approach to weight loss with the structure of weekly lessons used in both patient centered weight loss programs (Lutes et al., 2012; Sbrocco, Nedegaard, Stone, & Lewis, 1999) as well as standard behavioral weight loss interventions (Wadden, et al., 2012). In these types of programs, lessons focused on behavioral strategies are delivered on a weekly or biweekly basis through either face-to-face group meetings or via the Internet (Jakicic et al., 2012; Tate, Jackvony, & Wing, 2006; Tate, Jackvony, & Wing, 2003). This combination was selected as it was hypothesized to captilize on the simplicity of the lessons to minimize participant burden and to promote ongoing engagement with the intervention by providing the lessons weekly, rather than only at the beginning.

Choice of target behaviors and lessons. Many behavioral interventions encourage participants to set behavioral goals of their own choosing in order to emphasize a patient-

centered approach. However, the lessons are often still delivered in a predetermined order (Lutes et al., 2013; Sbrocco, et al., 1999). This may lead to incongruence between lesson topics and personal goals. By contrast, REFIT intervention allowed participants to select the target behavior they wanted to focus on and were then supplied a lesson related to that behavior. An example lesson is provided in Appendix A. Participants set their own selfselected goal related to the target behavior. The self-selection of target behaviors and weekly lesson topics in addition to self-selection of goals is hypothesized to be one way to increase feelings of autonomy among participants during a structured weight loss program. This sense of autonomy is in turn hypothesized to increase participants' self-efficacy and autonomous motivation for weight loss behaviors, as suggested by self-determination theory. However, during the review of the literature, no previous studies were identified that used this approach, thus making the approach employed in the REFIT program an addition to the literature.

Novel self-monitoring strategy. During most behavioral interventions for weight loss, participants are encouraged to closely monitor their diet through either tracking calories (Burke, Wang, et al., 2011) or through monitoring the categories of foods that they eat (Damschroder, et al., 2010; Damschroder, et al., 2014). Detailed self-monitoring has been used in some weight loss interventions for men (e.g., Morgan, Lubans, Collins, et al., 2011) however such behaviors are not preferred by men (e.g., de Souza & Ciclitira, 2005). Across studies, detailed self-monitoring is usually not sustained over time (Burke et al., 2012). Moreover, there is some evidence that men are able to lose weight without relying on detailed self-monitoring: in the SHED-IT trial, men were randomized to receive the weight loss information booklet alone or the booklet plus recommendations for daily self-monitoring

with periodic personalized feedback. In this study, both groups lost significant weight from baseline but were of similar magnitude at 3, 6, and 12-months (Morgan, et al., 2009; Morgan, Lubans, Collins, et al., 2011). As an alternative to the traditional self-monitoring recommendations, participants in the REFIT program were asked to track the changes they were making to their diet instead of all foods eaten. A simple checklist-type form was developed where participants could indicate that they made a change and could describe the change for their own records. An example checklist is provided in Appendix B. Participants were encouraged to track their changes in 100-calorie increments to simplify the tracking behaviors.

Gender targeted lesson content. The final novel aspect of the REFIT intervention was the targeting of study materials toward men. Targeting of messages is hypothesized to increase the perceived relevance of the messages and is associated with increased likelihood of behavior change (Kreuter & Wray, 2003). In the REFIT intervention, targeting included focusing topics relevant to men, for example how to integrate masculine foods such as meat and alcohol into a healthy diet and how to make changes both when participants are responsible for cooking for themselves and when others cook for the participants. The lessons also included surface tailoring by using male pronouns, pictures of men, and examples expected to be more salient to men. The lessons used straightforward but humorous language, a communication style that has been reported as preferred by men when communicating about weight loss (Morgan, Warren, et al., 2011). An example lesson is shown in Appendix A.

Study Methods and Intervention Description

Using the framework and intervention components described above, the Rethinking Eating and FITness (REFIT) intervention was tested in a six-month randomized controlled trial as compared to a waitlist control group. This intervention represents a combination of intervention components that are a significant enough departure from prior research to warrant the use of a waitlist control group. As described by Mohr and colleagues (Mohr et al., 2009), a waitlist control group is appropriate for testing interventions that are in early stages of testing and where use of a no-contact control group would be unethical or impractical. The present study meets the first criteria because of its novelty. To address Mohr's second requirement, a waitlist control group was warranted for this evaluation because it would likely be difficult to recruit participants who would be willing to undergo randomization to a no-treatment control group when they are seeking a weight loss program. Thus, a waitlist comparison group was the most appropriate selection for the current study.

The REFIT study tested the efficacy of the REFIT intervention over six-months. Assessments were conducted at baseline (pre-randomization), three months postrandomization, and six months post-randomization. The primary outcome was change in weight over the study period with secondary outcomes of change in waist circumference, body fat, caloric intake, and leisure time physical activity. It was hypothesized that those randomized to receive the REFIT program immediately would lose more weight than those randomized to the waitlist group.

Sample and recruitment. The sample recruited for this study included 107 adult men aged 18-65 with a BMI between 25-40 kg/m². The BMI and age criteria for this study were selected to avoid including those at increased risk for injury or harm from changing

physical activity behaviors in an unsupervised setting. In addition, the intervention delivered in this study was developed to produce modest weight losses; therefore, men with BMIs greater than 40 kg/m² may be better served by more intensive interventions (Sarwer, von Sydow Green, Vetter, & Wadden, 2009). Because the majority of the REFIT intervention was delivered via the Internet, men were required to have Internet access at least twice weekly. They also needed to be willing to receive the intervention materials via email or a study website and attend two group sessions. Additionally, participants were required to be free from medical conditions that could put them at risk for harm when changing diet and physical activity. Specifically, exclusion criteria included: weight loss greater than 10 pounds in the six-months prior to the intervention, current participation in another weight loss program, plans to move from the Chapel Hill area in the six-months after recruitment, diagnosis of schizophrenia, bipolar disorder, or depression leading to hospitalization in the previous year, current treatment for cancer, or endorsement of items 1-4 from the Physical Activity Readiness Questionnaire (Thomas, Reading, & Shephard, 1992). Participants who reported heavy alcohol use, as defined as a score of 10 or higher on the Alcohol Use Disorders Identification Test (Reinert & Allen, 2007), were also excluded. Participants who reported diagnosis of or treatment for high blood pressure, heart disease, or diabetes were required to obtain consent from their physician prior to participation in the intervention.

Participants for this study were recruited from the Chapel Hill, Durham, and Raleigh areas of North Carolina. Advertisements for this study in the form of flyers (see Appendix C) were distributed in the community at gyms and businesses. The recruitment messages focused on the benefits of participating in the program and used humorous language, as suggested by prior research (Morgan, Warren, et al., 2011).

Study procedures. Recruitment materials directed interested participants to a study website. This website contained a description of the study, information about the researchers, and a link to an online study eligibility screening form. This form included questions about the participant's health history, current height and weight, demographic information, and contact information. Participants who met eligibility criteria were called to complete the screening process and to schedule a time to attend an in-person orientation meeting. These meetings were held at the office of UNC Weight Research and included a description of the study and what could be expected when participating in a research study. Participants who chose to join the study were then guided through the informed consent process. After participants consented to be in the study, they were given instructions for completing the in-person baseline assessment and online questionnaires.

Randomization was completed prior to the first group meeting. All participants who have consented to participate and had completed the baseline assessment (including online questionnaires; described below) were considered eligible for randomization. Randomization was completed using a random number generator in Excel and was completed so that randomization will create two groups of approximately equal size. Randomization results were concealed from study participants until they arrived for the first group session.

All participants were asked to return for in-person assessment visits three and six months after randomization. During each assessment period participants were also asked to complete questionnaires online. After each assessment, all participants were given feedback forms that included their anthropomorphic measures and diet summary information. These forms included a description of how the measures are associated with health and current recommendations for health. For example, waist circumference was reported in inches and

was presented with the current recommendation for men to strive to maintain a waist circumference less than 40 inches. Participants were given a \$20 stipend for completing the three and six month assessments. All study procedures were reviewed and approved by the University of North Carolina non-biomedical institutional review board. The trial was registered with a clinical trials registry prior to beginning the study (NCT01843595).

Description of the REFIT intervention. The REFIT intervention was delivered during two face-to-face group sessions, 10 weekly online check-ins (described below), and three monthly online check-ins during months four through six. To complete the online check-ins, participants were sent a personalized link to the online system (Qualtrics) where they reported their past week's behaviors, received tailored feedback, and selected their next lesson (as applicable). After completing the online check-in, participants were sent a copy of their feedback and the lesson they selected via email. If participants did not complete an online check-in by midweek, they were sent a reminder email. Those who did not complete the check-in by the end of the week were sent the next lesson. If a participant did not complete check-ins for two weeks, they were contacted by telephone to ensure the emails were being received. Participants were encouraged to complete the next week's check-in.

Evaluation of current weight behaviors. The REFIT intervention began with two face-to-face group meetings one week apart. The first session was used to describe the study rationale and to present basic information about weight loss ("Weight Loss 101: Understanding Energy Balance"), the benefits of weight loss (to increase outcome expectancies), and rationale for the self-evaluation (to increase self-regulation). For the self-evaluation, participants were asked to closely monitor their diet and physical activity over the next week without making changes to their current behavior. The self-evaluation was

designed to provide a baseline for comparison, which helped participants to accurately evaluate their progress later in the program (Damschroder, et al., 2010; Damschroder, et al., 2014). The baseline also helped participants to select realistic goals each week, allowing for mastery experiences throughout the program. The experience of the self-evaluation was designed to enhance participants' self-regulation skills. Participants were given paper diaries to self-monitor their food and physical activity during the self-evaluation week but were given the option to self-monitor using a smartphone based application or website as well.

During the second group meeting participants were asked to identify aspects of their eating and physical activity habits that are not aligned with their desire to lose weight and that they were willing to change. A similar technique has been used in other weight loss programs (Damschroder, et al., 2010; Damschroder, et al., 2014). Based on this selfevaluation, participants were asked to select the first target eating behavior they wanted to change. As part of the self-evaluation, participants were given an estimate of their daily caloric needs as well as the prescribed intake level to produce a one- to two-pound weight loss per week. This estimate was based on their estimated total energy expenditure calculated during the baseline assessment (see assessments below). Participants were given a list of upcoming lesson topics and a description of the behaviors that indicate that the lesson would be a useful strategy to help them lose weight (see Table 3.1). Participants were asked to consider which behaviors they would be most willing to change and which behaviors they are not ready to change, emphasizing their autonomy in the program

Physical activity recommendations. Starting in week two, participants were encouraged to gradually increase their physical activity to 225 minutes of physical activity per week. To reach this goal, participants selected one of three exercise progression plans.

The plans started at varying levels of activity (ranging from 10 minutes, five days per week to 30 minutes, five days per week) but all followed a gradual progression up to 225 total minutes (45 minutes per day). The gradual increase in physical activity will help increase feelings of self-efficacy for the behavior by providing a chance for mastery experiences while also decreasing risk for injury.

Weekly lessons and behavioral goals. The lessons in this study focused on target behaviors and skills that would aid participants in reaching the diet goal of reducing their intake by six 100-calorie changes each day (see topics in Table 3.1). The behaviors and skills were identified by reviewing the literature and finding specific activities that have either been associated with weight loss in past studies—for example, reducing caloric beverages can produce weight loss over time (Tate, et al., 2012) or behaviors that have be targeted in other successful weight loss studies (Greaney et al., 2009; Lally, Chipperfield, & Wardle, 2008). The goal of selecting these specific behaviors was to select behavioral targets that could be articulated to participants in a simple manner, that could be monitored in a simple manner, and that could be implemented with minimal lifestyle disruption. Thirteen lessons were developed and delivered during the first 12 weeks of the REFIT intervention. The behaviors that were expected to yield to greatest caloric reductions were presented first. This was designed to help participants to begin to losing weight earlier in the intervention in order to prevent discouragement. Three additional lessons that focused on weight loss maintenance skills were presented as options during months four through six. These lessons ("Eating in Social Situations", "Slips, Slides, and Falls", and "Maintaining Your Momentum") were skill based versus focusing on specific eating behaviors. These topics were selected for use during

the tapered contact period of the program because these are skills that support making longterm changes to eating and exercise behaviors.

During online check-ins, participants were asked to select lesson topics associated with the target behaviors that they were willing to change and that represented areas of their diet that were currently impeding their weight loss. This selection of lessons was designed to increase the participants' feelings of autonomy within the intervention. Lessons began with a description of the "problem" associated with the target behavior and provided a "solution" that the participant could implement (see Appendix A for example lesson). This was included to increase positive outcome expectancies for the behaviors. In addition to increasing outcome expectation, this information is also in accordance with men's reported desire to have scientifically based information about weight loss. The second section of the lessons focused on how to integrate changes in the behavior into the participants' daily lives. Strategies suggested here integrated constructs from cognitive behavioral therapy similar to those techniques used in standard behavioral weight loss programs. Finally, the lessons provided example weekly goals to demonstrate how the behavior could be incorporated into their person weekly goal. This goal setting was used to increase participants' self-efficacy and self-regulation.

Online check-ins and tailored feedback. Starting in week three, participants were asked to complete an online check-in to report information from their self-monitoring records and select their new lesson. Participants reported their current weight, days of self-weighing, minutes of physical activity, and the number of changes they made to their diet over the past week. They were provided with feedback on their physical activity (met goal, did not meet goal, zero), days of self-weighing (\geq five days, <five days), their weekly weight loss (weight

losses of one pound per week will be the target for the intervention), their total weight loss (at or below the expected total), and whether they met the goal to make six 100-calorie changes per day. Appendix D provides an example feedback used during the check-in. Participants who met the goals received positive feedback and were encouraged to continue their current behaviors. Participants who did not meet the goals were encouraged to increase monitoring and to use problem solving to overcome current barriers that were preventing progress towards study goals.

If the participant met the weekly weight loss goal, he was encouraged to continue using the successful weight loss strategy and was given the option to select a new lesson to focus on or continue using the successful strategy. If the participant did not meet the weight loss goal (weight loss of < 1 pound), he was encouraged to select a new lesson topic and associated behavioral goal. This process of evaluation of weight losses and choices of adding or maintaining the target behaviors continued throughout the program.

Waitlist control group. After the six-month study, participants who were randomized to the waitlist control group were offered a single group session followed by 10 weeks of online check-ins. The check-ins were nearly identical to those received by those in the immediate treatment group. Participants in this group were not required to return to the study center at the end of the three-month treatment period.

Data Collection Procedures and Measures

Study assessments occurred prior to randomization, three months (12 weeks) after randomization, and six-months (24 weeks) after randomization. Objective weight, height, waist circumference, and body composition measurements were measured in-person at the office of UNC Weight Research. All self-report measures were completed online using

Qualtrics survey software and the National Cancer Institute's Automated Self-Administered 24-Hour Recall (ASA-24) system. A unique link to the questionnaires was created for each participant. This allowed participants to complete the questionnaires over multiple sessions, if desired. Questionnaires were expected to take approximately 60-90 minutes to complete. Table 3.2 includes a description of each of the self-report measures.

Physical measures. Weight was measured at each assessment using a calibrated digital scale (Tanita Model: BWB-800s) to the nearest tenth of a kilogram. Participants were measured without shoes while wearing spandex compression shorts. Height was measured at baseline only using a wall-mounted stadiometer to the nearest tenth of a centimeter. Waist circumference was measured to the nearest tenth of a centimeter parallel to the floor at the top of the iliac crest during exhalation using a flexible measuring tape (Gulick II). All measures were taken twice to ensure consistency. Third measures were taken as needed to gain a consistent result.

Body composition was assessed using air displacement plethysmograohy using the Bod Pod (COSMED USA, Inc., Concord, CA). This procedure provides an accurate assessment of body composition during a short and noninvasive procedure (Ginde et al., 2005). In addition to providing measures of body composition, this assessment also provides estimates of resting and total energy expenditure. These estimates are based on the participant's body composition measures as well as the age, height, and race (K. M. Nelson, Weinsier, Long, & Schutz, 1992).

Self-report measures. At baseline, participants were asked to complete a demographics and personal history questionnaire. This questionnaire included questions

about age, marital status, education status, chronic health conditions, weight history, weight loss program participation history, and motivation for joining the program (see Appendix E).

Dietary intake. Dietary intake was measured at each assessment using the Automated Self-Administered 24-Hour Recall (ASA24)-2011. This online dietary evaluation system was developed by the National Cancer Institute and is freely distributed by NCI to aid researchers in accurately assessing of intake patterns. This system guides participants through a multipass recall of foods eaten over the previous 24-hours. The system was modeled after 24-hour recall interviews and features options to aid participants with low literacy. Intake was measured twice (one weekday and one weekend day) at each time point to provide the most accurate representation of typical consumption. The system creates researcher reports of intake that include total energy intake, macronutrients, and micronutrients.

Physical activity. Physical activity was assessed using the Alumni Study Questionnaire, otherwise known as the Paffenbarger Physical Activity Questionnaire (Paffenbarger, Hyde, Wing, & Hsieh, 1986). This is an 8-item questionnaire that assesses walking, stair climbing, and sports, fitness, and recreational activities during the prior week. The summary variables include total minutes of activity and total energy expenditure from exercise.

Self-efficacy for weight loss. Self-efficacy for eating a diet necessary for losing weight was assessed using the Weight Efficacy Life-style Questionnaire (WEL-Q; Clark, et al., 1991). The WEL-Q has five subscales that assess self-efficacy for healthy eating in the presence of the following factors: negative emotions, food availability, social pressure to eat, physical discomfort, and positive activities. Most frequently, this scale is reported as a total score of the five subscales. This scale has demonstrated high internal consistency when

administered to men participating in a behavioral weight control program ($\alpha = 0.95$; Linde, et al., 2004).

Self-efficacy for exercise. Self-efficacy for physical activity levels needed for weight loss was measured using the self-efficacy for exercise questionnaire developed by Sallis and colleagues. This 12-item measure assesses self-efficacy for exercise related to resisting relapse and making time for physical activity. The internal validity of this scale was tested among a sample of individuals seeking weight loss treatment and was found to be acceptable ($\alpha = 0.83$; Sallis, et al., 1988).

Autonomous motivation. Autonomous motivation was measured in three ways: motivation for participating in the weight control program, motivation for healthy eating, and motivation for exercise. Motivation for these three behaviors were measured using the appropriate version of the Treatment Self-Regulation Questionnaire (Levesque et al., 2007). These scales have three subscales: autonomous motivation, controlled motivation, and amotivation. This scale has demonstrated high levels of internal consistency and has been frequently used for measuring motivation for weight loss (e.g., Silva, et al., 2010; Webber, et al., 2010).

Self-regulation. Self-regulation was assessed using the Eating Behavior Inventory (O'Neil et al., 1979). This is a 26-item measure that assesses behaviors associated with self-regulation for weight loss. The measure has been used extensively in behavioral weight control research since its development (O'Neil & Rieder, 2005). Weight loss during treatment has been associated with increases in Eating Behavior Inventory scores.

Outcome expectancy. The outcome expectancy subscales of the Health Beliefs Survey, developed by Anderson and colleagues, was used to assess outcome expectancies

related to healthy eating and physical activity (Anderson, personal communication). This scale, including previous versions, has been used in multiple studies (Anderson, Winett, Wojcik, & Williams, 2010; Anderson, Winett, & Wojcik, 2000; Anderson-Bill, Winett, Wojcik, & Winett, 2011; Winett, Anderson, Wojcik, Winett, & Bowden, 2007). This scale was developed to explicitly test outcome expectancies for changing diet and physical activity across social, mental, and physical health domains.

Self-weighing. Self-weighing was assessed at each assessment using a single item measure. The item asks how often the participant current weighs himself on a seven-point scale from "never" to "multiple times per day" (Linde, et al., 2005; Wing, et al., 2006).

Satisfaction with the program. To assess satisfaction with the REFIT intervention, participants in the active treatment arm were asked rate their level of satisfaction with the intervention and the intervention components. This evaluation occurred once the intervention was complete (as part of the six-month assessment; see Appendix F). Participants were asked to report their overall satisfaction with the intervention they received followed by rating if they would recommend the program to others both using a five-point Likert scale, similar to the satisfactions questions used by van Wormer and colleagues (VanWormer, Martinez, Cosentino, & Pronk, 2010). Additionally, because satisfaction with a weight loss program is closely tied to weight loss achieved during the program, participants were asked to rate their satisfaction with the program, given the effort they put into the program (Baldwin, Rothman, & Jeffery, 2009). These same three types of satisfaction questions were then asked related to specific treatment components including the initial self-evaluation, the topics of the weekly lessons, the focus on participant selection of lesson topics, and self-monitoring.

Program adherence. The online system used to deliver the online check-ins captured much of the program adherence data. These measures included the number of check-ins completed, lessons selected, and participants' goals. Participants were asked to report how often they used the strategies recommended as part of the REFIT program (e.g., use the self-monitoring form, make 100-calorie changes) during the six-month assessment (see Appendix F).

Sample Size and Analysis

Sample size calculation. In order to estimate the effect size that was expected from the REFIT intervention, published studies that evaluated the effectiveness of behavioral interventions for weight loss were reviewed. Studies that contained samples that were mostly (or entirely) comprised of overweight or obese men were then considered. Table 3.3 contains a summary of studies found that met these criteria and used a similar intensity of intervention as the REFIT intervention. The average difference between treatment groups is 2.71 kg with a mean standard deviation of 3.28. Because the REFIT intervention includes multiple novel components, a conservative stance on expected effect size was taken. In order to have sufficient power to detect a statistically significant (p < 0.025, adjusted for multiple comparisons) 2.0 kg difference between groups at three and six months with a standard deviation of 3.0 kg within each group with 80% power, 45 participants would be required in each group. In order to prepare for a maximum of 20% attrition, 112 participants was the initial recruitment goal. However, retention within the first cohort was significantly better than the 80% anticipated. Therefore, the power analysis was adjusted to allow for 15% attrition instead of the original 20%, which reduced the needed sample to N = 104. Thus, recruitment was completed when the final sample included N = 107.

Analysis. Data analysis was completed using SAS 9.3 (Cary, NC). Prior to hypothesis testing, the randomized groups were compared to check for equality on measured variables. No differences were found on any baseline demographic variables.

Data were analyzed in an intent-to-treat manner where all participant data were analyzed as part of their randomization group, regardless of engagement with study procedures. To test the primary hypothesis that the intervention group would lose more weight than the control group, multiple imputation was used to develop 100 datasets with data imputed for missing values using the Markov chain Monte Carlo procedure. Analyses were conducted using PROC MIXED and were combined using PROC MIANLYZE. Because participants who took part in the follow-up assessments were more likely to be married and employed full-time than those who did not return, mean centered values for marital status and full-time employment were included as covariates in all models.

To test the hypotheses that change in theoretical constructs between baseline and three months mediated the relationship between the intervention and weight loss assessed at six months, simple and multiple mediation models were tested. Similarly, the roles of changes in these behaviors were tested as mediators of the treatment effect. These models were analyzed using the PROCESS macro developed by Hayes (2013). This macro for SAS uses linear regression to test the significance of direct relationships and bootstrapping to develop estimated confidence intervals around the indirect effects. Using bootstrapping to using normal-theory testing as the distributions of the indirect effects are likely to be asymmetrical (Preacher & Hayes, 2008).

	This		
Do you	sounds like me	REFIT Lesson	
Do you usually order large sized foods and drinks or take second helpings at home?	\checkmark	Preventing Portion Distortion	
Do you regularly eat fried food, baked goods, high-fat dairy, or other foods that contain more than 30% fat?		Cutting the Fat	
Do you drink three or more drinks with calories per day?		Balance your Beverages	
Do you often find yourself snacking between meals?		Preventing Snack Attack	
Do you at least one serving of high-fat meat during each meal?		Manage Meats	
Do you ever use portion-controlled meals such as frozen meals, cans of soup, or meal replacement shakes? If not, this lesson is for you.		Replace to Reduce	
Do you eat fast food more than twice per week?		Format Fast-Food	
Do you eat sweets or baked goods most days?		Swap out Sweets	
Do you eat in restaurants at least a couple of times per week?		Reduce in Restaurants	
Do you eat less than 5 servings of fruits or vegetables each day?		Increase to Decrease	
Do you watch TV every day?		Tune out TV	
Do you skip breakfast on at least once per week or do you skip other meals?		Start with Breakfast	
Do you drink less than 6 glasses of water every day?		Hydrate to Reduce Waist	

 Table 3.1. REFIT Lesson Titles and Behavior Descriptors

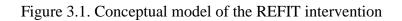
Purpose	Construct	Measure	Number of Items	Internal Consistency*	
Behavioral Mediator	Energy Intake	ASA-24	Varies		
Behavioral Mediator	Energy Expenditure	Paffenbarger Physical Activity Questionnaire	8		
Behavioral Mediator	Self-weighing	Single item	1		
Theoretical Mediator	Autonomous Motivation for Healthy Eating	Treatment Self-Regulation Questionnaire: Eating	15	0.90	
Theoretical Mediator	Autonomous Motivation for Exercise	Treatment Self-Regulation Questionnaire: Exercise	15	0.92	
Theoretical Mediator	Self-Efficacy for Weight Loss	Weight Efficacy Lifestyle Questionnaire	20	0.95	
Theoretical Mediator	Self-Efficacy for Exercise	Sallis' Exercise Self- Efficacy Questionnaire	20	0.90	
Theoretical Mediator	Self-regulation	Eating Behavior Inventory	26	0.61	
Theoretical Mediator	Outcome Expectancy	Healthy eating: Positive	10	0.89	
		Healthy eating: Negative	11	0.86	
		Physical Activity: Positive Health	5	0.77	
		Physical Activity: Positive Affective	5	0.86	
		Physical Activity: Negative	7	0.88	
Other					
	Weight history		16		
	Autonomous Motivation for Weight Loss	Treatment Self-Regulation Questionnaire	18	0.77	
	Weight Loss Strategies		45		
	Depression	Center for Epidemiologic Studies Depression Scale	20	0.89	
	Program Preferences	Wolfe and Smith, 2002	27		
	Masculinity	Conformity to Masculine Norms Index	46	0.83	
	Stress	Perceived Stress Scale	10	0.89	
	Medication Use		9		

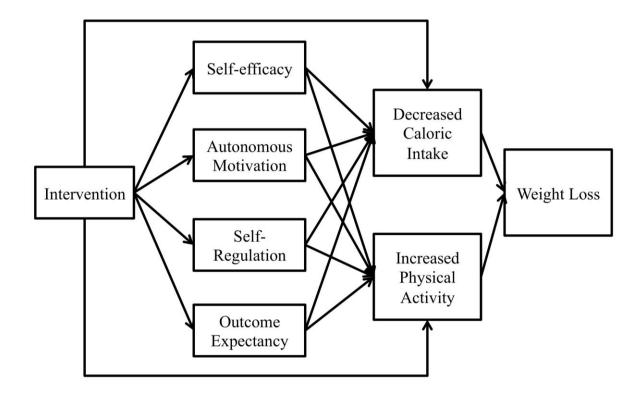
Table 3.2. Description of Self-Report Measures for REFIT Study

Note. Internal consistency assessed at baseline using Cronbach's alpha.

Table 3.3. Studies used for Effect Size Estimates

Citation	Sample Size	Percent Men	Duration	Description of Intervention	Weight Loss Means (SD)	Effect Difference (Pooled SD)
(Lally, et al., 2008)	104	33.7	8 weeks	Participants given leaflets with simple recommendations and self-monitoring checklist. Compared leaflet with weekly or monthly weighing vs. usual care.	Intervention: -1.8 (1.8); Control: -0.4 (1.5); p<.001	-1.3 (1.7)
(Morgan, Lubans, Collins, Warren, & Callister, 2009)	65	100	12 weeks	Common features: face-to-face information session, handbook with weight loss advice, study website to report self-monitoring. Intervention: daily self-monitoring	Intervention: -4.8 (4.6); Control: -3.0 (4.4); p=0.23	-1.8 (4.5)
(Morgan, et al., 2012)	159	100	6 months	Compared booklet plus paper monitoring (P), booklet plus online monitoring (O), and waitlist control	Intervention P: -3.0 (3.9); Intervention O: -4.4 (4.3); Control: -0.5 (1.8); p <.001	-3.4 (3.4)
(Morgan et al., 2011)	110	100	14 weeks	Intervention: face-to-face information session, handbook with weight loss advice, study website to report self-monitoring, pedometer, group based competition with financial incentive. Control: Waitlist	Intervention: -4.0 (4.5); Control: 0.3 (3.1); p < .001	-3.7 (3.8)
(Bennett et al., 2010)	101	52.5	12 weeks	Participants worked toward four behavioral goals (changed at 6-weeks). Progress monitored via website. Compared to usual care.	Intervention: -2.7 (3.3); Control: 0.3 (2.0); p < .05	-3.1 (2.7)





CHAPTER 4: RECRUITMENT OF YOUNG ADULTS FOR WEIGHT GAIN PREVENTION: RANDOMIZED COMPARISON OF DIRECT MAIL STRATEGIES

Overview

Recruiting young adults (ages 18-35 years) into weight gain prevention studies is challenging and men are particularly difficult to reach. This paper describes two studies designed to improve recruitment for a randomized trial of weight gain prevention. Study One used a quasi-experimental design to test the effect of two types of direct mailings on their overall reach. Study Two used a randomized design to test the effect of using targeted messages to increase recruitment of men into the trial.

For Study One, 60,000 male and female young-adult households were randomly assigned to receive either a recruitment brochure or postcard. Visits to recruitment websites during each mailing period were used to assess response rates to each mailing. Study Two focused on the postcard recruitment only. These households were randomly assigned to receive either a targeted or generic recruitment postcard, where targeted postcards included the word "Men" in the headline text. Response rates to each type of card were categorized based on participant report of mailing received.

The reach of the postcards and brochures were similar (421 and 386 website visits respectively, p = 0.22). Individuals who received the brochure were more likely to initiate the online screener than those who received a postcard (p = 0.01). Study 2: Of those who completed the telephone screening, 60.9% of men (n = 23) had received the targeted postcard

as compared to the generic postcard (39.1%, p = 0.30). The reverse was true for women (n = 62, 38.7% vs. 61.3%, p = 0.08).

These studies suggest there was little difference in the reach of postcards versus brochures. However, recipients of brochures were more likely to continue to the next stage of study participation. As expected, the response rates of men in general were lower than women to weight gain prevention messages; but using targeted messages modestly increased the proportion of male respondents. These studies add to the limited experimental literature on recruitment messaging and provide further evidence for using targeted messages to reach underrepresented populations while providing initial evidence on the effect of mailing type on message reach.

Background

Young adulthood has been identified as a high-risk developmental period for weight gain and a potential time for weight management intervention (Loria, Singnore, & Arteaga, 2010; M. C. Nelson, Story, Larson, Neumark-Sztainer, & Lytle, 2008). Weight gained during this period averages approximately 30 pounds (Lewis et al., 2000) and is associated with a doubling in the prevalence of obesity between the early 20s and the late 20s or early 30s (Gordon-Larsen, The, & Adair, 2010). Across racial and gender subgroups, weight gained during this period is also associated with developing poorer cardiovascular health markers including increased blood glucose and systolic and diastolic blood pressure (Truesdale et al., 2006). Despite this, young adults report minimal concern about gaining weight. In a recent survey, college freshmen reported that they would need to gain an average of five to eight percent of their body weight (3.1 to 6.2 kg) before they took action to reverse the weight gain in (Gokee LaRose, Gorin, Clarke, & Wing, 2011). Proven approaches to prevent weight gain in

young adults are not readily available and are the subject of clinical trials seeking to reverse those trends, including those funded through the Early Adult Reduction of weight through LifestYle Intervention (EARLY) cooperative agreement sponsored by the National Heart, Lung, and Blood Institute (NIH 5U01HL096720) (Lytle et al., 2014). The task of recruiting this age group into these trials has proven somewhat challenging (Tate et al., 2014).

Direct mailings are a commonly used avenue for recruitment into randomized trials due to broad reach and relatively low cost (Lovato, Hill, Hertert, Hunninghake, & Probstfield, 1997). Additionally, this approach can be particularly effective when trying to reach underrepresented populations via purchasing targeted lists from sources such as magazine subscription lists or lists of registered drivers in the target area (Yancey, Ortega, & Kumanyika, 2006). Direct mail has been used successfully to recruit adults into weight loss programs (Schmid, Jeffery, & Hellerstedt, 1989) as well as for recruiting young adults into weight loss programs (Batch et al., 2014). Although direct mailings are often used, there is little evidence to guide researchers when developing the messages to use when recruiting for randomized trials. Using health communication theory, there are aspects of direct mailings that can be experimentally tested in order to create more effective direct mail recruitment materials for trials.

One aspect of recruitment messages that needs to be examined is how to maximize the persuasiveness of the messages. The elaboration likelihood model suggests that if a message topic is of personal relevance, individuals process the message more critically via central processing than if the topic has little impact on the person's life (Petty & Cacioppo, 1986). Increased central processing leads the recipient to consider features such as the message's source (expert versus non-expert), level of trustworthiness, and the number and

quality of the arguments included in the message, described together as the "quality" of the argument or message (Petty & Cacioppo, 1986). It stands to reason that considering participation in a weight management program (either weight loss or weight gain prevention) would be a topic that could have a great impact on a person's life, involving daily changes to eating and exercise behaviors. Therefore, developing and testing higher quality messages that will be positively evaluated during central processing may be important in recruiting difficult to reach populations into research trials.

To date, no studies have specifically manipulated the quality of the message used for recruitment into weight management studies. Gerace and colleagues conducted the closest comparison found in the published literature where the amount of information, or number of arguments, included in the recruitment mailing (Gerace, George, & Arango, 1995), was experimentally manipulated. The number of arguments included in a message is one aspect of message quality but if the quality of the arguments is low, number becomes less important (Petty & Cacioppo, 1986). In the Garace et al. study the additional length of the message did not improve recipient response, perhaps due to arguments that did not improve message quality. Given the lack of research on message quality on recruitment yield, it is important to test whether the quality of the message can influence its persuasive qualities and result in recipients seeking more information about the study or enrolling in the study. This question was assessed in Study 1, where we tested whether varying the "quality" of the messages by manipulating the amount of information provided as well as type of information provided would improve the yield of young adults seeking information about a weight gain prevention trial.

Recruiting men into weight gain prevention. While young adults are challenging to reach with messages of weight gain prevention, men appear to be particularly difficult to reach. Men report needing to gain 6.2 kg before they would change their behavior as compared to 3.1 kg in women and significantly fewer men (17%) than women (61%) report interest in participating in a weight gain prevention program (Gokee LaRose, et al., 2011). Qualitative evidence suggests that young men perceive that there is societal acceptability for men to gain weight with age, but that the same does not hold true for women (Bordogna, Tate, LaRose, Espeland, & Wing, 2015). These perceptions among young men have been apparent in studies that have focused on weight control using diet and physical activity among 18-35 year olds. In a pilot study for the current research, only 2% of participants were men (Gokee LaRose, et al., 2010). Similar results were found when looking at studies of weight loss among adults (Gokee-LaRose et al., 2009) as well as for weight loss targeted toward young adults (Laska, Pelletier, Larson, & Story, 2012; Poobalan, Aucott, Precious, Crombie, & Smith, 2010). In addition to men's low interest in weight control, the low percentage of men in the programs may be due to the perception that the programs are designed for women and not men (Sabinsky, et al., 2007). To overcome this perception, it may be beneficial to use message targeting to increase the likelihood that men identify with recruitment messages, pay attention to the recruitment message and, in turn, express interest in the program.

Using targeted language and images is one well-researched approach to improving the reach of health communications within specific subpopulations (Davis & Resnicow, 2012). Targeting uses group identification, often race or ethnic group, to increase the personal relevance of the message to the recipient. Increased personal relevance is

hypothesized to increase the attention given to and the cognitive processing of the message (Petty & Cacioppo, 1986). There is experimental evidence from two studies that targeting recruitment messages increases interest in participation in weight loss programs. The first study by Kiernan and colleagues found that including targeted health risk information in direct mailings for recruitment for a weight loss program for Hispanic employees increased response rates from 6.5% to 9.1% (Kiernan, Philips, Fair, & King, 2000). Although this increase did not reach statistical significance, the authors suggest that a meaningful trend was evident but that the study was not adequately powered to detect the sizeable increase due to their relatively small sample (N= 561). In a later study, Brown et al. compared using direct mailing of recruitment information sent to Hispanic women that contained generic health information, targeted health information, personalization of the letter or both targeting and personalization. In this study, women who received the targeted mailing were more likely to respond than women who received the generic information. There was no effect found for personalizing the letter nor a targeting by personalization effect (Brown et al., 2012). Finally, Brown and colleagues completed a second study testing targeted recruitment letters sent to women with gestational diabetes inviting them to join a study focused on promoting healthy behaviors during pregnancy (Brown et al., 2015). In this study, targeting increased response rates among Spanish speaking women (6.7% vs 33.3%, p = .06) but decreased response among English speaking women (9.6% vs 57.1%, p = .04). These studies suggest that targeting may be a useful tool for recruitment for weight loss studies however no studies have experimentally tested targeting recruitment messages for other subgroups beyond Hispanic populations.

The purpose of this is paper is to report the results of two studies designed to evaluate direct mail recruitment efforts from one site of the multicenter trial of Study of Novel Approaches to Weight Gain Prevention (SNAP). While many modes of recruitment were used during recruitment for this study (Tate, et al., 2014), direct mailing provides a more accurate estimate of the number of recipients of a message as compared to estimates associated with other modes of study advertising (e.g., television, newspapers, flyers, email etc.). This provides the benefit of providing a clear "denominator" for testing the reach of the messages and was therefore chosen for use in these studies. In Study One, we compared the relative reach of a shorter, potentially lower quality message delivered via postcards to a longer and potentially higher quality message provided via a tri-fold brochure. We sought to test whether the quality of the message would influence participant response using a quasiexperimental design. We hypothesized that the message delivered via the brochure, which included a more detailed message, including a greater description of the study staff expertise and benefits of participating in the study, would generate a greater response as compared to the brief message delivered via postcards. In Study Two, we compared generic messages focused on weight gain prevention to messages that targeted men using a randomized experimental design. Here, we hypothesized that a greater proportion of male respondents would report receiving a postcard that included targeted communication than generic communication.

Main Study Methods

This paper used data collected during the direct mail recruitment at University of North Carolina for the Study of Novel Approaches to weight gain Prevention (SNAP). Full details of the study are available in the design and rationale paper for SNAP (Wing et al.,

2013). However, in brief, SNAP is a multicenter, NIH-funded randomized trial comparing the effect of two approaches to weight gain prevention among normal and overweight (BMI 21.0-30.0 kg/m²) young adults (18-35 years). The approaches being evaluated include self-regulation with Small Changes or self-regulation with Large Changes as compared to a minimal intervention control (Wing, et al., 2013).

Five hundred ninety-nine young adults (n=307, North Carolina and n=292, Rhode Island) were randomized into the SNAP study across the two clinical research sites. Recruitment efforts varied by research site and have been described in detail elsewhere (Tate, et al., 2014). Messages for recruitment were developed based on results from focus groups conducted with young adults about their views on weight and the potential for weight gain (Bordogna, et al., 2015; Tate, et al., 2014). Across both clinical centers, direct mail was the method through which the majority of participants were recruited.

All modes of recruitment directed potential participants to a study website to begin participation. Three websites were created: a general website to use for general recruitment and two websites that were developed specifically for these direct mail recruitment studies. All three websites were identical and provided a description of the SNAP study including eligibility criteria, the purpose of the study, a BMI calculator, and a link to an online preeligibility screening form. Individuals interested in participating were instructed to access the online screening form using a link on the website. This link took visitors to a secure website to complete the pre-screening form. The online screening forms were assessed for initial eligibility. Participants who met the age and BMI criteria were then contacted via telephone to further determine eligibility. As described by Tate et al., 33.9% of participants who completed the online screener were pre-eligible and completed the telephone screen (Tate, et

al., 2014). The final recruitment step included attending an in-person study orientation session. All study procedures were approved by the University of North Carolina non-biomedical institutional review board.

Study One

Methods. Data for this analysis come from recruitment from the North Carolina clinical research site only. A targeted mailing list of 60,000 names and addresses of male and female head-of-households between the ages of 18 and 35 within 30 miles of the North Carolina clinical site was purchased from USA Data, Inc. The addresses were randomly assigned to receive either a postcard or a brochure. This quasi-experimental analysis examines 30,000 postcards sent in May 2011 and 30,000 brochures mailed in December 2011 due to their use in recruiting different cohorts to begin the study.

To analyze the reach of the mailings, website visits to the two websites associated with the mailings were recorded. Internet protocol (IP) addresses of all visitors to the websites were recorded and time stamped. Each visit was classified as including a click on the link to the pre-screening form or not. To assess independent visits to the websites, duplicate addresses were removed such that the earliest visit or the visit that contained a click on the screening form link was retained.

The postcards (216 mm x 139.5 mm; see Figure 4.1) included a brief description of the SNAP study including the general purpose of the study, eligibility criteria, and study sponsors. The postcard was full-color, two-sided and contained 160 words including the study description and generic headline text. The brochures (tri-fold, full-color, 216 mm x 279 mm unfolded) contained the same information as the postcards but also included additional information hypothesized to make the message more persuasive. During formative work for

this study, young adults in focus groups stated that the immediate benefits of participating in the study would be more persuasive than focusing on the longer-term benefits (Tate, et al., 2014) To address this, the brochures included a list of immediate of benefits of participating in the study (including free personalized analysis of nutrition and physical activity). The brochures also included a description of the expertise of the study staff, (i.e., "Expertise of weight control professionals (nutritionists, exercise physiologists, physicians, health educators, psychologists, nurses)" while the postcard used a more general (i.e., "team of professionals"). The brochure also included a participant testimonial and a lengthier description of why weight-gain prevention is important. The brochure contained 444 words, including the generic headline text. To allow a comparable comparison between the postcards used in Study 2 and the brochures, half of the brochures were also included the targeted text "men."

To analyze the reach of these different types of direct mailings, website visits associated with the mailings were recorded during the two six-month recruitment periods: May 2011 to December 22, 2011 and December 23, 2011-August 2012. Binomial proportion tests were used to compare the number of website visits by mailing type. The null hypothesis tested was that the proportion would be equal across both mailing types. To test whether mailing type influenced the rate at which participants continued to the online screener, chisquare analysis was used.

Results. As shown in Figure 4.2, there were 807 independent visits to the two websites associated with the direct mailings, a response rate of 1.3%. Website visits during the period associated with the mailing of the postcards made up 52.2% of website visits while the period for the brochures represented 47.8% of visits (p = 0.22). Of the 807 visits to the

websites, 535 (66.3%) of visitors initialized the online screening form. Those who were sent a brochure were significantly more likely to initialize the online screener process than those who received a postcard (71.0% vs. 62.0%, OR = 1.21, p = 0.01).

Study Two

Methods. Study Two compared the effect of male-targeted messages on rates for increasing male response to recruitment messages. The headline text of the generic postcards featured a social norms-based message "Don't Settle for Average. The average American gains 30 pounds between the ages of 18 and 35" (see Figure 4.1). For the targeted postcards, this phrase was changed to "Men: Don't Settle for Average..." Targeted postcards and generic postcards directed interested recipients to separate, but identical websites, with unique web addresses (uniform resource locator; URL) to initiate the screening process. Generic postcards directed participants to www.snapaverage.org while targeted postcards directed par

Participants who were initially eligible based on the online screening form were contacted via telephone to complete the study eligibility screening. During the telephone screening, participants were asked to indicate how they heard about the study. Those who indicated they heard about the study via a postcard were asked to indicate which website they visited (either www.snapaverage.org or www.snap4men.org), which served as the self-report of the type of message received. The names and addresses of participants who received a postcard were compared to the names and addresses to which the postcards were sent. This served as a confirmation for the classification of type of message sent (generic or targeted). Among participants for whom both self-reported and confirmed mailing information was available, 86% correctly reported their direct mailing message. In the absence of confirmed

mailing information (n=12, 14%), self-reported mailing type was used to classify respondents.

To test whether the targeted messages increased the proportion of male respondents, a chi-square analysis was used. For analyses that compared counts across two levels (i.e., compared number of website visits), binomial proportion tests were used. In each case, the null hypothesis tested was that the proportion would be equal across both groups. Logistic regression was used to test whether final randomization rates varied by gender or postcard type received.

Results. In response to the postcards, there were 421 visits to the recruitment websites (see Figure 4.2). The website associated with the targeted postcards (i.e., www.snap4men.org) received significantly fewer visits (n = 190, 45.1%) than the generic website (i.e., www.snapaverage.org; n = 231, 54.9%, p = 0.05). There was no difference in initialization rates of the online screener by website: 64.2% of those receiving the targeted vs. 60.2% of generic initiated the study enrollment screener (p = 0.40).

After initial online screening, a telephone screening was conducted. A total of 85 respondents (23 male; 62 female) indicated that they received a postcard as their mode of recruitment. There was no difference in the number of screenings completed by those receiving targeted (n = 38) versus generic postcards (n = 47, p = 0.33). Of the 23 men, 60.9% were responding to the targeted mailing compared to 39.1% for the generic mailing (p = 0.30). The reverse was true for women (Targeted 38.7%; Generic 61.3%, p = 0.08). Together, the gender of respondents was moderately associated with the type of mailing received (OR= 2.46, p = 0.07). Among eligible participants recruited by postcards, there was no difference

in randomization rates by gender (OR = 0.51, p = 0.37) or by type of postcard received (targeted vs. generic, OR = 0.57, p = 0.30).

Discussion

This study used quasi-experimental (Study One) and experimental (Study Two) designs to compare the effect of varying the quality of the message (postcard versus brochure) and the type of message (targeted versus generic) to recruit normal and overweight young adults into a randomized controlled trial of methods for weight gain prevention. The results indicate that while both brochures and postcards yielded comparable response rates, those receiving brochures had a higher rate of initializing enrollment via the initial online screening form. Further, using targeted communication messages increased the proportion of male respondents relative to generic communication, (60.9% vs. 39.1%) although this did not reach statistical significance (p = 0.30).

Our hypothesis that a more persuasive message delivered by the brochures would lead to greater response than the shorter message delivered via postcards was partially supported. While the brochures contained all of the information included in the postcards, the brochures included additional information. One type of information included in the brochures focused on the *benefits* of participating in the SNAP study. Formative work with young adults suggested that focusing on immediate benefits would make the program more appealing than a focus on long-term benefits alone and these data appear to support this assertion. Many young adults do not see themselves at risk for gaining weight (Bordogna, et al., 2015; Truesdale, et al., 2006), therefore explicitly listing the immediate benefits of participating in the study more appealing beyond the potential distal benefits for their weight and health. By presenting

these benefits in the mailing, rather than relying on participants to identify them while visiting the website, the messages may have been more persuasive and the positive evaluation of the program may have been enhanced.

Additionally, the brochures may have been viewed as more persuasive due to the inclusion of more information about the expertise of those conducting the study and delivering the intervention. As put forth in the Elaboration Likelihood Model, messages from a trusted and expert source are more persuasive than messages that are perceived as less trustworthy. The brochures included a statement that focused on describing the expertise of the university-employed interventionists and study investigators while postcard included less information on the staff's expertise. This description of study staff may have served to increase the perceived trustworthiness of the source and increased the interest in the study. This effect, though not able to be tested in this study, may have been particularly relevant to men who have reported seeking information regarding weight loss only from what they perceive as trustworthy sources (de Souza & Ciclitira, 2005).

Our hypothesis in Study Two that men would be more likely to respond to a message targeting men was also somewhat supported. This result is consistent with the findings reported by Kiernan et al. and Brown et al. both of which found that minority recipients who received a targeted recruitment letter were more likely to respond than those who received a generic letter (Brown, et al., 2012; Kiernan, et al., 2000). However, in both the current study and the previous studies, response rates were low among the targeted groups. If it is assumed that approximately half of the addresses randomized to receive a postcard in the current study belonged to men, there were 15,000 potential male recipients of the mailings. Only 23 men completed the telephone screening process: a 0.15% response rate. While this gives a sense

of the response rate, it is important to note that a significant portion of potential participants were deemed ineligible <u>prior</u> to the phone screen and could not be included in response rate reported here (Tate, et al., 2014). However, even with this limitation, this response rate is lower than that seen in Brown's study (0.8%), which also utilized community-based recruitment (Brown, et al., 2012). In response to all mailings, the response rate as measured as the number of online screeners initiated was 0.9%. The lower response rate among men, along with the overall low response rate in this study, further emphasizes the challenge of promoting weight gain prevention among young adults for whom concern about weight gain may not be a priority.

One argument that may arise *against* using targeted recruitment messages is a reduced overall response rate. While the results of this study support this concern, it also demonstrated its minimal actual impact. Although the targeted messages did yield a lower response rate to the study website (45.1% of website visits) than the generic message (54.9% of visits), there were no differences in the proportion that started the online screener by type of recruitment message. However, as is common in programs focused on weight management (Pagoto, et al., 2011), women were still overrepresented as compared to men. Further, although the targeted mailing explicitly mentioned men in the headline and the study web address, women still responded. In fact, 38.7% of female respondents recruited via a postcard were responding to the targeted version. Therefore, although the targeted mailing likely deterred some women, others overlooked this targeting and initiated the screening process.

This study is unique in its use of a randomized comparison of recruitment messages and quasi-experimental comparison of mailing types. This contributes to the literature on recruitment techniques for clinical trials, which currently contains descriptive studies rather

than experimental evidence. By directing interested recipients to separate but identical websites, we were able to assess the reach of each message objectively. Participants were also able to recall which website they visited with a high level of accuracy. This method of tracking message reach could be a useful technique for monitoring recruitment techniques and messages in other studies, provided that website addresses are designed to be easy to remember. Finally, this study tested the effects using direct mail, a commonly used and cost-effective recruitment strategy. This approach to reaching young adults was the most effective technique for recruitment in both the SNAP study as well as another weight loss program for young adults (Batch, et al., 2014). It was also one of the most cost-effective approaches for recruitment for SNAP (Tate, et al., 2014) suggesting continued investigation of how to best develop direct mailing recruitment messages is a realistic and needed field of research.

The limitations of this study are related to the design as well as the response rates from recipients. The comparison between the mailing types of postcards and brochures is limited due to its quasi-experimental design and this study is unable to separate any effects that may be due to timing from the effects of the mailing type itself. Specifically, there may be differences in responses due to month during which the mailing was received (May vs. December). Secondly, we were also unable to test the effect of the type of mailing on increasing the proportion of male respondents due to prioritization of recruitment of men and minorities during brochure recruitment. Also, as described above, the response rates to this study were low: only 1.3% of recipients visited one of the study websites. While this rate is lower than the 9.6-22.4% response rate reported by Gerace and colleagues when recruiting for weight loss among women 50-79 years old (Gerace, et al., 1995) it was greater than the 0.7% response rate among Hispanic women reported by Brown et al. (Brown, et al., 2012)

and may reflect the additional challenge of recruiting for weight gain prevention compared to weight loss. The low response in this study limited the power available to test for differences between message and mailing types and the interaction between these. However, this limitation further demonstrates the need to better understand how to reach potential research participants with health promotion programs.

Recruiting adequate samples is necessary for the success of clinical trials. Despite this, there is little information in the published literature about how to successfully recruit for trials using data from randomized comparisons, especially for studies focused on health promotion behaviors, such as weight gain prevention. This paper compared two aspects of direct mail recruitment that future program planners can use to expand their own recruitment efforts. The comparison of types of mailings may be of great interest to those using staff contact (e.g., telephone screening) as the first point of contact. In this situation using brochures, which lead to a greater proportion of potential participants continuing with the study, may be a cost effective technique. In this situation, the slightly higher cost of the brochures compared to the postcards (i.e., \$7,914 vs. \$7,422) may be offset by reduced cost of paying staff to complete unnecessary telephone screening. The use of targeted messages did not increase the cost of the recruitment and thus, even for studies with limited budgets is an avenue for consideration.

There is ongoing and growing interest within the public health community in preventing negative health outcomes by preventing weight gain and building healthpromoting habits before habits are well established in middle adulthood. Despite this interest within the research community, potential participants often remain disinterested in participating in trials focusing on this type of health promotion. This study provides initial

work on how to better reach potential participants with these types of programs but it is clear that further research is needed to increase response rates within the target population. Additionally, there is a need for more research focused on the effect of recruitment messages on recruitment outcomes conducted in a more rigorous manner. Although reporting recruitment yields anecdotally can provide guidance into how to recruit research participants, there is a need for more studies that experimentally test recruitment methods and messages.

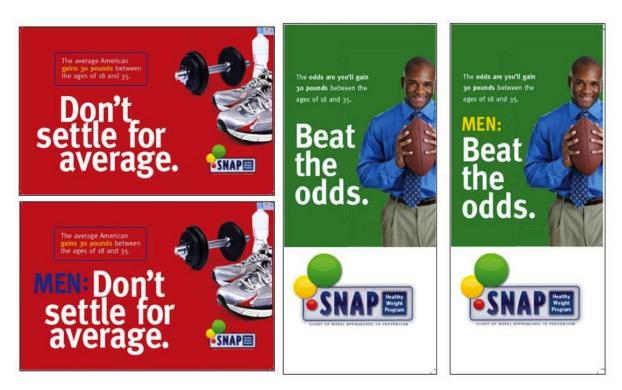


Figure 4.1. Direct mail recruitment materials

Front of recruitment materials. Top left Generic Postcard, bottom left Targeted Postcard,

middle Generic Brochure, right Targeted Brochure.

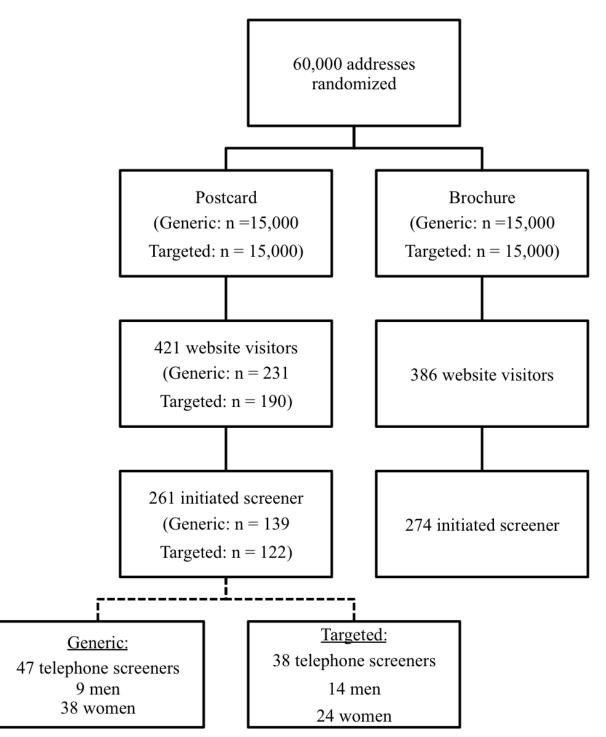


Figure 4.2. Website visits and screening rates by message and mailing type

CHAPTER 5: A RANDOMIZED TRIAL TESTING THE EFFICACY OF A NOVEL APPROACH FOR WEIGHT LOSS AMONG OVERWEIGHT AND OBESE MEN

Overview

The purpose of this study was to test the efficacy of a novel weight loss intervention designed to appeal to men through minimal lifestyle disruption and individualization delivered primarily online.

A randomized trial tested the efficacy of the REFIT (Rethinking Eating and FITness) weight loss program compared to a waitlist control. The six-month intervention was delivered via two face-to-face sessions followed by Internet contacts. REFIT encouraged participants to create calorie deficits by making six 100-calorie changes to their eating daily, without detailed diet monitoring, while also increasing physical activity. To further increase the program's appeal, participants were allowed to customize the specific behaviors and associated lesson materials to focus on each week.

Participants (N=107, age 44.2 \pm 11.4 years, BMI 31.4 \pm 3.9 kg/m2, 76.6% white) were randomized into the study and 90.6% provided data at six months. The REFIT group lost significantly more weight (-5.3 kg [95% confidence interval (CI) -7.2, -5.4]) than the waitlist group (-0.6 kg [CI: -2.0, 0.8]; p<0.001) over six months. The REFIT group also had greater reductions in waist circumference (-4.8 cm [CI: -6.0, -4.1] vs. -1.1 cm [CI -2.3, 0.1]) and percent body fat (-4.2 [CI -5.3, -3.0] vs. -1.1 [-2.1, -0.2]; p's<0.001). Intervention participants completed an average of 11.2 (\pm 2.7) of 13 of the interactive online contacts.

The REFIT program produced clinically significant weight losses using a novel intervention. This approach holds promise as an alternative to traditional behavioral therapy for men.

Background

In the United States, men have consistently been more likely than women to be overweight though women have been more likely to be obese (Flegal, et al., 1998). However, this situation is changing: over the past decade, the prevalence of obesity has increased among men while it has stabilized among women. The most recent estimates suggest that men and women have near equal rates of obesity at approximately 35.7%; meanwhile, the combined prevalence of overweight and obesity remains higher among men (Flegal, et al., 2012).

To reduce the negative health effects of obesity, behavioral interventions for weight control have been developed that are able to produce weight losses of approximately 5-10% of initial body weight (Wadden, et al., 2012) and improve cardiovascular, endocrine, and mental health outcomes (Diabetes Prevention Program Research Group, 2002b; Faulconbridge et al., 2012). Across multiple reviews, men reliably make up approximately 27% of study samples (Franz, et al., 2007; Pagoto, et al., 2011; Robertson et al., 2014; Wieland, et al., 2012) indicating that some overweight men are benefiting from these programs. In order to combat the increased obesity in men and help them to reduce the negative consequences of obesity, it is important to better involve overweight and obese men in behavioral weight loss interventions.

In recent years, there has been growing attention to the scarcity of men participating in behavioral weight loss. It does not appear that men are avoiding participating in weight

loss programs due to a lack of success. Recent reviews suggest that men can lose weight when participating in weight loss programs and often lose as much or more weight than women in the same program (R. L. Williams, et al., 2015). It is hypothesized that one explanation for men's low involvement in these programs is a mismatch between men's preferences for weight loss programs and the programs that are currently available. When asked about their barriers to joining a weight loss program, many men indicate that they view weight loss as a feminine activity (de Souza & Ciclitira, 2005; Gough & Conner, 2006; Sabinsky, et al., 2007) and that weight loss programs are targeted toward women (de Souza & Ciclitira, 2005). Reducing intake is also a major deterrent for men considering joining a weight loss program (de Souza & Ciclitira, 2005; Egger & Mowbray, 1993; Sabinsky, et al., 2007) due to the perception that diets for weight loss are too restrictive and would not provide sufficient fuel for their daily lives (Egger & Mowbray, 1993). When asked what features of a program would be appealing, men report wanting individually focused programs that do not include strict meal plans and the ability to tailor the diet to their preferences, (Gough & Conner, 2006; Sabinsky, et al., 2007; Wolfe & Smith, 2002). Men also report preferring programs that would not disrupt their daily routine, that are delivered in worksites or in fitness facilities, and that provide information in a clear and direct manner (Egger & Mowbray, 1993; Wolfe & Smith, 2002).

Programs that meet men's reported preferences have begun to be evaluated. In the United Kingdom, researchers have worked to develop gender-sensitized weight loss programs delivered via face-to-face groups and exercise sessions where participants are recruited through sports venues (Gray et al., 2013; Wyke, et al., 2015). A pilot study of this approach yielded positive outcomes with weight loss of approximately 6 kg after 12-weeks.

In Australia, a research group has tested providing concise behavioral recommendations in order to make the weight loss program more appealing to men. These brief recommendations, delivered via brochures, have been accompanied by daily calorie goals and access to calorie tracking materials (either online or via paper diaries). This approach was initially delivered via one group session followed by online contact (Morgan, Collins, et al., 2011; Morgan, et al., 2009; Morgan, Lubans, Collins, et al., 2011) but has since been delivered remotely in a community-based trial (Morgan, et al., 2012). These programs have been successful in producing weight losses ranging from 3.0 to 5.3 kg in active treatment groups (Morgan, et al., 2012; Morgan, Collins, et al., 2011; Morgan, et al., 2009; Morgan, Lubans, Collins, et al., 2011). Another study, which was conducted in the United States, also tested an intervention focused on making specific recommendations for changing five key areas of diet and physical activity during an Internet-delivered weight loss program for men (Patrick, et al., 2011). In this study, participants focused on improving the healthfulness of their diets in order to promote weight loss. Unlike the UK and Australian trials discussed above, this program did not promote using detailed self-monitoring and did not produce weight loss significantly greater than the waitlist control group.

The shift to focusing on lower intensity, self-directed programs was undertaken to better meet men's preferences for weight loss programs that are concise and do not require group sessions. However, the it is unclear if this approach balances men's preferences with their need for weight loss as this approach has been successful in some studies of men (e.g., Morgan, et al., 2012) though not universally successful (Patrick, et al., 2011). It is unclear if the differences in outcome are related to the population under study (i.e., Australians vs.

Americans) or if the detailed self-monitoring and focus on calorie reduction used in the successful studies accounted for the difference.

The purpose of this study was to test the efficacy of a novel weight loss program designed to appeal to men which features simplified self-monitoring and reducing caloric intake through discrete behavior changes without making dramatic changes to diet and lifestyle: the Rethinking Eating and FITness (REFIT) program. The Internet-delivered REFIT program was tested in a two-arm randomized controlled trial as compared to a waitlist control group over six months. It was hypothesized that those randomized to receive the REFIT program immediately would have greater weight losses at months three and six of the program than those randomized to the waitlist comparison group. Additionally, it was hypothesized that those receiving the REFIT program would have greater reductions in waist-circumference, body fat, and caloric intake and greater increases in calories expended via leisure time physical activity than those in the waitlist condition. Program utilization and program satisfaction was also assessed.

Methods

Participants. Participants were recruited via email, flyers, and word of mouth between July 2013 and March 2014 to form three cohorts. To be eligible to participate, men were required to be 18-65 years of age, have a body mass index (BMI) 25-40 kg/m², have regular access to the Internet, and be able exercise safely as determined using the Physical Activity Readiness-Questionnaire (PAR-Q; Thomas, et al., 1992). Men were excluded from participating if they reported high alcohol intake (>10 on the Alcohol Use Disorders Identification Test; Reinert & Allen, 2002), a major psychiatric condition, weight loss greater than 10 pounds over the past six months, current treatment for cancer, or if they were unable

or unwilling to attend group sessions. Participants who reported a diagnosis of high blood pressure, high cholesterol, or diabetes, a history of cancer, or an endorsement of items 5-7 from the PAR-Q (i.e., currently being treated for high blood pressure, any joint problems, or any other reason to avoid physical activity) were required to obtain consent from their physician consent prior to participation.

Procedure. All modes of recruitment directed potential participants to a study website with a description of the study. From there, interested participants completed an online eligibility questionnaire. Two hundred seventy-seven potential participants completed the online screener (see Figure 5.1). Those who were initially eligible were contacted via telephone to complete the screening process and schedule a time to attend a study orientation session. At the orientation, all study procedures were explained and participants took part in the informed consent process. Participants were then scheduled for an individual in-person baseline assessment visit and were asked to completed online questionnaires and online diet recalls. Randomization occurred after baseline assessments were complete and was revealed to participants during a face-to-face group session. Participants were randomized to receive the REFIT program immediately (REFIT) or after six months (Waitlist). Randomization was conducted using a random number generator in a 1:1 ratio and was concealed from participants until they attended the group session.

Follow-up assessment visits were conducted at three and six months postrandomization. Assessments were conducted by the first author who was unblinded to participant randomization. After each assessment period, all participants received feedback reports that included their anthropometric measurements and a summary of their diet. Participants received \$20 for completing assessments at three and six months. The University

of North Carolina at Chapel Hill Institutional Review Board approved this study. This study is registered through ClinicalTrials.gov (NCT01843595).

Intervention Description. The purpose of the REFIT intervention was to aid participants in changing their eating and exercise behaviors in order to produce weight loss of 1-2 pounds per week up to 10% weight loss. The program was designed to maximize the participant's sense of autonomy within a structured program while also encouraging participants to make changes that could be sustained after the program ended. The intervention was designed to target theoretical constructs from social cognitive theory (Bandura, 1991) and self-determination theory (Ryan & Deci, 2000). Both theories have been used to guide successful weight loss programs (Silva, et al., 2010; Teixeira, et al., 2012; The Look AHEAD Research Group, 2006). Table 5.1 describes the theoretical constructs that guided intervention development and how the intervention targeted each construct. Delivery of the intervention and development of all intervention materials was completed by a doctorate-level trainee in the field of health behavior.

The REFIT program included recommendations for dietary intake, exercise, and selfregulation and was delivered via two one-hour, face-to-face group sessions and thirteen online check-ins with interactive, tailored feedback, personally selected target behavior and lessons, and individualized goal setting. Prior to making changes to diet and physical activity, participants took part in a one-week self-evaluation to familiarize them with their eating patterns, the calories in the foods they typically eat, and their physical activity. Participants were encouraged to maintain their current eating habits and use detailed self-monitoring (i.e., recording all calories and grams of fat eaten and all physical activity) during this one-week period. In addition to monitoring their behaviors, participants were encouraged to begin

weighing themselves each day to begin to establish an understanding of the relationships between their behaviors and their weight. Participants were given paper diaries for selfmonitoring; and were also permitted to use a mobile app or website. To aid participants in understanding their personal calorie needs, they were provided estimates for calorie needs to lose approximately one and two pounds per week that were 500 and 1,000 calories under their total energy expenditure (taking into account their body composition, weight, and current activity level; 1,200 to 3,308 calories). The estimates were provided for reference only and participants were not instructed to continue tracking their total daily calories from foods after the self-evaluation. Finally, participants wrote a message to themselves about their personal motivation for weight loss. These messages were collected, scanned, and sent to participants during week eight of the program. If participants were unable to attend the group sessions, an individual make-up session was held (n = 3).

Following the face-to-face sessions, participants were sent emails that provided a personalized link that took them directly to a set of weekly check-in questions available on the Internet (or monthly check-ins in months 4-6). Check-ins were delivered via an online survey platform (Qualtrics). During this check-in, participants went through a linear process where they reported their weight, physical activity, number of daily changes to diet (described below), and days of self-weighing. Automated feedback was provided based on meeting or not meeting their reported physical activity goal, days of daily weighing (5 or more), and their weight loss (\geq 1 pound) and the number of changes made to eating (\geq 42 changes per week). If goals were not met, the feedback included suggestions for problem solving, barrier identification and reduction, and techniques for increasing motivation. Participants then selected their next specific strategy they could use to achieve calorie

reduction. Following the selection of their strategy, a short lesson was provided, and participants were encouraged to submit a SMART goal related to eating or exercise to accomplish over the next week. Check-ins, lessons and goal setting were designed to take participants less than 15-30 minutes to complete each week. After the check-in was completed, a copy of the check-in results (e.g., the tailored feedback) were also emailed to participants to provide them with a record of the feedback received online. If a participant did not complete a check-in by midweek, an email reminder was sent. If a check-in had not been completed by the end of the week, a new behavioral strategy lesson was sent via email. If a participant did not complete check-ins for two consecutive weeks, they were called to ensure that the emails were being received and were encouraged to complete next week's check-in.

Dietary recommendations. The goal of the REFIT program was to reduce intake by making a minimum of six 100-calorie changes from typical eating habits each day as a means to creating a calorie deficit (theoretically creating a weekly deficit of approx. 4200 calories per week). This is a novel approach to caloric reduction as compared to the standard practice of providing calorie goals and tracking specific intake to insure daily intake remains at or below daily goals. Approaching creating a negative calorie balance via calorie reduction has been used in prior studies of weight loss (Damschroder, et al., 2014; Lutes, et al., 2012) and weight gain prevention (Gokee-LaRose, Gorin, & Wing, 2009; Wing, et al., 2013).

Weekly lessons. To aid participants in meeting the goal of making six 100-calorie changes per day, lessons focused on specific eating behaviors or food groups that could be targeted to create a calorie deficit. These included reducing fat, portion sizes, calories from beverages, modifying fast-food consumption habits, etc. The lessons integrated behavioral techniques that have been emphasized in traditional weight loss programs (Diabetes

Prevention Program Research Group, 2002a; The Look AHEAD Research Group, 2006) including stimulus control, problem solving, and planning ahead. Specific examples of 100calorie changes were included as part of each lesson. Lessons later in the program focused on lifestyle changes that have demonstrated positive effects on weight loss (e.g., increasing water consumption; Tate, et al., 2012) or weight loss maintenance (e.g., maintaining consistent eating patterns; Wyatt, et al., 2002). All lessons focused on diet because men have more difficulty implementing changes to their diet than to their physical activity (Collins, et al., 2011).

Sixteen lessons were available; however, not all participants selected all lessons. Participants selected one target behavior and associated lesson per week in order to allow them the opportunity to use each strategy independently and to evaluate the effect of the strategy on their weight loss. If the strategy was successful and the participant lost weight, they were given the option to continue using the successful strategy for another week or to select another lesson and strategy. If they were not successful in producing a minimum of a one-pound weight loss, participants were encouraged to select a new lesson and strategy to evaluate. Participants could select from at least three lessons each week starting in week two (e.g., after the self-evaluation period). Lessons were ordered so that behaviors that were projected to have the largest impact on calorie reductions were introduced earlier in the program while lessons focused on weight maintenance strategies were introduced later. Starting during the 12th week of the intervention, participants were allowed to select multiple target behavior lessons to allow maintenance lessons to be coupled with weight loss strategy lessons.

Physical Activity. The REFIT program provided exercise plans with weekly exercise goals that encouraged participants to increase their moderate to vigorous physical activity to 225 minutes of activity over six months. Three sets of gradual goal progressions were used (starting at 50, 100, or 175 minutes) to allow participants to choose a progression considering their baseline activity level (Tate, Crane, Valle, & Erickson, 2013). Participants were encouraged to engage in cardiovascular activity for bouts of at least 10 minutes in order to meet the weekly goals. Behavioral strategies for increasing MVPA including planning ahead, goal setting, and stimulus control were included in the tailored feedback.

Self-regulation. Participants were encouraged to monitor their diet through tracking the number of 100-calorie changes they made to their eating each day using a simple, paper tracking form. Participants were not instructed to continue detailed self-monitoring after they completed the initial evaluation period. Returning to detailed self-monitoring was a suggested strategy provided to participants who were consistently not meeting the weight loss goal of one pound per week.

Daily self-weighing was presented as a form of self-regulation where participants could use the daily weights as objective feedback on their behaviors, a successful approach to self-regulation (Steinberg, et al., 2013; Wing, et al., 2013; Wing, et al., 2006). They were instructed that if their weight was decreasing, they should continue their current diet changes and physical activity. If their weight was stable or increasing, participants were encouraged to modify energy balance by increasing the number of the changes they were making to their diet by two per day (e.g. "Try to make eight 100-calorie changes instead of six") and increase their physical activity by an additional 15 minutes per day.

Wait-list condition. Participants who were randomized to the waitlist control condition attended one group session to receive their randomization assignment. There was no further contact with these participants until the assessments at three and six months. After the six-month assessments were completed, participants were offered one group session and 10 weeks of the online program.

Outcome measures. The primary outcome was weight change at three and six months. Secondary outcomes were changes in waist circumference, percent body fat, calorie intake, percent calories from fat, and calorie expenditure through physical activity at three and six months.

Demographic information. Demographic information including race, age, employment status, and marital status were obtained at baseline.

Anthropometrics. Weight, height, waist circumference, and body composition were measured during the in-person assessment visits. Participants were instructed to fast for two hours and avoid physical activity for eight hours prior to their appointment to prepare for the body composition assessment. All measures were taken with the participant wearing spandex compression-style shorts without shoes. Weight was measured to the nearest 0.1 kg on a calibrated digital scale (Tanita BWB 800). Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer at baseline only. Waist circumference was measured at the top of the iliac crest using a flexible tape measure (Gulick II) parallel to the floor during exhalation to the nearest 0.1 cm. All of these measures were assessed twice for consistency. Body composition was assessed using air displacement plethysmography (Bod Pod, Cosmed). Thoracic gas volume was measured at each assessment. If an accurate TGV was not obtained

after three attempts, a predicted value was used. The BodPod provides accurate estimate of body composition among overweight and obese adults (Ginde, et al., 2005).

Dietary Intake. Dietary intake was measured using the National Cancer Institute's Automated Self-Administered 24-hour Recall (version 2011; ASA-24). Participants completed two recalls at each assessment period in order to assess typical intake for weekdays and weekend days. Daily caloric intake was calculated by the system and percent calories from fat were calculated based on the grams of fat reported. Recalls that were outside of a probable range for a single day intake for an adult man (650-5,700 calories) were removed (Baseline: n = 2, 3M: n = 3). This tool has performed well as compared to an interviewer-administered 24-hour recall (Kirkpatrick et al., 2014).

Physical activity. Physical activity was measured using the Paffenbarger Activity Questionnaire (Paffenbarger, et al., 1986). This questionnaire assesses leisure time physical activity, walking for exercise and transportation, and daily flights of stairs climbed. Caloric expenditure was estimated by classifying activities using the metabolic equivalents for each activity using the Compendium of Physical Activities (Ainsworth et al., 2011). This procedure is being used in the EARLY consortium (Lytle, et al., 2014).

Program adherence. Completion of check-ins and selection of lessons were collected automatically through the online system during each week of the program.

Process evaluation. REFIT group participants were asked to report how frequently they used strategies recommended by the program during the six-month assessment. They were asked to rate how often they: made 100-calorie changes to their diet, used the 100-calorie change tracking sheet, tracked their intake using an app or website, recorded their exercise, or set goals related to their diet or physical activity. These were reported on a five-

point scale ranging from 1 "Never or hardly ever" to 5 "always or almost always". Participants were asked at baseline, three, and six months how frequently they weighed themselves on a seven point scale from "Never" to "Multiple times per day" (Linde, et al., 2005; Wing, et al., 2006). Those who indicated they weighed "every day" or multiple times per day were classified as weighing themselves daily.

Program satisfaction. Participants in the REFIT group rated their satisfaction with the program they received on a scale of 1 "very dissatisfied" to 4 "very satisfied". They were also asked how likely they were to recommend the program to other men from 1 "very unlikely" to 4 "very likely". Modeled after the EARLY program evaluation questions (Lytle, et al., 2014) and the framework developed by Baldwin and colleagues (Baldwin, et al., 2009), participants rated their satisfaction with the program considering the effort they put in to the program on a scale from -4 "very dissatisfied" to 4 "very satisfied". Finally, participants were asked to rate how confident they were that they would be able to continue using the approach to eating and exercise recommended by the program. These questions were answered on a scale from 1 "not confident" to 8 "very confident" (VanWormer, et al., 2010).

Statistical analyses. An a priori power analysis was completed to estimate the sample size needed to detect a 2.0 kg difference between treatment groups (SD 3.0), a reasonable estimated effect size based on prior studies with men (Morgan, Collins, et al., 2011; Morgan, et al., 2009; Patrick, et al., 2011). Assuming a 15% attrition rate, 104 participants would be needed to detect these effects with 80% power and a probably of 0.025 (adjust for multiple comparisons at three and six months).

Data were analyzed using SAS 9.3. Differences between groups at baseline and differences between study completers and non-completers were tested using t-test and chi-

square analyses. Changes in weight, waist circumference, body fat, caloric intake, and caloric expenditure were tested separately using linear mixed model analyses with multiple imputation to account for missing data. PROC MI was used to develop 100 datasets with data imputed for missing values using the Markov chain Monte Carlo procedure. The analyses were conducted using PROC MIXED and were combined using PROC MIANLYZE. Mean centered values for marital status and full-time employment were included as covariates in all models, although results were similar when these values were not included in the model (see Appendix G). The data for calories expended through physical activity were not normally distributed and were square root transformed prior to analysis. An intention to treat analysis was performed; thus, all participants who received their randomization assignment were included in the analyses for primary and secondary outcomes (N = 107). The relationships between intervention targets and weight loss were tested among those who completed the six-month assessment in the immediate treatment group (n = 48) using Pearson's correlations.

Results

Baseline demographic characteristics are presented by treatment group in Table 5.2. There were no differences between treatment groups (p's > 0.05). Overall, participants were 44.2 ± 11.4 years of age, 76.6% non-Hispanic white with an average weight of 99.8 ± 14.5 kg (BMI 31.4 ± 3.9). Most had at least a college education (83.2%), were employed full-time (88.8%), and were married or living with a partner (79.4%). The majority of participants returned for the three-month (94.4%) and six-month (90.7%) assessments, with no difference in completion rates by treatment group (p's = 0.98; see Figure 5.1). Participants who did not return for the follow-up assessment at three months were less likely to be married than those

who returned (50.0% vs. 81.2%, p = .07) but did not otherwise differ on baseline characteristics (p's > 0.13). At six-month assessments, dropouts were less likely to be employed fulltime (70.0% vs. 90.1%, p = 0.05), but did not did otherwise differ from those who participated in the assessments (p's \ge 0.16).

Weight loss and secondary outcomes. Table 5.3 shows the baseline values as well as change between baseline and three or six months for anthropomorphic values, intake, and exercise. Weight loss was significantly greater in the REFIT group as compared to the waitlist group at both months three and six (p's < 0.001; see Figure 5.2). The REFIT group lost an average of -5.0 kg at three months (95% CI: (-6.1, -3.9) and -5.3 kg at six months (95% CI: -6.5, -4.2) as compared to -0.6 kg at both three and six months for the waitlist group (3-month 95% CI: -1.7, 0.5; 6-month 95% CI: -1.8, 0.5). Similarly, there were greater reductions in the REFIT group in waist circumference and percent body fat at both three and six months (p's < 0.001). The average percent of initial weight that was lost was by the REFIT group was -5.0% (95% CI: -5.9, -4.0) at three months and -5.2% at six months (95% CI: -6.2, -4.2). A greater proportion of participants achieved a five percent weight loss in the REFIT group at the six-month assessment (49.1%) than in the waitlist group (9.3%, Odds ratio 9.4; 95% CI 3.2, 27.4). Similarly, a greater proportion of REFIT participants also achieved a 10% weight loss (18.9% vs. 3.7%; OR = 6.0, 95% CI 1.3, 29.1).

There were significantly greater increases in calories expended through physical activity reported by the REFIT group as compared to the waitlist group at both follow-up time points (p's ≤ 0.001). There was a significant reduction in caloric intake reported by both groups at three months and the group by time interaction was not significant at three months (p = 0.28). At six months, the waitlist group had returned to baseline levels while the REFIT

group remained a lower level, however this group by time difference did not reach significance (p = 0.08). There was no change in percent calories from fat reported by either group at either follow-up period (see Table 5.3).

Program utilization. All participants randomized to the REFIT group completed the first two face-to-face group sessions (n = 50) or attended individual make-up sessions (n = 3) within one week of the group session. Participants completed an average of 11.2 (\pm 2.7) of the 13 online check-ins. Most participants (79.2%) completed at least 10 of the 13 check-ins and only three participants completed fewer than half of the check-ins. Participants reported making an average of 27.7 (\pm 16.4) of the 42 recommended 100-calorie reductions per week during the first 12 weeks of the intervention. Table 5.4 shows the completion rates of each of the check-ins, the strategy that was introduced each week, and number participants who chose each strategy by program week. All participants either chose to stick with a successful strategy or use a strategy presented in a previous week at least once during the program. Participants selected an average of 12.6 (\pm 2.9) strategies during the program.

During the six-month assessment, participants were asked how frequently they used the strategies recommended in the program. More than half (61.7%) reported that they used the strategy of making 100-calorie changes to their diet "much of the time" or "always or almost always". Few participants (23.4%) reported tracking these changes using the checklist form developed for this study. A larger percentage reported routinely self-monitored their diet using a mobile app or website (44.7%). More participants reported developing goals related to exercise "much of the time" or more frequently (50.0%) than setting goals related to diet (29.8%). A greater percentage of participants reported daily self-weighing during the six-month assessment (62.5%) than at baseline (16.7%; p < 0.001).

Program utilization, as measured by number of online check-ins completed, was associated with weight loss at six months (r = -0.34, p = 0.02). There was also an association between frequency of self-reported focus on making six 100-calorie changes to diet and weight loss (r = -0.37, p = 0.01). There was a trend for greater weight loss when using the study-created tracking sheet (r = -0.28, p = 0.06) and use of a mobile app to track diet was also associated with greater weight loss (r = -0.35, p = 0.02). Similarly, more frequent self-weighing was also associated with greater weight loss (r = -0.41, p = 0.005). Participant report of goal setting for diet and physical activity was not associated with weight loss (p's > 0.17).

Program satisfaction. Participants who completed the program evaluation as part of the six-month assessment (n = 47; 88.7% of randomized participants) positively evaluated the REFIT intervention: 91.5% reported that they were satisfied or very satisfied with the program they received. Further, 95.7% reported they would recommend the program to a friend. Similar to the overall satisfaction measure, when asked to consider their satisfaction with the program considering the effort they put into the program, 84.8% reported feeling satisfied. On a scale from 1: "not at all confident" to 8 "very confident", participants reported feeling confident that they would be able to maintain the changes they made to their eating habits (6.2 ± 1.9) and physical activity (6.3 ± 1.7) after the program ended.

Discussion

The REFIT program was developed to test whether a novel Internet-delivered approach to weight loss that focused on autonomy and an alternative approach to calorie reduction would be effective in producing weight loss among overweight and obese men. This approach demonstrated effectiveness, as compared to a waitlist control group, by

producing weight losses of approximately 5 kg (5%) at three and six months post randomization among those randomized to receive the REFIT program as compared to a 0.6 kg (0.6%) weight loss observed in the waitlist comparison group. About 50% of REFIT participants lost 5% or more of initial body weight; an amount shown to be associated with significant health improvements. In addition to the weight losses, there were improvements in waist circumference; percent body fat, and physical activity among REFIT program recipients. The REFIT program was well utilized and was positively reviewed by recipients with more than 90% of participants reporting they were satisfied with the program and would recommend it to a friend.

This study contributes to the limited literature that has focused on creating behavioral weight loss programs that are tailored to men. The current study builds particularly on previous studies conducted by Patrick and colleagues (Patrick, et al., 2011) and Morgan and colleagues (Morgan, et al., 2012; Morgan, Collins, et al., 2011; Morgan, et al., 2009; Morgan, Lubans, Collins, et al., 2011). In both groups of studies, participants were encouraged to change their eating and exercise through following recommendations related to a limited number of diet and physical activity behaviors. In both cases, as in the REFIT program, the focus on a smaller number of behaviors was selected to streamline communication and minimize the time participants spent interacting with the intervention, thus making it more appealing to men. The current study differed somewhat in how this was implemented. In Patrick's study, the program focused on techniques that would reduce the caloric density of the diet (e.g., improving the healthfulness by increasing fruits, vegetables, whole grains, etc.) rather than focusing on calorie reduction itself. Without additional guidance or supports, this approach did not appear to have enabled men to reduce their

calories as there was no difference in weight loss among the men who received the program and those on the waitlist after one year (0.9 kg vs. 0.2 kg) (Patrick, et al., 2011). Using a more traditional approach, Morgan and colleagues provided participants with calorie goals and encouraged participants to stay below their calorie goal by using detailed selfmonitoring, an approach that produced significant weight loss (Morgan, et al., 2012; Morgan, Collins, et al., 2011; Morgan, et al., 2009; Morgan, Lubans, Collins, et al., 2011). In the REFIT program, there was an emphasis on reducing calories (e.g., making six discrete 100calorie changes per day) and participants were encouraged to track; however the selfmonitoring was simplified by encouraging participants to track the changes they were making rather than their complete diet. Therefore, the approach used in this study falls between the two approaches previously used, focusing on discrete behaviors and foods (Patrick) and requiring some monitoring (Morgan) but with reduced requirements for detail in tracking the changes. Given that men in REFIT achieved clinically meaningful weight losses, continuing to emphasize calorie reduction during weight loss programs with men, despite their initial reluctance to focus on calories appears important.

Another important distinction between the prior studies with men and the REFIT program was the provision of choice of behaviors to focus on each week within a structured program. In the study by Patrick and colleagues, men worked towards achieving small but achievable goals in all five domains each week, without participant selection of new behaviors to focus on over time. In REFIT, by providing structure and guidance on which behaviors to change (i.e., providing three lessons/behaviors to choose from each week) while still allowing participants to make own their final selection, participants were given autonomy while also being "nudged" towards focusing on behaviors theorized to have

greater impacts on their weight. Furthermore, in REFIT specific foods to change were gradually introduced rather than changing multiple areas right from the start. Future studies are needed to determine the ideal combination of choice and structure to provide in weight loss programs.

Moving beyond the focus on men, this study also contributes to the field of behavioral weight control. The approach to calorie reduction utilized in the REFIT that focused on making at least six 100-calorie changes per day was selected because it was hypothesized as being more appealing to men than traditional approaches (i.e., staying below a calorie goal) while still producing a calorie deficit great enough to produce weight loss. This approach is similar to that used in previous studies developed for general populations (e.g., Damschroder, et al., 2014; Lutes, et al., 2012; Lutes, et al., 2008) that also encouraged participants to make changes from their baseline eating and exercise behaviors. Unlike the standardized goal used in the REFIT program, these earlier studies took a client-centered approach by encouraging participants to select a single eating and physical activity goal and continuing to work towards meeting this goal until it was attained. This goal setting strategy was accompanied by encouragement for participants to closely self-monitor their diet using traditional self-monitoring. This approach has demonstrated efficacy in producing significant weight losses of -5.3 kg among women at nine months (Lutes, et al., 2012) and -2.8 kg and -1.9 kg weight losses among veterans after 12 months following group and telephone delivered interventions, respectively (Damschroder, et al., 2014). By contrast, the REFIT program encouraged participants to work towards a study-developed goal (i.e., making six 100-calorie changes per day) however the participants were allowed to personalize their approach towards reaching this goal via selection of lessons to focus on each week. Also in

contrast to the prior studies, the REFIT program did not encourage detailed self-monitoring of diet past the initial assessment period.

The decision not to include detailed self-monitoring as part of the REFIT program was made to address the concern that men want weight loss program has minimal lifestyle disruption. Detailed self-monitoring creates lifestyle disruption due to the time commitment needed to complete calorie tracking. While detailed self-monitoring is key to successful weight loss, it is burdensome and is generally discontinued by many participants (Burke, Wang, et al., 2011). Instead, this program used detailed self-monitoring for a short period followed by an abbreviated self-monitoring protocol. Combining detailed and simplified selfmonitoring has been used with traditional approach to calorie reduction and has shown similar results to using detailed self-monitoring consistently (Helsel, et al., 2007).

Interestingly, and unexpectedly, more participants in the REFIT study reported using a mobile application or website to self-monitor diet than the simplified paper self-monitoring checklist created for this study. This result raises many questions that will need to be addressed in future studies. First, it is possible that weight losses are the result of the participants following a more traditional approach to calorie reduction despite it not being required (i.e., detailed monitoring to stay below a calorie goal). Men were asked to monitor diet traditionally in the first week and then told they could discontinue. Some men may have found the method useful and continued using the approach on their own choosing. It is not known how detailed men were in using the apps. It is also possible that men preferred electronic tracking (Burke et al., 2011) and that a simple app version of the checklist would have been more utilized.

This intervention also uniquely provided participants with the ability to choose the strategy and associated lessons they wanted to focus on each week. In traditional behavioral interventions, lesson order is determined by the program developers with the goal of providing participants with the most important skills first. In this program, lessons that were hypothesized to provide the most impact on diet were presented first, but the participants decided the exact order of the lessons. The emphasis on choice was guided by masculinity theory which suggests that men desire independence (Courtenay, 2000) but was also based on self-determination theory, which suggests that autonomy is needed for long-term behavior change (Ryan & Deci, 2000). There is a need for more studies to investigate the role of choice and independence in weight loss, especially among men. While this study suggests that providing choice may be helpful to men, this result has not been consistent. Similar to this study, Gabriele and colleagues found that men lost more weight when a weight loss program was delivered using a non-directive approach (-9.2 kg) than when using a directive (-4.2 kg) or minimal support (-6.7 kg) approach while the directive approach was more effective for women (Gabriele, Carpenter, Tate, & Fisher, 2011). Unfortunately, due to the small number of men in that study (n=17), it is unclear whether these differences are significant or due to chance. Another study tested whether providing choice in diet plan would impact weight loss (Coles, Fletcher, Galbraith, & Clifton, 2014). In that study, participants were assigned to a choice group (participants selected which diet plan to follow (South Beach, Mediterranean, or high-protein/low-fat diet) or to a no-choice group (highprotein/low-fat diet only; Coles, et al., 2014). The researchers found that men were more successful when the diet was assigned to them (-6.2 kg after six months) rather than when they selected the diet themselves (-2.9 kg). This finding, though it may indicate that men

were less successful when given choice, is confounded by only testing one type of diet in the no-choice group (Coles, et al., 2014). Taken together, there is emerging evidence that providing choice may be beneficial for men but there is a need to better understand how providing choice within a structured weight loss program could be used to enhance the appeal of weight loss programs and their impact among overweight and obese men.

This study contributes to the limited literature on men's weight loss programs and indicates several avenues for future exploration; however, there are several limitations that need to be considered. First, the sample that participated in this study is not representative of all overweight men. The participants were primarily employed, college-educated, White men so the results of this study may not generalize to other groups. Secondly, the study followed participants for only six months post-randomization. Although treatment contact was significantly reduced for the final three months of the program, this does not constitute a true test of weight loss maintenance. Third, this program was implemented, and largely assessed, by the same unblinded researcher (MMC) as part of her dissertation research. This may have influenced participants and increased their compliance to program recommendations and participation in follow up assessments in order to "help" the researcher. Finally, this study utilized a waitlist control group. Because the comparison group did not receive any treatment components during the study, there is no way to test which intervention components were more effective in producing weight loss.

Despite these limitations, this study evaluated the effect of a novel weight loss program designed to meet men's weight loss needs in a manner that was appealing to them. This study used a randomized design to test the effect of this intervention over six months, used objective outcome measures of weight change and body fat change, with excellent

retention to the study and high program utilization rates. Future studies are needed to test the approach used in this program using a more generalizable sample of men in order to understand if the results can be replicated. Additionally, there is a need to test the effects of this approach over a longer time period. Because there was no evidence of weight regain after the weekly sessions ended, the weight loss approach encouraged in this program may be more sustainable than the calorie-counting approach used in more traditional programs.

This study provides evidence that will help future program developers with information for developing weight loss programs for overweight men. This is an important area of research as the overweight and obese rates among men continue to climb while their participation rates in weight loss programs remain low. Using the simplified approach to calorie reduction advocated in the REFIT program holds promise as an alternative to traditional weight loss programs for the growing and under-served population of overweight and obese men.

Theory Construct	Intervention Component
Self-efficacy	 Create opportunities for mastering one dietary change before adding another. Encourage participants to make personally relevant weekly goals. Encourage gradual exercise progression to 225 min/week starting at one of three initial levels of activity. Provide reinforcement of goal achievement and options for overcoming barriers during online check-ins.
Autonomous Motivation	 Provide participants with choice of lesson topics with specific behaviors to master each week. Encourage participants to evaluate their motivation for weight loss and weight loss behaviors regularly.
Outcome Expectancies	 Group sessions focus on connections between behaviors and weight loss; emphasize health and psychological benefits with moderate (5-10%) weight loss. Pre-intervention self-evaluation provides opportunity for participants to identify changes they want to make. Lessons describe the expected outcome of changing each behavior and provide options for how that change can be achieved.
Self-Regulation	 Encourage consistent self-monitoring via a simple self-monitoring form ("Aim for 6"). Record: 100-calorie changes to diet Minutes of physical activity Daily weight Evaluate progress during weekly online check-ins.

Table 5.1	Intervention	Components an	nd Theory Constructs
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	REFIT	Waitlist	p-value (between groups)
N	53	54	
Age	44.7 ± 11.3	43.7 ± 11.6	0.63
Race/ethnicity			0.19
White	44 (83)	38 (70)	
Black	5 (9)	12 (22)	
Other	4 (8)	4 (7)	
Marital Status			0.67
Married, living with partner	43 (81)	42 (78)	
Not married	10 (19)	12 (22)	
Education			0.64
High school, vocational training, or partial college	8 (15)	10 (19)	
College graduate or more	45 (85)	44 (81)	
Employed full-time	48 (91)	47 (87)	0.56
Weight (kg)	99.6 ± 14.3	99.9 ± 14.8	0.91
BMI (kg/m^2)	31.4 ± 3.9	31.5 ± 4.0	0.96
Waist (cm)	109.0 ± 10.2	108.5 ± 10.4	0.80
Percent body fat	34.5 ± 6.1	34.1 ± 6.3	0.74

Table 5.2. Baseline Sample Characteristics

		Assessment Period ^a				p-value ^b		
	Baseline	3 month	6 month	Ti	ime	-		x Time
				3 mo.	6 mo.			
				vs.	vs.	Group	3 mo.	6 mo.
				BL	BL			
Weight (kg)								
REFIT	99.5 (95.7, 103.3)	94.5 (90.7, 98.3)	94.2 (90.3, 98.0)	<.001	<.001	0.85	<.001	<.001
Waitlist	100.0 (96.2, 103.8)	99.4 (95.6, 103.2)	99.4 (95.6, 103.3)	0.28	0.30			
Percent weight los	SS							
REFIT	Ref	-4.9 (-5.9, -4.0)	-5.2 (-6.2, -4.2)	<.001	<.001	0.96	<.001	<.001
Waitlist	Ref	-0.6 (-1.5, 0.4)	-0.6 (-1.6, 0.4)	0.31	0.28			
Waist Circumfere	nce (cm)							
REFIT	108.7 (106.1, 111.8)	104.7 (101.0, 108.3)	103.8 (100.1, 107.6)	<.001	<.001	0.92	<.001	<.001
Waitlist	108.5 (105.0, 112.0)	107.7 (104.1, 111.2)	107.4 (103.8, 110.9)	0.09	0.02			
Percent Body Fat								
REFIT	34.5 (32.7, 36.2)	31.4 (29.7, 33.2)	30.3 (28.5, 32.1)	<.001	<.001	0.80	<.001	<.001
Waitlist	34.1 (32.4, 35.9)	33.7 (32.0, 35.5)	33.1 (31.9, 34.8)	0.32	0.02			
Caloric Intake (kc	cal)							
REFIT	2334 (2169, 2499)	1899 (1720, 2078)	1915 (1740, 2090)	<.001	<.001	0.29	0.28	0.08
Waitlist	2460 (2296, 2623)	2184 (2013, 2355)	2291 (2121, 2462)	0.007	0.10			
% Calories from H	Fat							
REFIT	35.9 (34.1, 37.8)	35.6 (33.6, 37.7)	36.5 (34.5, 38.5)	0.82	0.62	0.31	0.51	0.43
Waitlist	37.3 (35.4, 39.1)	35.9 (34.0, 37.9)	36.6 (34.6, 38.5)	0.24	0.55			
Caloric Expenditu	ure (kcal)*							
REFIT	717.1 (492.5, 983.9)	1437.6 (1104.8, 1814.1)	1305.7 (984.9, 1671.7)	<.001	<.001	0.75	<.001	.001
Waitlist	774.1 (541.8, 1047.7)	723.6 (495.8, 994.3)	756 (529.5, 1045.0)	0.65	0.94			

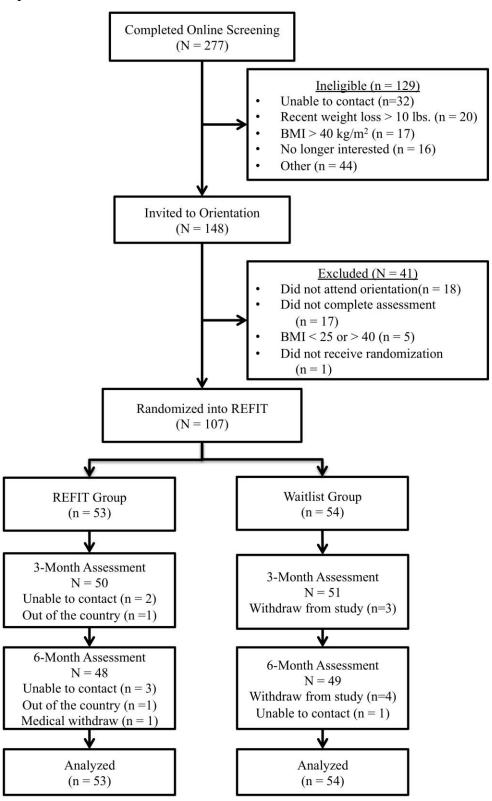
Table 5.3. Weight, Body Composition, and Behavior Outcomes by Treatment Group.

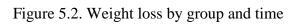
Note. ^aValues are model estimated means and 95% Confidence Interval ^bLinear mixed model analysis using 100 imputed datasets adjusting for marital status and education. *Analysis performed on square root transformed values.

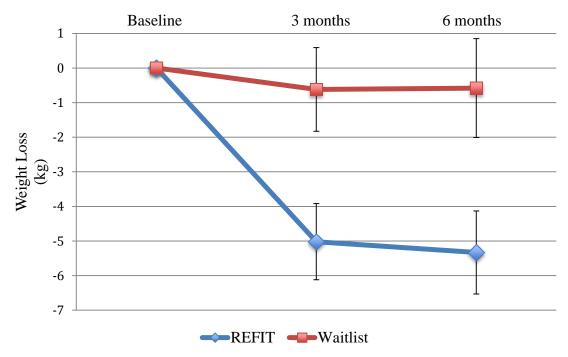
Table 5.4. Check-in Completion Rates, Target Behaviors, and Participant Selections

		Program Week													
	2	3	4	5	6	7	8	9	10	11	12	15	19	22	
Complete check-in (n)		48	48	48	48	48	51	45	48	47	42	40	39	42	
Complete check-in (%)		90.6	90.6	90.6	90.6	90.6	96.2	84.9	90.6	88.7	79.2	73.6	75.5	79.2	
Offered to continue with prior strategy		39	39	42	35	41	37	31	36	32	28	31	30	24	
Pt. select to continue with prior strategy		13	6	9	9	14	11	5	14	13	5	7	4	6	
Target Behaviors					Numbe	er of Pa	articipa	ants Se	lected	Behavi	or				To
Preventing Portion Distortion	24	4	7	5	2	1		1							4
Cutting the Fat	19	8	8	1	1	1	2	2	1						4
Balance your Beverages	10	4	3		4		2	2			1				2
Preventing Snack Attack		19	12	1	3	2	1		2						4
Manage Meats			12	6	7	2			1	2	3	1	1	1	3
Replace to Reduce				26	6	2	1	1			1	1		2	4
Format Fast-Food					16	6	1	1		1					2
Swap out Sweets						20	7	3	1	2	1	2		2	3
Reduce in Restaurants							26	6	1	4		1	1	2	4
Increase to Decrease								24	9	2	1	2	1		3
Tune out TV									19	2		1	1		2
Start with Breakfast										20	4	2	2	2	3
Hydrate to Reduce Waist											35	3	1	2	4
Eating in Social Situations												23	1	2	2
Slips, Slides, & Falls													31	3	3
Maintaining your Momentum														25	2

Figure 5.1. Participant flow







CHAPTER 6: ANALYSIS OF THE THEORETICAL AND BEHAVIORAL MEDIATORS OF A WEIGHT LOSS INTERVENTION FOR MEN

Overview

Although there is growing interest in developing weight loss programs that appeal to men, little is known about the mediators of program effects in these interventions. This analysis tested the theoretical and behavioral mediators of an Internet-delivered weight loss program that was developed to incorporate men's preferences for weight loss with evidenced based strategies. Theoretical constructs that were targeted by the intervention and tested as mediators included: self-efficacy, autonomous motivation, self-regulation, and outcome expectancies. The behaviors tested as hypothesized mediators were caloric intake, caloric expenditure, and frequency of self-weighing. Change in the theoretical mediators between baseline and three months were tested as mediators of the intervention effect on weight change at six months in both single and multiple mediator models. Change in behaviors between baseline and six months were tested in the same manner.

In this study, participants in the intervention group lost more weight than those in the control group (-5.57 kg \pm 6.6 vs. -0.65 kg \pm 3.3, p < 0.001). The intervention was successful in increasing autonomous motivation for diet and exercise, self-efficacy for diet, self-regulation of diet behaviors, physical activity, and self-weighing frequency while also decreasing negative outcome expectations of eating a healthy diet and caloric intake (p's < 0.05). In simple mediation models, after controlling for the intervention group, increases in diet-related autonomous motivation, self-efficacy, and self-regulation; physical activity, and

self-weighing frequency were all associated with greater weight loss (all p's < 0.05). Decreases in negative outcome expectancies for physical activity and caloric intake were also associated with greater decreases in weight. Changes in diet-related autonomous motivation, self-efficacy, and self-regulation all significantly mediated the relationship between the intervention group and weight loss in simple and multiple mediation models. A change in autonomous motivation for physical activity was a significant mediator of the effect only when tested in a simple mediation model. The intervention effect was also mediated by changes in intake and self-weighing frequency. Autonomous motivation for exercise mediated the relationship between the intervention group and changes in physical activity. No other theoretical variables mediated the relationships between intervention group and changes in diet or physical activity.

By testing the theoretical mediators of this intervention in a multiple mediator context, this study contributes to current knowledge related to the development of weight loss interventions for men. The evidence suggests that interventions should target multiple dietfocused psychosocial constructs in order to produce weight loss among men.

Background

The prevalence of obesity among men has recently become equal to that among women for the first time in the United States (Flegal, et al., 2012; Ogden et al., 2006). Along with the rise in the prevalence of obesity in men, there has been growing attention to the fact that men are traditionally underrepresented in behavioral programs focused on weight reduction where only 27% of participants in studies of behavioral weight control are men (Pagoto, et al., 2011). Once men enter a weight loss program, they typically lose as much weight as women (R. L. Williams, et al., 2015) however the reach of these programs remains

limited and it is unclear whether the men who take part in mixed-gender weight loss programs are representative of all men in need of weight loss assistance.

A small number of studies have been conducted to test weight loss programs developed specifically for men (Young, et al., 2012). Although these programs have generally been successful, few studies have been published that focus on the mechanisms through which the interventions produce weight loss. Of the studies that have been published, the focus has been on testing only behaviors as mediators of the treatment effect. Potential mediators that have been considered are: physical activity (steps per day), total calorie consumption, habitual portion size, and specific eating behaviors such as consumption of "take-away" meals, high-caloric-density snacks, sugar-sweetened beverages, and alcoholic beverages (Lubans et al., 2012; Lubans, Morgan, Collins, Warren, & Callister, 2009; Young et al., 2015) These studies have found that steps taken per day is generally a mediator of the intervention effect on weight loss, (Lubans, et al., 2012; Young, et al., 2015) but this finding has not been consistent (Lubans, et al., 2009). Of the eating behaviors that have been tested, only portion size and take-away meals were significant mediators in one of the analyses (Young, et al., 2015). While these studies advance the understanding of how some behaviors may be mechanisms for weight loss among men, there is a need to understand the way in which interventions produce these effects.

Applying and testing theories is needed to help to advance the field of behavioral intervention development (Jeffery, 2004). Although all of the interventions that were included in the analyses described above were based on theory, there have been no studies that have tested whether the interventions influenced the intended theoretical mechanisms

and whether those theoretical constructs were related to behaviors and weight loss, thus more fully exploring the way in which the interventions may be producing weight loss.

Theoretical model of the **REFIT** intervention. Data for the current analysis come from the Rethinking Eating and FITness (REFIT) study. The intervention evaluated in this study was developed to target the theoretical constructs shown in the conceptual model (Figure 6.1). The conceptual model incorporates constructs from self-determination theory (SDT; Ryan & Deci, 2000) as well as social cognitive theory (SCT; Bandura, 1991, 2004). SCT and SDT are two of the most often used theories used to guide weight loss intervention development. The target constructs were included in the conceptual model because of their association with weight loss in prior studies of weight control. Higher levels of autonomous motivation for diet and exercise have been associated with both short and long-term weight loss (Silva, et al., 2011; Teixeira et al., 2010). Similarly, changes in self-efficacy (Linde, Rothman, Baldwin, & Jeffery, 2006; Palmeira et al., 2007) and self-regulation (Steinberg, et al., 2013; Wing, et al., 2006) have also been associated with weight loss. Although these constructs have significant support for their association with weight loss, these studies have been conducted using samples comprised entirely or nearly entirely of women. Therefore it is important to test which the constructs that have been associated with weight loss for women are also important intervention targets for men as well. The final construct in the conceptual model of the REFIT intervention is outcome expectancies. Although outcome expectancies have not generally not associated with weight loss (e.g., Anderson, et al., 2010; Palmeira, et al., 2007) this was selected as an intervention target because of reports that men avoid weight loss programs due to concerns about the negative outcomes of making changes to their diet (Egger & Mowbray, 1993; Gough & Conner, 2006). Targeted ways to overcome these

negative expectations was hypothesized to help men better implement the recommended changes.

The purpose of this study was to test the theoretical and behavioral mediators of the effect of the Rethinking Eating and FITness (REFIT) intervention on weight loss for men. This intervention was developed to match men's preferences for weight control while incorporating evidenced based strategies and theoretically based intervention targets. By using validated measures of theoretical constructs measured before and during the intervention period, this analysis contributes to the field of behavioral weight control by testing the theoretical and behavioral mediators of the intervention effect.

Methods

Data for this analysis come from a six-month randomized controlled trial testing the efficacy of the REFIT intervention. Briefly, the REFIT intervention was delivered via two group sessions and 13 online contacts. The treatment was delivered weekly for three months followed by monthly contact for three months. In the intervention, participants were encouraged to decrease their caloric intake by making a minimum of six 100-calorie changes each day from their baseline eating habits. They were also encouraged to increase their energy expenditure by increasing their physical activity gradually up to 225 minutes of moderate-to-vigorous physical activity per week. Participants were encouraged to track the changes to their diet, along with their daily weight, and minutes of activity. In order to create a sense of autonomy in the structured program, multiple eating behavior targets were presented to participants to select from each week. Brief lessons were provided that focused on how to make the selected behavior change. Tailored feedback was provided to participants

during the online contacts. Further information about the REFIT intervention can be found in Chapters Three and Four.

Assessments were conducted prior to randomization (baseline) and at three and six months post-randomization. Weight, all psychosocial, and behavioral measures were measured at each assessment. Participants were given \$20 for completing the three and sixmonth assessments. All procedures were reviewed and approved by the institutional review board at the University of North Carolina.

Participants. Participants were recruited for this study via email listservs and flyers in the community. To be eligible, men needed to be 18-65 years old, have a BMI 25-40 kg/m², be healthy enough to exercise independently (as determined by the Physical Activity Readiness Questionnaire; Thomas, et al., 1992), be able to attend two face-to-face group sessions, and be able to access online intervention content. Men were excluded if they reported high levels of alcohol intake ((> 10 on the Alcohol Use Disorder Identification Test; Reinert & Allen, 2002), had lost more than 10 pounds in the prior six months, or were currently being treated for a major psychiatric condition. Randomized participants (N=107) were an average age of 44.2 (\pm 11.4) years, obese (BMI 31.4 \pm 3.9), predominately non-Hispanic white (76.6%), married (79.4%), and had at least a bachelor's degree (83.2%). There were no differences between the randomized groups on baseline characteristics (p's > 0.19).

Measures. Weight was measured twice (average used) at each assessment using a calibrated digital scale (Tanita Model: BWB-800s) to the nearest tenth of a kilogram. Participants were measured without shoes while wearing spandex compression-style shorts.

Diet-related measures. Autonomous motivation for eating a healthier diet was assessed using the Treatment Self-Regulation Questionnaire for diet (Levesque, et al., 2007). This 15-item questionnaire assesses motivations underlying change to healthy eating or continued healthy eating on subscales of autonomous motivation ("I feel that I want to take responsibility for my own health"), controlled motivation, and amotivation. Only the autonomous motivation subscale was used in this analysis. This scale demonstrated excellent internal consistency in the current sample (assessed at baseline, Cronbach's alpha = 0.90). Self-efficacy for controlling eating was assessed using the Weight Efficacy Lifestyle Questionnaire (Clark, et al., 1991). The 20-item measure assesses feelings of being able control eating in response in five types of situations (presence of negative emotions, food availability, social pressure, physical discomfort, and positive activities). A total score across the five domains was created (alpha = 0.95). Outcome expectancies for eating a healthy diet were assessed using the Health Beliefs Survey: Healthy Food Outcomes, developed by Anderson and colleagues (Anderson, et al., 2010). This 22-item scale assesses degree of agreement with statements of positive outcomes of eating healthier foods ("I will have more energy") and negative outcomes ("The food I eat will not taste good"). Scores for positive and negative outcomes were developed (alpha = 0.89; 0.86, respectively). Finally, selfregulation of eating behaviors was assessed using the Eating Behavior Inventory (O'Neil, et al., 1979). This 26-item index assesses frequency of using weight control strategies that promote self-regulation of eating behaviors ("I carefully watch the quantity of food that I eat."). In the current sample, an internal reliability was acceptable (alpha = 0.61).

Exercise-related measures. Autonomous motivation for exercise was assessed using the Treatment Self-Regulation Questionnaire for exercise (Levesque, et al., 2007). This 15-

item measure assesses motivations for exercising regularly, along the dimensions of autonomous motivation ("Because I personally believe it is the best things for my health"), controlled motivation, and amotivation. Only the autonomous motivation subscale was used in this analysis (alpha = 0.92). Self-efficacy for exercise was assessed using a scale developed by Sallis and colleagues (Sallis, et al., 1988). The measure uses 12 items to assess belief that one can exercise consistently ("Stick to your exercise program after a long, tiring day") and can make time for exercise ("Get up early, even on weekends to exercise"). In the current sample, this measure demonstrated high internal consistency (alpha = 0.90). Outcome expectancies for exercising regularly were assessed using the Health Beliefs Survey: Physical Activity Beliefs scale, developed by Anderson and colleagues (Anderson, et al., 2010). This survey uses 27 items to assess agreement that the potential outcome would occur following a regular exercise routine and whether the outcome would affect the respondent's decision to exercise. Outcomes were assessed for positive health outcomes ("I will sleep better"), positive affective outcomes ("I will feel less stressed"), and negative outcomes ("I will have less time to spend with my family"). Multiplying the ratings of agreement and relevance to the respondent created a score for each item. These were summed to create the three subscale scores. The subscales were all internally consistent (alpha's = 0.77; 0.86; 0.88, respectively).

Behavior measures. Dietary intake was measured using the National Cancer Institute's Automated Self-Administered 24-hour Recall (version 2011; ASA-24). Participants completed two recalls during each assessment: one each for a weekday and a weekend day. Recalls that were outside of a probable range for a single day intake for an adult man (i.e., 650-5,700 calories) were removed (Baseline: n = 2, 3M: n = 3, 6M: n = 0). This tool has performed well compared to an interviewer-administered 24-hour recall

(Kirkpatrick, et al., 2014). Physical activity was measured using the Paffenbarger Activity Questionnaire (Paffenbarger, et al., 1986). This questionnaire assesses leisure time physical activity, walking for exercise and transportation, and daily flights of stairs climbed over the previous week. Caloric expenditure was estimated by classifying activities using the metabolic equivalents for each activity from the Compendium of Physical Activities (Ainsworth, et al., 2011). This procedure is being used in the EARLY consortium (Lytle, et al., 2014). Self-weighing was assessed at each assessment using a single-item measure which asks how often the participant current weighs himself on a seven-point scale from "never" to "multiple times per day." This measure has been used in prior studies (Linde, et al., 2005; Wing, et al., 2006).

Statistical analysis. Changes in the theoretical constructs between baseline and three months were tested as mediators of the treatment effect on weight loss between baseline and six months. Similarly, changes in the theoretical constructs were also tested as mediators of the treatment effect on changes in calorie intake and calorie expenditure through physical activity between baseline and six months. These time points were selected in order to establish a temporal relationship between the delivery of the intervention, the change in the cognitive construct, and the weight loss or target behaviors as measured at the final assessment. Changes in the behaviors between baseline and six-months were also tested as mediators of the treatment on weight loss. Because these measures assess behaviors over the past week, they were selected due to their proximity to the weight outcomes but remain temporally prior to the final weight loss. Change scores for each mediator were calculated by regressing the later measure on the baseline measure. Weight change was calculated such that negative values indicated a weight loss between baseline and six months.

All analyses were conducted using SAS 9.3. Differences between study groups at baseline and differences in assessment completion were assessed using independent-group ttests and chi-square as appropriate. Changes over time by within each treatment group were assessed using paired t-tests. Caloric expenditure at each assessment was moderately positively skewed and was transformed using a square root transformation prior to analysis. Mediation effects were tested using the PROCESS macro developed by Hayes (2013). This macro uses regression analysis to test the relationships between the independent variable and the mediator (referred to as the A-path in mediation terminology), the relationship between the mediator and the outcome while controlling for the independent variable (B-path), and finally the indirect effect of the independent variable on the dependent variable through the mediator (a*b). The significance of the A-path and B-paths were assessed using normaltheory probability testing. Estimated coefficients, standard errors, and probability values are reported. To test the significance of the indirect effects, this macro develops 1000 bootstrapped samples of the indirect effect and reports the bootstrapped standard errors and 95% confidence interval around the mean estimated effect. This technique is superior to older methods such as the Sobel test which assumes that the potential indirect effects are normally distributed (Preacher & Hayes, 2008). Estimated coefficients and bootstrapped standard errors and 95% confidence intervals are reported. The effect size of the mediated effect is reported as mediated R^2 . This provides an estimate of the variance in the outcome explained by the mediated effect.

The conceptual model that underlies the intervention used in this analysis includes many potential mediators of the treatment effect. In order to understand how these potential mediators contribute to the treatment effect, mediators were first tested as simple mediator

models (i.e., one mediator in the model). The variables that were found to be significant mediators of the treatment effect from the simple models were then tested as part of a multiple mediation analysis where all significant mediators were included simultaneously. Separate models were tested for the behavioral and theoretical mediators.

Results

There were few differences between those randomized to the intervention group and the waitlist control group on the theoretical and behavioral constructs of interest at baseline (see Table 6.1). The intervention group reported higher levels of positive outcome expectations for eating a healthier diet (4.26 ± 0.53 vs. 4.02 ± 0.67 , p = 0.02) and for exercise (15.91 ± 5.11 vs. 13.46 ± 4.69 , p = 0.04) than the control group. There were no differences in retention between treatment groups (p's = 0.98) with 101 participants returning for the three-month assessment (94.4%) and 97 returning for the six-month assessment (90.7%). Those who took part in the three-month assessment were more likely to be married (81.2%) than those who did not (50.0%, p = 0.07). and those who returned for the six-month assessment were more likely to be employed full-time than those who did not (90.7% vs. 70.0%, p = 0.05). No other significant differences were observed (p's > 0.05).

The intervention produced a significant decrease in body weight at three and six months such that the average weight loss of those who returned for the six-month assessment in the intervention group was -5.57 kg (\pm 6.6) as compared to -0.65 kg (\pm 3.3) in the control group (p < 0.001). Similar changes were observed in analyses using multiple imputations to account for missing data (see Crane et al., 2015).

Simple mediation. Changes in the theoretical mediators between baseline and three months and the changes in the behaviors between baseline and six months are described in

Table 6.1. The effect of the intervention on changes in the meditators is indicated as the Apath relationship in Table 6.2. All changes within the intervention group were in the expected direction. For instance, the intervention group reported greater increases than the control group in feelings of autonomous motivation for healthy eating between the start of the program and the three-month assessment. Conversely, the intervention group reported greater decreases in perceptions of negative outcomes associated with eating a healthy diet than the control group.

The relationships between changes in the mediators between baseline and three months and change in weight between the baseline and six-month assessments, controlling for the effect of the intervention group, are shown in Table 6.2 (B-path). The associations between changes in weight and changes in autonomous motivation (p = 0.02), self-efficacy (p = 0.001), and self-regulation (p < 0.001) for diet were all statistically significant and in the expected direction. For example, increases in self-efficacy between baseline and three months were associated with greater weight losses between baseline and six months. Outcomes expectancies for healthy eating (positive and negative) were not associated with weight change (p's = 0.19 and 0.20, respectively). Reductions in negative outcome expectancies for physical activity were associated with reductions in weight (p = 0.02). There were trends for significant relationships between weight loss and changes in autonomous motivation for exercise (p = 0.11) and self-efficacy for exercise (p = 0.07), although these did not reach statistical significance. Changes in positive outcome expectancies for physical activity were not associated with weight loss (p's ≥ 0.34). Changes in diet (p = 0.003), physical activity (p = 0.01), and frequency of self-weighing (p < 0.001) between baseline and six months were also associated with changes in weight over the same period.

The effect of the intervention on weight loss was mediated primarily through dietrelated constructs and the target behaviors of diet, physical activity, and self-weighing. Autonomous motivation for eating a healthy diet (estimate = -0.72, 95% confidence interval: -1.41, -0.28), self-efficacy for eating a healthy diet (-1.06, 95% CI: -2.04, -0.42), and selfregulation of eating behaviors (-4.02, 95% CI: -6.35, -2.15) all mediated the relationship between the intervention and weight loss. For the exercise related constructs, only autonomous motivation for exercise mediated the relationship (-0.37, 95% CI: -0.89, -0.04). Changes in diet (-0.97, 95% CI: -2.09, -0.34), physical activity (-0.91, 95% CI: -1.86, -0.23), and self-weighing frequency (-4.03, 95% CI: -5.99, -2.56) all significantly mediated the effect of the intervention as well.

Table 6.3 displays the tests of mediation of the treatment effect on changes in diet and physical activity by the theoretical constructs. The diet-related constructs were tested as mediators of the treatment effect on changes in diet between baseline and six months whereas the exercise-related constructs were tested as mediators of the treatment effect on changes in caloric expenditure through physical activity. As shown in Table 6.3, the effects of the changes in the theoretical constructs on changes in the behaviors were largely not significant. Only the change in autonomous motivation between baseline and three months significantly mediated the treatment effect on change in physical activity between baseline and six months. Because only one theoretical mediator was significant, the theoretical construct to behavior relationships were not further tested in multiple mediation.

Multiple mediator models. The significant mediators of the effect of the intervention on weight loss were tested in two models testing the effects of multiple mediators simultaneously. Models were developed that tested changes in the theoretical mediators and

behavioral mediators of the treatment effects separately (see Figures 6.2a and 6.2b). As shown in Table 6.4, autonomous motivation for diet (-0.82; 95% CI: -2.22, -0.11), self-efficacy for diet (-0.66; 95% CI: -1.63, -0.08), and self-regulation for diet (-3.06; 95% CI: -575, -0.71) mediated the treatment effect on weight loss after controlling for the effects of the remaining variables. Autonomous motivation for exercise did not mediate the relationship between the intervention and weight loss (0.53; 95% CI: -0.10, 1.98) with the other mediators in the model.

The model testing the indirect effects of the behavioral mediators indicated that the intervention effects on weight change compared to the control group were achieved via changes in dietary intake (0.85; 95% CI: -1.90, -0.26) and self-weighing (-3.8; 95% CI: -6.24, -2.00) but not exercise (-0.01 95% CI: -0.82; 0.89).

Discussion

This study tested the theoretical and behavioral mediators of a weight loss program developed for men. The results from the simple and multiple mediation analyses suggest that the effect of the intervention on weight loss compared to the control was significantly mediated by changes in many of the proposed constructs related to diet (autonomous motivation, self-efficacy, and self-regulation) and changes in self-weighing and eating behaviors. Changes in autonomous motivation for exercise and caloric expenditure through physical activity were significant mediators of the treatment effect only when tested in models of simple mediation. Only changes in autonomous motivation for exercise between baseline and three months significantly mediated the relationship between the intervention and changes in calorie expenditure through exercise. No theoretical constructs mediated the relationship between the treatment effect and changes in diet.

Self-efficacy is often an intervention target of studies of behavioral weight control although it is not consistently associated with weight loss. In some studies, baseline selfefficacy has been associated with weight loss among men but not women (French, et al., 1994; Jeffery, et al., 1984; Presnell, et al., 2007). Although other studies report that selfefficacy at baseline is predictive of weight loss among all participants (Linde, et al., 2006; Teixeira et al., 2002). Similar to the results of the current study, changes in self-efficacy during treatment have also been associated with weight loss (Nezami et al., 2015; Warziski, Sereika, Styn, Music, & Burke, 2008; Wingo et al., 2013). The relationship between change in self-efficacy and weight loss is particularly important because some studies observe decreases in self-efficacy during an intervention (Linde, et al., 2006; Wingo, et al., 2013). This suggests that interventions need to insure adequate intervention strategies focused on preserving or increasing self-efficacy during intervention to maximize weight loss efforts. In the present study, self-efficacy was preserved and increased in the intervention group. To our knowledge, this is the first study that has looked at change in self-efficacy as a mediator of weight loss among men.

Autonomous motivation was hypothesized to be an important construct to target when developing a weight loss program for men because independence is a key characteristic of masculinity (Addis & Mahalik, 2003). Additionally, in studies of women change in autonomous motivation for diet has been found to mediate the relationship between an intervention and weight loss in the short-term (Teixeira, et al., 2010) while autonomous motivation for exercise has been associated with long-term weight loss maintenance (Silva, et al., 2011). The results of this analysis support results found in these previous studies. In this study, autonomous motivation for eating a healthy diet was a significant mediator of the

treatment effect in the multiple mediation model as well as in the simple model. On the other hand, autonomous motivation for physical activity only mediated the intervention weight loss relationship in this simple mediation model. This weaker relationship between autonomous motivation for physical activity and initial weight loss supports the prior findings, which suggest that autonomous motivation for exercise is less influential in the early stages of weight loss. Although in the current study men lost much of their weight during the first three months and treatment was tapered in the current study between the three- and sixmonth assessments, previous studies examining exercise during weight loss maintenance examine this behavior between six and 12 months or 12 and 18 months after initiating weight loss.

Self-regulation behaviors measured by the Eating Behavior Inventory and selfregulation through daily self-weighing both mediated the intervention's effects on weight loss in the simple and multiple mediator models. This supports the assertion that selfregulation is key for behavior change (Bandura, 1991; O'Neil & Rieder, 2005). The finding that self-weighing frequency mediated the treatment effect supports the growing evidence that daily self-weighing is a simple form of self-regulation that can be important for weight loss and weight loss maintenance (Steinberg, et al., 2013; Wing, et al., 2006; Zheng et al., 2015).

The modest relationships between physical activity and weight loss found in this study add to the inconsistent relationships found between these variables in past studies of men. Some studies (Jeffery, et al., 1984; Lubans, et al., 2012; Young, et al., 2015) have found that physical activity was associated with weight loss while other studies (Lubans, et al., 2009) have not found the same effect. Although weight loss can be achieved by men via

physical activity alone (Ross et al., 2000), the general finding is that physical activity alone is not associated with significant weight losses (Swift, et al., 2014) and that changes in diet are more closely associated with initial weight loss (e.g., Wadden et al., 1997). Similarly, theoretical constructs associated with exercise change have weaker associations with shortterm weight loss than diet-related constructs (Palmeira, et al., 2007). In contrast, high levels of physical activity is associated with long-term weight loss (Jakicic, et al., 2011; Jeffery, et al., 2003; Johns, Hartmann-Boyce, Jebb, Aveyard, & for the Behavioural Weight Management Review Group, 2014; Wing, et al., 2006), thus it will be important for future studies to test whether autonomous motivation for exercise is an important construct for long-term weight loss maintenance among men as it is for women (Silva, et al., 2011).

This study additionally tested the relationships between the theoretical constructs described above and the behaviors they are hypothesized to change. Although changes in both diet and physical activity mediated the relationship between the intervention and weight loss, the theoretical constructs did not mediate the intervention to behavior relationship. It is not clear why these relationships were not observed. One potential explanation is that the self-report measurement of the theory constructs and the self-reported assessment of behaviors introduced sufficient measurement error that the current sample size was insufficient to detect the relationships. Self-reported measurement of diet and exercise behaviors is notoriously challenging and prone to errors (Dhurandhar et al., 2014). This is a logical explanation for the non-significant findings in the current study given that the relationships between one self-report measure (either construct or behavior) and the objectively measured weight change were generally in the expected direction, though not significant. Future studies will need a combination of larger samples sizes and more precise

measurement of diet and physical activity in order to be better suited to assess these relationships.

While this study contributes to the nascent literature on men's weight loss programs, there are limitations that need to be addressed in future studies. First, this study utilized a waitlist control condition. Although this was appropriate for testing the efficacy of the intervention, the minimal changes in the control group may have diluted this study's ability to detect relationships between the changes in the mediators and weight loss outcomes. Secondly, this study used data only from those participants who returned for the three- and six-month assessments. Although there was high retention to the study and few differences were observed between completers and dropouts, this reduced the available power for the analyses. The study also only followed participants over six months. Because there is evidence that predictors of weight loss are different than those of weight loss maintenance (Silva, et al., 2011; Teixeira, et al., 2010), future studies will be needed to test these longer-term relationships with samples of men.

This study utilized data from a six-month randomized trial with excellent retention to test the effects of theoretical and behavioral constructs as mediators of the intervention effect on weight loss. By using established measures of the theoretical constructs, the results of this study can be compared descriptively to other studies and samples. By testing both simple and multiple mediation models, this study was able to assess the mediators in isolation, which is often done in studies of behavioral trials, as well as testing the mediators together. This simultaneous analysis better fits the conceptual model underlying this intervention and most behavioral interventions, which are multicomponent and multidimensional. By focusing on theoretical mediators as opposed to focusing only on behaviors, this analysis contributes

information that may be generalized beyond this intervention and can help future intervention developers to select intervention targets that are most consequential to men.

Table 6.1. Observed Means by Treatment Group and Time	
ruble 6.1. Observed Medals by Medallent Oroup and Thile	

		Waitlist			<u>REFIT</u>			
	Baseline	3 mos.	Within group ^a	Baseline	3 mos.	Within group ^a	Baseline Differen ce ^b	
Eating related								
Autonomous motivation	5.78 ± 0.93	5.64 ± 1.17	0.60	5.87 ± 1.05	6.12 ± 0.98	0.02	0.63	
Self-efficacy diet	122.01 ± 32.16	118.72 ± 35.01	0.12	126.59 ± 31.48	132.03 ± 30.01	0.009	0.46	
Outcomes-Positive	4.00 ± 0.55	4.02 ± 0.67	0.67	4.26 ± 0.53	4.29 ± 0.50	0.45	0.02	
Outcomes- Negative	2.94 ± 0.67	2.91 ± 0.75	0.94	2.69 ± 0.70	2.45 ± 0.53	0.008	0.06	
Self-regulation	72.27 ± 8.78	74.32 ± 9.18	0.01	74.63 ± 8.38	91.72 ± 10.00	< 0.01	0.16	
Exercise related								
Autonomous motivation	5.92 ± 0.92	5.74 ± 1.23	0.25	6.17 ± 1.07	6.21 ± 0.98	0.47	0.21	
Self-efficacy	3.87 ± 0.69	3.78 ± 0.83	0.12	3.88 ± 0.69	3.81 ± 0.75	0.55	0.95	
Outcomes- Positive Health	18.80 ± 4.63	17.98 ± 5.08	0.21	18.89 ± 4.17	18.78 ± 4.73	0.37	0.92	
Outcomes- Positive Affect	14.01 ± 4.48	13.46 ± 4.69	0.24	15.91 ± 5.11	15.75 ± 4.85	0.64	0.04	
Outcomes- Negative	10.03 ± 4.69 Baseline	9.22 ± 4.67 <u>6 mos.</u>	0.22	9.43 ± 4.36 Baseline	8.81 ± 3.72 <u>6 mos.</u>	0.41	0.06	
Behaviors								
Intake (kcals)	2460 ± 619	2286 ± 692	0.17	2332 ± 665	1890 ± 468	< 0.001	0.30	
Exercise (kcals)	1055 ± 1095	926 ± 805	0.91	1032 ± 1175	1650 ± 1303	0.001	0.92	
Self-weighing frequency	3.44 ± 1.68	3.49 ± 1.52	0.21	3.68 ± 1.59	5.60 ± 0.84	< 0.001	0.46	
Weight (kg)	99.95 ± 14.78	99.43 ± 15.00	0.17	99.61 ± 14.30	94.46 ± 13.64	< 0.001	0.91	

Note. All values are mean ± standard deviation. ^aWithin group differences results of paired sample t-tests. ^bDifferences at baseline tested with independent t-tests.

	A-path (s.e.)	B-path (s.e.)	Indirect Effect (95% CI)	Direct Effect (s.e.)	Effect Size (med R ²⁾
Diet-related Constructs					
Autonomous motivation	0.51 (0.18)**	-1.41(0.59)*	-0.72 (-1.41, -0.28)	-4.21 (1.06)***	0.06
Self-efficacy	12.17 (4.01)**	-0.09 (0.03)**	-1.06 (-2.04, -0.42)	-4.29 (1.06)***	0.09
Positive outcomes	0.10 (0.10)	-1.51 (1.16)	-0.15 (-0.83, 0.07)	-4.98 (1.06)***	0.01
Negative outcomes	-0.34 (0.10)**	1.35 (1.12)	-0.46 (-1.20, 0.01)	-4.67 (1.12)***	0.05
Self-regulation	14.84 (1.56)***	-0.27 (0.06)***	-4.02 (-6.35, -2.15)	-0.77 (1.35)	0.18
Exercise-related Constructs					
Autonomous motivation	0.36 (0.17)*	-1.03 (0.63)	-0.37 (-0.89, -0.04)	-4.56 (1.06)***	0.04
Self-efficacy	0.07 (0.12)	-1.61 (0.90)	-0.11 (-0.66, 0.24)	-5.05 (1.04)***	0.01
Positive health outcomes	1.15 (0.68)	0.15 (0.16)	0.17 (-0.08, 0.83)	-5.47 (1.07)***	-0.001
Positive affective outcomes	1.22 (0.63)	-0.04 (0.18)	-0.05 (-0.85, 0.34)	-5.25 (1.08)***	0.01
Negative outcomes	-0.13 (0.68)	0.37 (0.16)*	-0.05 (-0.60, 0.54)	-5.25 (1.03)***	0.004
Behaviors					
Intake (kcals)	-353.50 (111.76)**	0.003 (0.001)*	-0.97 (-2.09, -0.34)	-4.13 (1.04)***	0.08
Exercise (kcals) ^a	9.49 (2.69)***	-0.10 (0.04)*	-0.91 (-1.86, -0.23)	-4.06 (1.07)***	0.08
Self-weighing frequency	1.92 (0.22)***	-2.10 (0.44)***	-4.03 (-5.99, -2.56)	-1.07 (1.26)	0.20

Table 6.2. Simple Mediation Analyses with Weight Outcome

Note. * p < 0.05, **p < 0.01, ***p < 0.001. ^a Analysis performed on square root transformed values.

Table 6.3. Simple Mediation	Analyses with Diet an	d Physical Activity Outcomes
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	A-path (s.e.)	B-path (s.e.)	Indirect Effect (95% CI)	Direct Effect (s.e.)	Effect Size (medR ²)
Eating related: Change in					
Calorie Intake as Outcome					
Autonomous motivation	0.54 (0.18)**	-34.73 (64.24)	-18.73 (-90.19, 40.36)	-360.66 (115.47)**	0.02
Self-efficacy	12.17 (4.01)**	-3.95 (2.90)	-48.13 (-161.54, 27.82)	-363.56 (115.82**	0.04
Positive outcomes	0.11 (0.10)	-17.15 (124.19)	-1.93 (-42.27, 21.30)	-378.29 (113.93)**	0.003
Negative outcomes	-0.35 (0.10)**	-8.46 (113.60)	2.94 (-72.51, 90.12)	-383.16 (119.79)**	0.01
Self-regulation	15.10 (1.55)***	1.29 (7.46)	19.49 (-155.56, 209.42)	-387.64 (158.10)*	0.05
Exercise related: Change in					
Caloric Expenditure ^a as					
Outcome					
Autonomous motivation	0.36 (0.17)*	3.39 (1.63)*	1.22 (0.07, 3.29)	8.36 (2.74)***	0.03
Self-efficacy	0.07 (0.12)	6.23 (2.32)**	0.44 (-0.96, 2.41)	9.56 (2.68)***	0.01
Positive health outcomes	1.15 (0.69)	0.50 (0.41)	0.58 (-0.56, 2.69)	9.99 (2.77)***	0.02
Positive affective outcomes	1.22 (0.63)	0.66 (0.45)	0.81 (-0.15, 3.39)	9.76 (2.78)***	0.03
Negative outcomes	-0.13 (0.68)	0.25 (0.42)	-0.03 (-1.02, 0.45)	10.60 (2.74)***	< 0.01

Note. * p < 0.05, **p < 0.01, ***p < 0.001. ^a Analysis performed on square root transformed values.

		Coefficient	95% Confidence
		(s.e.)	Interval
Model 1.			
	Total Effect (c-path)	-5.22 (1.06)	-7.34; -3.11
	Direct Effect (c'-path)	-1.21 (1.45)	-4.10; 1.68
	Indirect Effects		
	Autonomous motivation: Diet	-0.82 (0.50)	-2.22; -0.11
	Self-efficacy: Diet	-0.66 (0.38)	-1.63; -0.08
	Self-regulation: Diet	-3.06 (1.27)	-5.75; -0.71
	Autonomous motivation: Exercise	0.53 (0.52)	-0.10; 1.98
Model 2.			
	Total Effect (c-path)	-5.10 (1.03)	-7.15; -3.05
	Direct Effect (c'-path)	-0.44 (1.24)	-2.91; 2.02
	Indirect Effects		
	Intake (kcals)	-0.85 (0.40)	-1.90; -0.26
	Exercise (kcals) ^a	-0.01 (0.43)	-0.82; 0.89
	Self-weighing frequency	-0.85 (1.07)	-1.90; -0.26

 Table 6.4. Multiple Mediator Analyses

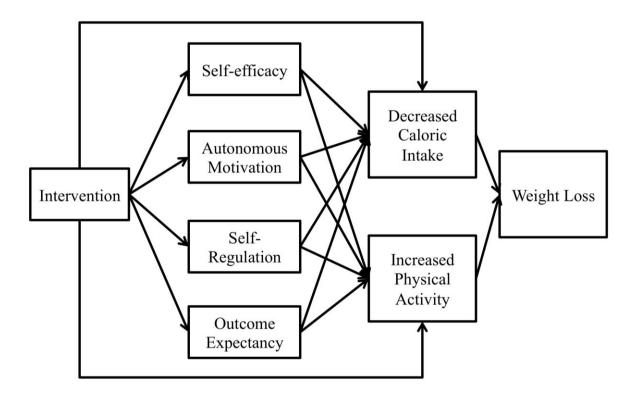
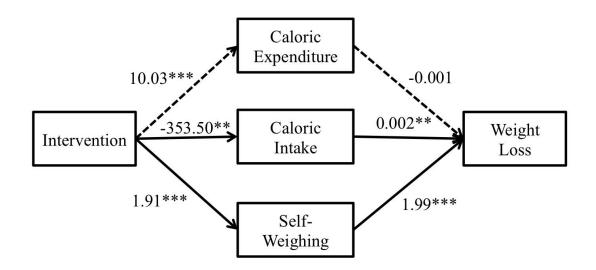


Figure 6.1. Conceptual model of the REFIT intervention

Figure 6.2. Theoretical and behavior mediators

A. Self-efficacy: Diet 12.06* 0.06† Autonomous 1.54 † 0.53* Motivation: Diet Intervention Weight Loss 15.82*** -0.19** Self-Regulation: Diet 1.29 0.41 Autonomous Motivation: Exercise

B.



Note. † p < 0.10, * p < 0.05, **p< 0.01, ***p < 0.001

CHAPTER 7: SYNTHESIS AND DISCUSSION

Summary of Findings

Overall, the findings of this study suggest that men's involvement in behavioral weight control interventions can be increased modestly through targeting the recruitment messaging used for these programs, such as highlighting the word "men" as a call to action. Further, the novel approach to weight control used in the study, which emphasized autonomy and an alternative approach to calorie reduction, resulted in weight losses of clinical significance, and can be considered a viable alternative option to traditional weight control programs for men. The meditational analysis showed that the program produced effects on weight loss through changes in the theoretical mediators of autonomous motivation, self-efficacy, and self-regulation for diet as well as through changes in diet and self-regulation behavior. The following sections summarize the results of this study and provide implications for future research.

Aim One summary and discussion. The primary purpose of Aim One was to investigate how changing the type of direct mailing used for recruitment and the message included in that mailing would impact recruitment for a weight gain prevention trial. The elaboration likelihood model (ELM) served as a theoretical basis for the studies conducted in Aim One (Petty & Cacioppo, 1986; Petty, Priester, & Brinol, 2002). The first study in this aim tested the effects of modifying the type of recruitment mailing to assess the effects on message reach. Here, potential participants were sent either a short and less detailed message, via a postcard or a longer and potentially more persuasive message, via a brochure. Website visit data demonstrated that both types of mailings had similar reach (p = 0.22), but potential participants who received the brochure were more likely to continue to the next stage of program participation than those sent the postcard (OR = 1.21, p = 0.01). The second study tested whether including a targeted headline using the word "men" as a cue to action in the recruitment mailing would increase men's response to the recruitment message. It was hypothesized that using targeting would increase the personalization of the message and therefore would increase the likelihood that men would attend to the message. Although men represented a greater proportion of respondents to the targeted card (36.8%) versus the generic card (19.1%) this did not reach statistical significance (p = 0.07). There was no significant difference in the number of men responding to each card type (p = 0.30). Once participants completed the telephone screening, a similar proportion of men and women were randomized into the study (p = 0.37).

This study contributes to the literature focused on improving recruitment for behavioral trials by using a quasi-experimental design to compare the type of direct mailing on recruitment results and by using a randomized comparison to test the effect of message targeting on male recruitment. Recruiting an adequate sample with sufficient representation of key groups is an essential aspect of behavioral research trials that is needed to best evaluate their public health impact (Glasgow, Vogt, & Boles, 1999) but little experimental research has been conducted studying how recruitment messages can be developed to be most effective.

Direct mailings are often used as a mode of recruitment for behavioral trials thus making this an important recruitment mode to study (Lovato, et al., 1997). In addition to

being highly utilized, it is appropriate to use direct mailings to assess the reach of a recruitment message because it to provides a clearer number of message recipients than other modes of recruiting (e.g., flyers). Despite their regular usage for recruitment, there is little guidance in the literature to aid researchers in making decisions on which type of mailing to use (e.g., postcard, brochure, letter, etc.). Direct mailings have been extensively researched in the context of conducting surveys via mail (e.g., Dillman, Smyth, & Christian, 2014). While it might be tempting to suggest that advertising for longitudinal studies should be comparable to recruiting for survey participation, this may not be the case. As an example, a recommended practice is to personalize a survey by including the individual's name in the cover letter. When Kiernan and colleagues tested whether personalization and hand-signed letters improved recruitment efforts for a clinical trial, no effect was found (Kiernan, et al., 2000). While survey and recruitment may both use mail to contact participants, the task requested of the recipient is much different. As suggested by ELM, because participation in a longitudinal behavioral research study has a much greater impact on a person's life, surface level personalization may not be as impactful as when asking someone to complete a onetime survey, typically for payment.

This study found that the brochures yielded a prolonged response among potential participants as evidenced by participants initiating an online screener to assess study eligibility. It is hypothesized that this greater response was due to the more persuasive message delivered by the brochure. It is important to note that all of the information included in the brochure was available on the websites all participants were directed to. This means that all participants, regardless of the mailing received, could have accessed the same messages persuading them to join the study. For those who received the brochure, the

information was presented in the mailing they received whereas those who received the postcard would have needed to find the information on the study website. Presenting more persuasive messages about joining the study in the brochure may have increased the likelihood that recipients read the messages (i.e., they were not required to find the information on the study website). Alternatively, those who received the brochure may have found the same information on the website as was available on the brochure thus may have experienced repetition of the messages. Despite not being able to identify the mechanism through which the additional information influenced response, it will be important for future research to determine the point at which more information yields diminishing returns. In other words, future studies will need to test how much information at the initial contact is sufficient to increase interest without overwhelming participants.

The second contribution to the literature made by Aim One is the further support of the use of targeting messages for recruitment efforts. While targeting has been used extensively in recruitment of minority participants into studies (UyBico, Pavel, & Gross, 2007; Yancey, et al., 2006) and for improving the impact of health communications (e.g., Kreuter & Wray, 2003), few studies have compared the effects of targeted versus nontargeted messages for recruitment in a direct experimental comparisons (Brown, et al., 2012; Brown, et al., 2015; Kiernan, et al., 2000). The results from Aim One support previous findings that targeting is generally useful for recruiting participants that are generally underreached by generic recruitment messages. Similar to developing other types of targeted messages, it is important to identify variables or characteristics that are relevant to the target population (Boslaugh, Kreuter, Niicholson, & Naleid, 2005). In a recent study by Brown and colleagues English-speaking, Hispanic women who were sent a letter that included targeted

health risk information for Hispanic women, their screening rates decreased (Brown, et al., 2015). This may have been due to incorrect targeting of the messages on characteristics not relevant to the recipients. This finding demonstrates the importance of testing the effects of different recruitment messages.

The challenges this study faced in its efforts to recruit men into a program focused on weight gain prevention mirror young men's low interest in this type of program. A survey of college students found that young men would need to gain more weight than young women before they were concerned about the gain. Further, the men were less likely than the women to be interested in a weight control program (Gokee LaRose, et al., 2011). In order to reach these young men, a more extensive targeted argument surrounding why weigh gain prevention is important will likely be needed in addition to targeting headline text of the messages. Young men report that there it is socially acceptable for men to gain weight as they age, but the same is not true for women (Bordogna, et al., 2015). With this information, the recruitment message alerting young men to the information of weight gain may not have been enough for them to join the program. Instead, a future approach that better incorporates young men's values (e.g., economic success) and emphasizes more clearly the immediate benefits of participating in a weight gain prevention program may be more successful.

A limitation of this study was that it was unable to test the interaction between mailing type (postcard versus brochure) and message type (generic versus targeted). In order to maximize male and minority recruitment into larger SNAP NIH-funded trial, women who identified as non-Hispanic white were put on a waiting list and not fully telephone screened during the brochure phase of study recruitment. This decision, though the correct decision for the SNAP trial, demonstrates one of the challenges of embedding recruitment studies into

actual recruitment of clinical trials. Recruitment is often more challenging than anticipated and, as an effect, the recruitment plans may need to be modified in order to reach recruitment targets. In the future, the question of whether there is an interaction between message length and targeting will need to be tested.

The results from Aim One as a whole highlight the challenges that face public health professionals as they strive to aid populations in taking steps to prevent future negative health outcomes. The overall response rate to the direct mailings that were sent was 1.3%. This suggests that despite being faced with evidence that negative health repercussions could occur, young adults were not motivated to join a weight gain prevention program. The especially low response rate among men is particularly concerning. Moving forward, there is a need for more research that delves deeper into young adults' perspectives on prevention to understand what, if anything, would be a call to action to help them manage their weight in a preventive manner. Although focus groups were conducted that focused on the perception of weight (Bordogna, et al., 2015) and on recruitment message development (Tate, et al., 2014), this remains a poorly understood topic.

Aim Two summary and discussion. Aim Two included the development and evaluation of a novel weight loss program for men, as described in Chapters Three and Five. The Rethinking Eating and FITness (REFIT) program was compared to a waitlist control group in a six-month randomized study. At the end of six-months, participants in the REFIT group had lost more weight (as measured in kilograms and percent of initial body weight), reduced their percentage body fat, reduced their waist circumference, and increased their physical activity more than those in the control group (all p's \leq 0.01). There was also a trend

for greater reductions in total caloric intake in the REFIT group (p = 0.08). The program was well utilized and well received by program participants.

The weight losses that were achieved during the REFIT program were similar to those reported by other studies testing novel weight loss interventions among men. In fact, the average weight loss achieved in REFIT (5.3 kg from multiple imputation analysis, 5.6 kg all available data analysis) was nearly identical to the average weight loss computed as part of a meta-analysis of weight loss programs for men (5.6 kg; Young, et al., 2012). This suggests that the REFIT program was as successful as other remotely delivered weight loss programs (e.g., Morgan, et al., 2012; Morgan, Collins, et al., 2011) or face-to-face delivered weight loss programs (Morgan, Lubans, Callister, et al., 2011; Wyke, et al., 2015). These weight losses are clinically relevant as they average about 5% of initial body weight.

While direct comparisons are not possible, weight losses achieved in men-only weight loss programs may be somewhat lower than average weight losses achieved by men during mixed-gender, traditional weight loss programs (average 6.7 kg; R. L. Williams, et al., 2015), which are typically delivered face-to-face and are of 12-24 months duration. Future research is needed to determine if the programs delivered to men only are not currently as successful as mixed-gender programs or if the larger weight losses in mixed-gender studies are due to differences in the samples attracted to these two types of studies. Specifically, men who are especially motivated to lose weight eschew the perception and norm that weight loss programs are for women and join mixed-gender programs. This additional motivation and willingness to overcome these perceptions may contribute to their additional weight loss. The clearest way to determine if it is the standard programs or the sample of men in these

programs that lead to the greater weight loss will be to compare a male-targeted weight loss program to a standard, mixed-gender weight loss program.

The REFIT program was positively reviewed by participants: 91.5% of participants reported being satisfied with the program they received and 95.7% reported that they would recommend the program to a friend. These positive evaluations appear to indicate that men's preferences for weight control were well incorporated into the intervention. The program fit many of the preferences reported by men in previous literature including delivery primarily at locations convenient for them (via the Internet), options for individualization of the program, no strict diet plan, and options for including male-preferences for foods (Egger & Mowbray, 1993; Sabinsky, et al., 2007; Wolfe & Smith, 2002). However, because this study used a waitlist control, it cannot be determined how the men in this study would have rated a standard weight loss program. Again there is a need to compare the weight loss approach tested in this study to a standard, mixed-gender program.

This program was successfully able to recruit the men needed to conduct this study: the reason for the successful recruitment is not clear. For example, it is unclear if the same recruitment would have occurred if it had been a standard weight loss program. However, as a comparison, a prior study conducted by a doctoral student at the University of North Carolina which recruited participants through similar avenues as used here randomized 25.3% men (Steinberg, et al., 2013). This indicates that in a descriptive comparison, it appears that the men-only program was more successful at recruiting men than a mixedgender weight loss program.

One unexpected finding in this study was that despite men reporting preferences for programs with minimal lifestyle interruption, almost half of the program participants (44.7%)

reported tracking their intake using a mobile application or website at the six-month assessment. This was unexpected because self-monitoring in this manner was not encouraged after the self-evaluation week. Instead participants were encouraged to use a simple selfmonitoring checklist; however, few reported using this form (23.4%). These findings also stand in contrast to past findings that suggest that use of detailed self-monitoring decreases over time during a weight control program (e.g., Burke, et al., 2008). While the reason men reported choosing to spontaneously self-monitor their intake is unknown, a number of potential explanations are offered. As described in Chapter Five, a likely explanation is the difference in mode of self-monitoring. The paper-form provided for the brief monitoring recommended in this study may not have been as appealing to this population, of whom the majority owned and used smartphones (this was not measured explicitly but was observed during group sessions). In a prior study, self-monitoring has been found to be more highly utilized when using an electronic device than when using a paper diary (Burke, Conroy, et al., 2011). Second potential explanation is that numerical calorie-balance information provided by apps was of interest and motivating to this highly educated (over 83% had at least a bachelor's degree) sample of males. By exposing the participants to this mode of selfmonitoring during the self-evaluation period, participants may have found that they enjoyed the data and feedback the apps provided. A third hypothesis is that participants used this form of self-monitoring not because it was required but because it was their choice. As previously mentioned, independence is a key factor in masculinity (Courtenay, 2000). Perhaps by not requiring participants to use detailed self-monitoring—as is done in many behavioral weight control programs-participants were more likely to choose to use detailed self-monitoring because they realized the usefulness during the self-evaluation period. Thus their sense of

autonomy for this behavior was higher than it may have been if they were told to use this type of monitoring by intervention staff. A recent study conducted by Steinberg et al, showed a similar finding: despite promoting daily self-weighing as the primary form of selfmonitoring, rather than detailed calorie intake tracking, there was an increase in detailed selfmonitoring within the treatment group (Steinberg, et al., 2013).

Because autonomy is important when working with men, the REFIT intervention encouraged participant selection of target behaviors and accompanying lessons. This is in contrast to the approach used by most behavioral interventions for weight loss which follows a structured curriculum with selected topics in a preselected order (Wadden & Butryn, 2003). While other studies have tested providing choice of diets to follow (Coles, et al., 2014) and using directive versus nondirective language (Gabriele, et al., 2011), this is the first study that allowed participants to select target behaviors within a structured program.

Participants in REFIT were encouraged to select behaviors that were relevant to their current behaviors and were also encouraged to consider choosing behaviors that they were willing to change. This makes the REFIT program similar to the client-centered approach developed by Lutes and colleagues (Damschroder, et al., 2010; Damschroder, et al., 2014; Lutes, et al., 2012; Lutes, et al., 2008) which also encouraged participants to work on behaviors that are of personal relevance to participants. In contrast to the approach used by Lutes, the lessons participants in REFIT received each week were specific to the behaviors the participant chose to focus on. This allowed for further personalization that was not possible in the group-delivered treatment used in the prior study.

The participants in the REFIT program appear to have used the option to self-select the behaviors to focus on each week. As shown in Table 5.4, the percent of participants who

were allowed and elected to continue with their successful weight loss strategy (after a week of weight loss) ranged between 13.3% and 40.6% during each week of the program. Also shown in Table 5.4, many participants choose to select target behaviors after the week they were initially introduced (these are shown in the off-diagonal values). This suggests that participants were selecting target behaviors and not simply choosing the new behavior introduced each week. This self-selection of target behaviors was hypothesized to increase feelings of autonomy and self-efficacy; however, future analyses are needed to test whether there is support for these hypotheses.

A major shortcoming of this, and many studies of weight control, is the homogenous sample that was recruited. The sample recruited in Aim Two included 23.4% ethnic minority participants, though nearly all participants were highly educated and mostly employed full-time. The proportion of minority men in this study is higher than the percent reported in a review of men's inclusion in weight loss programs where only 1.8% of participants were minority participants (Pagoto, et al., 2011). Inclusion of minority participants has been a challenge for the field of behavioral weight control generally (Kumanyika, 2008) and future studies among men will need to focus improving recruitment efforts in order to test interventions using samples that represent a better cross-section of overweight and obese men.

Aim Three summary and discussion. The REFIT program was developed to target theoretical constructs from self-determination theory and social cognitive theory. In Chapter Six, the roles of these constructs as mediators of the treatment effect were tested alongside hypothesized behavioral mediators. In this analysis changes between baseline and three months in self-efficacy for diet, autonomous motivation for diet, and self-regulation of diet

were all found to be consistent mediators of the treatment effect on weight loss at six-months. Changes in autonomous motivation for exercise between baseline and three months also mediated the treatment effect, but only in a simple mediation model. When included with the diet related constructs, autonomous motivation for exercise was no longer a significant mediator. In the models testing the change in behavioral mediators between baseline and six months, changes in caloric intake and self-weighing frequency were both mediators of the treatment effect. Similar to autonomous motivation for exercise, changes in calories expended in leisure-time physical activity were a significant mediator of the treatment effect only when tested in a simple mediation model. Despite the meditating the relationship between the intervention and weight loss, the theoretical constructs did not mediate the relationship between the intervention and changes in diet and physical activity.

The stronger effects of the diet-related constructs and diet behaviors found in this study are consistent with prior studies using samples of women and mixed-gender participants. Short-term weight loss is generally more closely associated with changes in diet than changes in exercise (Wadden, et al., 1997). Similarly, the constructs related to eating behaviors, such as autonomous motivation for eating a healthy diet and self-efficacy for eating a healthy diet have been more strongly associated with weight loss than similar constructs focused on exercise behaviors (Palmeira, et al., 2007; Teixeira, et al., 2010). This study extends these previous studies by replicating the results using a sample of all men, rather than all women as in the prior studies.

Interestingly, the results of the analyses testing the roles of changes in diet and physical activity in this study are not consistent with prior studies among men. Previous studies have found physical activity to be a mediator of the treatment effect while the dietary-

constructs tested have not been consistent mediators (Lubans, et al., 2012; Lubans, et al., 2009; Young, et al., 2015). In the current study, change in total caloric intake was a significant mediator of the treatment effect and change in physical activity was only a mediator in a simple mediation model. It is possible that the current study indeed did have larger effects on dietary changes than the prior studies with men which explains the significant mediation in this study but not the prior studies. However, this is not likely since weight losses between this and the prior studies were similar. More likely, the measure of diet used in the current study was better able to assess changes in diet that led to the small, but meaningful, weight losses. Here, diet was assessed with repeated 24-hour assisted recalls whereas in the prior studies, validated food frequency measures were used. Though food frequency measures are considered valid, they are not as precise as a 24-hour recalls (Schatzkin et al., 2003). This difference in measurement may explain why the results of studies testing the mediating role of changes in diet on weight loss have been inconsistent. Moving to the other side of the energy balance, the studies mentioned above which have found physical activity to mediate the treatment effect used a more precise measure of activity (pedometers) while the current study used a self-reported recall of activities. Both types of measures are valid, but the pedometers are likely more accurate (Tudor-Locke, Williams, Reis, & Pluto, 2002).

One notable strength of this study is it tested of several theoretical mediators of the treatment effect simultaneously. Although behavioral weight loss programs are developed by targeting many theoretical constructs (Wadden & Butryn, 2003), few studies have evaluated the role of these constructs as mediators of the treatment effect in a multiple mediation framework (e.g., Anderson, et al., 2010; Teixeira, et al., 2010). Instead, the focus is often on

testing the role one mediator in insolation (e.g., Linde, et al., 2006). This limited selection of constructs that have been tested makes it difficult for theory to be advanced and develop future weight loss intervention development (Jeffery, 2004).

While this study used previously validated measures to assess the theoretical constructs of interest, these constructs were assessed a limited number of times. The changes between baseline and three months were selected as the potential mediators of the treatment effects because the goal was to test the effect of the intervention, mostly delivered during this period, on weight loss. By measuring the theoretical constructs at the three-month assessment, there is a chance that these measures were influenced by the weight loss already achieved at this point as well as by the intervention. To better assess how change in the theoretical constructs influence weight loss and weight loss behaviors, it will be important for future studies to assess these constructs more frequently and assess the changes in behavior more proximally to the actual weight loss.

Implications of Findings

Historically, women have been the group that is recruited first and have made up the majority of participants when programs focused on weight control are offered. Due to this overwhelming response among women, one misperception that has arisen is that men do not want or need assistance with weight control. The results from this collection of studies indicate that at least some men are interested in improving their health through controlling their weight, but they may require messages that reach them in a more targeted manner.

In order to reach men and other underrepresented groups, there is a need to improve recruitment messaging. Although effective theory-based interventions are often developed, the reach of these programs remains limited. Improving the reach of interventions and the

efficacy of the interventions will require a better understanding of how messages can be used to recruit participants. The studies in Aim One demonstrated that studies focused on recruitment can, and likely should, be embedded within the recruitment for intervention trials. If randomized comparisons are not feasible, other study designs could be utilized including interrupted time-series or pre-/post-designs.

Self-monitoring of behavior is a core recommendation in behavioral weight control programs. Traditionally, this has focused on using detailed self-monitoring of all foods and drinks consumed, which is onerous. This study, along with others, suggests that this level of monitoring may not be required for modest weight losses. Instead, simplified self-monitoring, such as frequent self-weighing may be valuable (Linde, et al., 2005; Steinberg, et al., 2013; Zheng, et al., 2015) to guide behavior change. In the current study, it was found that changes in self-weighing mediated the relationship between the intervention and weight loss, even when including diet and physical activity change in the model. This suggests that keeping track of behaviors may not need to be as detailed as previously thought. Promoting this simple behavior as part of a self-regulation system may be helpful for aiding individuals in controlling their weight.

Although the approach for weight loss developed in this study netted positive results, further research is needed before this approach begins to be promoted to a broader audience. Of most importance, this program was tested with a sample that was very homogenous with regard to education, socioeconomic background, geographic region, and race. It is not clear if the results observed in this study will replicate in other groups and in settings outside of an academic facility. Despite this major caveat, this research lays the groundwork for future studies.

Recommendations

This study was undertaken to expand the understanding of how to better include men in behavioral weight control programs. Building off this research, there are a number of recommendations for future research:

- Although targeting the recruitment messages modestly increased men's interest in the weight gain prevention program, the response rate remained extremely low. There is a need for more research that investigates what would motivate young men to focus on weight control in a preventative manner and what barriers—perceived and actual—exist that limits their response. Although efforts were made to understand this group prior to recruitment (Bordogna, et al., 2015; Tate, et al., 2014), they were not as responsive as women to the developed messages. Future research should focus on how young men can be motivated to take control of their future health through weight management at a younger age.
- There is a need to expand the application of health communication theory to recruitment messages. As discussed above, targeting alone does not consistently improve recruitment efforts. Although targeting increases the personal relevance of recruitment messages, it does not necessarily make the message more persuasive. Future research should continue to test how modifying the content of recruitment messages can increase the response rates among targeted subgroups through randomized experimental and quasi-experimental designs. Using these designs will help to separate the effects of the messages from other potential confounders.
- More broadly, there is a need for more research focused on effective methods of recruitment for behavioral trials. A review of the literature focused on recruitment

techniques demonstrates that while many papers are published that report recruitment efforts, most are descriptive in nature and rarely are recruitment methods compared to one another. There are a few exceptions (Brown, et al., 2012; Brown, et al., 2015; Gerace, et al., 1995; Kiernan, et al., 2000), but this is clearly an area of research that can be expanded. The techniques used in Aim One demonstrated efficacy for testing the reach of and response to the recruitment messages by using direct mailings to provide an estimate of message recipients and the website visits to estimate the response to the individual messages and response rates were easily calculated. This approach could be used in future attempts to test recruitment messages. By improving recruitment messages, steps will be taken to reach a broader audience. In turn, this greater reach will aid public health science to produce studies with greater generalizability by minimizing the extreme self-selection bias that occurs with volunteer programs.

- The intervention developed for men used in the randomized trial study yielded clinically meaningful weight losses after six months. Building on this approach, there are a number of studies that are needed. First, as mentioned previously, the weight losses achieved in this study may be smaller than those achieved by men in traditional weight loss programs but this finding needs further exploration. A clear need exists to test whether male-targeted approaches to weight loss can achieve similar weight losses as standard approaches within the same sample. Therefore, studies are needed that directly compare these two approaches in a randomized study.
- Weight loss maintenance continues to be a major stumbling block for the field of behavioral weight control (MacLean, et al., 2015). The approach to calorie reduction for weight loss used in this study, which focused on making changes from typical behavior

rather than focusing on staying below a calorie goal, should be tested over a longer period of time. The weight losses achieved by participants in the REFIT program were largely sustained between the three-month assessment and the six-month assessment between which there was little intervention contact. Therefore, participants were maintaining their weight loss with little intervention input. This suggests that the approach tested in this study may be more beneficial for long term weight loss maintenance than the standard approach, though studies are needed to test this hypothesis.

- This study is one of few that have tested multiple theoretical mediators of a behavioral weight loss program simultaneously. There is an ongoing need to test the effects of theories that underlie intervention development as a complete model within behavioral interventions. As described by Jeffery (2004), theories for behavioral interventions need to be tested rigorously and modified based on research results. Studies that test the mediators simultaneously will help to fulfill this need. Through the development of analysis techniques that utilize common software (e.g., Hayes, 2013), intervention researchers will be better equipped to easily test more complex mediation models to better replicate their conceptual model in their analysis procedures.
- There is also a need for testing for consistency of theory effects across populations. Few studies were identified that tested the relationships between theoretical constructs and weight loss across gender using similar measures. In most cases, this is likely due to limited samples of men, but this leaves many questions unanswered. Therefore, is it difficult to assess if theoretical mediators that are important for one group (e.g., women) are equally important for other groups (e.g., men). In this analysis, most of the hypothesized mediators were supported but unclear if the same program would have the

same mediation effects when tested using a sample of women. As a result, there is a need for more research testing for moderators in mediation analyses. Increasing research in this area would enhance efforts to tailor program development.

• Like other areas of health behavior, there is a need for longer studies to test not only behavior change but also behavior change maintenance. There are few theories that have been thoroughly tested to describe the maintenance of changed behavior. The work that has been conducted (e.g., Baldwin et al., 2006; Silva, et al., 2011; Teixeira, et al., 2010) indicates that maintenance of new behaviors have different theoretical basis than behavior change. Therefore, as maintenance studies focused on men's weight loss are developed, it will be important to also develop and assess conceptual models that address this shift from behavior change initiation to behavior maintenance.

Conclusion

Overweight and obese men represent one segment of the US population that has yet to be well represented in studies of behavioral weight control. This study approached this problem by addressing both the messages used to involve men in weight control and the weight control program itself. The results demonstrate that even simple modification of the messages used to recruit participants does appear to increase men's involvement, though modestly. Building upon this research, studies are needed that expand the testing of recruitment messages beyond simple targeting.

This study also laid the groundwork for expanding research focused on incorporating men's preferences for weight control into novel weight control programs. The strategy tested here was successful in producing weight loss and was achieved through many of the hypothesized mediators. Though this program was successful in the sample recruited, future

research is needed to test similar approaches in more diverse male populations over a longer duration in order to fully aid overweigh men in improving their health through weight control.

APPENDIX A: EXAMPLE LESSON

Balance Your Beverages

<u>Highlights</u>

REFIT LESSON

- Beverages can be a major source of unwanted calories for many people.
- Cutting back on drinks that contain calorie can be a good way help you reach your goal of 6 changes to your diet per day.
- <u>Replacing</u>, <u>removing</u>, & <u>reducing</u> are strategies that can minimize your caloric intake from drinks.

Problem:

Liquid calories are often overlooked. The calories in soda, juice, alcohol, and coffee drinks can really add up without contributing any real nutritional benefit. This is problematic when trying to lose weight.

Solution:

Become aware of the beverages that you are drinking and how many calories they contain. You can work towards the REFIT goal of making six changes to your diet each day by targeting calories from drinks. The calories from drinks add to your total intake without filling you up, so this can be a good place to make changes to your diet without feeling hungry.



Did you know? The average can of soda contains 140 to 200 calories.

What do I need to watch for in my drinks?

- **Sugar** is a main source of calories in drinks. Soda is often the focus when talking about sugary drinks but *juices, coffee drinks, and energy drinks* all contain high levels of sugar as well. Did you know juice contains almost the same amount of sugar and calories as soda? That means "healthy" juice drinks aren't going to help you lose weight if you drink them too often!
- Alcohol is another source of calories in drinks. By the gram, alcohol contains more calories than carbohydrates or protein but provides no nutritional value. Add into the equation mixers for liquor and multiple servings, and you can see why alcohol is problematic.
- **Dairy**. Full-fat dairy products contain high levels of fat which increases the amount of calories. In addition, many dairy based beverages are mixed with sugary flavorings, increasing their calories.

BALANCE YOUR BEVERAGES



Replace caloric beverages with lower calorie or nocalorie options

One option for cutting calories from drinks is to switch to a lower calorie alternative. These alternatives include:

-Diet soda	-Un-sweetened tea
-Light beer	-WATER

Estimate the difference between your regular drink and your replacement to estimate the number of 100-calorie changes you are making. Replacing a 20 oz. bottle of regular soda with diet will be 2 changes.

If you add sugar to drinks, you may want to try a sugar-alternative such as Sweet-n-Low or Splenda.

If you haven't tried some of the new diet sodas, give it a shot! Many people find they don't like Diet Coke but enjoy Coke Zero (they have different sweeteners).

Thirst can be mistaken for hunger. Staying hydrated by drinking water throughout the day will help prevent this confusion.

Did you know?

If you don't like the taste of water, try adding slices of fruit or a small splash of juice to enhance the flavor. Sparkling water is also a good alternative to soda because it has the carbonation without the calories.

Remove extra servings to reduce your calories

If you are not ready to switch your beverages completely, another way to reduce your calories is to remove extra of servings of drink you have per day. Aim for drinking only 1-2 drinks per day that contain calories.

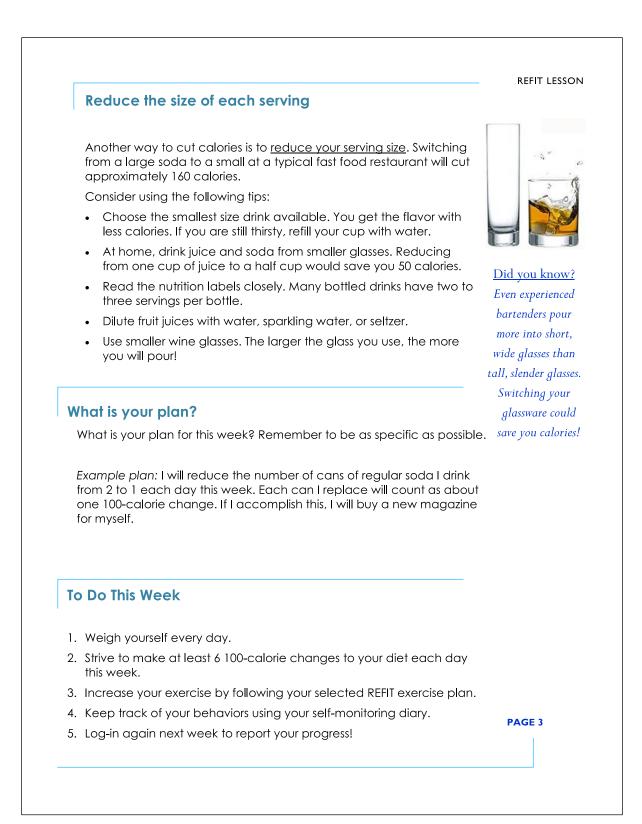


Here's some math to consider: suppose you drink 3 Budweiser beers per day. With145 calories each, you are drinking 435 extra calories. That's more than a McDonald's Quarter Pounder! Cutting back to 1 will save you almost 300 calories per day and could be two of your daily changes this week.

Reducing your servings is especially important with alcohol. As you drink more alcohol, your willpower is reduced and you may end up eating more along with the extra calories from your drinks.

PAGE 2

Cutting back on the number of servings you drink per day can still give you the satisfaction of your favorite beverage without the extra calories.



Day 1:	Day 2:
Number of Beverage Changes:	Number of Beverage Changes:_
Total Number of Changes:	Total Number of Changes:
Weight:	Weight:
Minutes of Exercise!	Minutes of Exercise
Day 3:	Day 4:
Q	
Q	
Q	<u> </u>
Q	<u> </u>
	Q
□	
□	
□	
Number of Beverage Changes:	Number of Beverage Changes:_
Total Number of Changes:	Total Number of Changes:
Weight:	Weight:
Minutes of Exercise!	Minutes of Exercise

APPENDIX B: SELF-MONITORING CHECKLIST FORM

Day 5:	Day 6:
	D
<u> </u>	
□	
□	
0	D
Number of Beverage Changes:	Number of Beverage Changes
Total Number of Changes:	Total Number of Changes:
Weight:	Weight:
Minutes of Exercise	Minutes of Exercise
Day 7:	
, ,	
	WEEKLY SUMMARY
	Total Beverage Changes:
	Total Number of Changes:
L	Total Minutes of Exercise:
□	Tatal Davis Woighod
	Total Days Weighed:
Number of Beverage Changes:	
Total Number of Changes:	
Weight:	
Minutes of Exercise	



Have you poured on some pounds?

Sign up for REFIT, a no-fee research study testing a new weight loss program designed specifically to help <u>men</u> improve their eating and exercise to lose weight. The 12-week program has been designed to meet men's unique needs and will be delivered through a combination of online and in-person contacts to fit your busy schedule. More information is online at

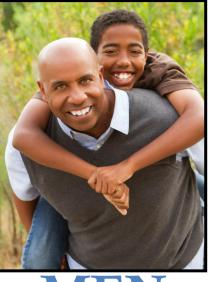
www.refitstudy.org.

Call us! (919) 966-5852



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MEN: REFIT IS THE RIGHT FIT!

Sign up for REFIT, a no-fee research study testing a new weight loss program designed specifically help <u>men</u> improve their eating and exercise to lose weight. The 12week program has been designed to meet men's unique needs and will be delivered through a combination of online and in-person sessions to fit your busy schedule. **More information is online at www.refitstudy.org or call us 919-966-5852.** WANT TO IMPROVE YOUR HEALTH?

WANT TO FEEL BETTER?

WANT TO LOOK BETTER?

THE WEIGHT IS OVER!

GO TO www.refitstudy.org to find out more



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www.refitstudy.org															

APPENDIX D: EXAMPLE FEEDBACK AND ONLINE CHECK-IN

Hi John, Thanks for logging on again this week to complete your check-in. Be sure to have your self-monitoring records with you as you complete the check-in. Let's get started!
Survey Powered By Qualtrics
How much did you weigh this morning? Between last Monday and today, how many days did you weigh yourself?
Survey Powered By Qualifics BACK NEXT

How many minutes of aerob	ic exercise did you do each day this past week?	
Monday		0 minutes
Tuesday		0 minutes
Wednesday		0 minutes
Thursday		0 minutes
Friday		0 minutes
Saturday		0 minutes
Sunday		0 minutes
Total		0 minutes
Survey Powered By Qualtrics		BACK NEXT
_		
Last week, you focused on	the REFIT lesson: "Preventin Portion Distortion". How	many changes were you able
to make to your diet each da	ay this past week? Monday Tuesday Wednesday Thursday Friday Sa	turday Sunday Total
How many	Nonday Tuesday Wednesday Hursday Thuay Sa	
changes did you make to your diet focused on		0 0
"Preventin Portion Distortion"?		
How many other changes did you		
make to your diet?		0 0
Survey Powered By Qualtrics		BACK NEXT



Survey Powered By Qualtrics



Survey Powered By Qualtrics

NEXT

Fantastic job losing weight this week! You are making enough changes to your diet and exercise to lose weight
but you reported fewer than six changes per day. Given your weight loss, it is likely that you made changes but you may not have reported them as the total number of 100-calorie changes per week.
There is a new lesson available this week: "Manage Meats". This lesson will focus on helping you manage your
calorie intake from meats by reducing portions and making lower fat choices. A second section will include tips
for buying meats and a recipe for an easy vegetarian dinner. This would be a good lesson for you to choose if you eat least one serving of high-fat meat during each meal or if cutting back on meat is a change you want to
make.
Do you want to stick with "Preventin Portion Distortion" or do you want to add a new lesson?
Stick with "Preventin Portion Distortion"
Add "Cutting the Fat"
Add "Balance your Beverages"
Add "Preventing Snack Attack"
Add "Manage Meats"
Survey Powered By Qualifics NEXT
What is your plan for this week?
What is your plan for this week? Research has demonstrated that people with clear and specific plans are more likely to make behavior changes and meet their goals than people who don't have clear plans.
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Exercise Feedback

Met goal: Excellent work meeting your exercise goal this week! Consistently meeting your exercise goal will help you build, or reinforce, the habit of regular exercise. How can you remind yourself to be more active? Add some cues to your environment! Cues are signals in our environment to do something. Cues to be active could be a reminder in your calendar of your planned exercise time or it could be seeing your walking shoes by the front door so you are reminded to be active as soon as you get home from work. What can you do this week to cue yourself to be active?

Did not meet goal: You found time to be active this week: good job. Although you didn't meet the REFIT exercise goal, getting in some exercise, even if it isn't the full amount, is progress in the right direction! As the exercise goal increases this week for all of the exercise plans, think about how you can remind yourself to be more active. How can you remind yourself to be more active? Add some cues to your environment! Cues are signals in our environment to do something. Cues to be active could be a reminder in your calendar of your planned exercise time or it could be seeing your walking shoes by the front door so you are reminded to be active as soon as you get home from work. What can you do this week to cue yourself to be active?

No exercise: When it comes to exercising, the hardest step is the first step out the door. If you are finding yourself struggling to find the time to exercise, look for 10-minute blocks of time that you can squeeze in a brisk walk before or after work, after dinner, or any other time during the day. Getting some exercise, even if you don't meet the REFIT weekly goal, is a step closer to your goal. Strive this week to get at least some exercise: commit to getting just 5 minutes each day. Use cues in your environment to help you take that first step out the door. How can you remind yourself to be more active? Add some cues to your environment! Cues are signals in our environment to do something. Cues to be active could be a reminder in your calendar of your planned exercise time or it could be seeing your walking shoes by the front door so you are reminded to be active as soon as you get home from work. What can you do this week to cue yourself to be active?

Self-Weighing Feedback:

Met Goal: It's great to see that you are weighing yourself most days. Keep it up! This week, pay attention to how your weight fluctuates and how you're eating and exercise habits impact whether your weight goes up or down. Take a minute each day to identify what changes you made to your eating and exercise habits over the past week as a result of weighing daily.

Did not meet goal: It can be difficult to start weighing yourself, especially if you prefer to avoid weighing and don't like to see your weight on the scale. Research does show that people who weigh often lose more weight compared to those that avoid weighing. The scale is an important tool that can help guide your eating and exercise choices: it lets you know when the changes you have made are working or not! Be sure to leave your scale in a prominent place--this would be your "cue" to weigh yourself.

Diet and Weight Loss Feedback

Met weight loss goal/Met diet goal: Fantastic job losing weight and meeting your diet goal! Continue making at least six 100-calorie changes per day to help keep this momentum up over the upcoming week. There is a new lesson available this week: "Manage Meats." This lesson will focus on helping you manage your calorie intake from meats by reducing portions and making lower fat choices. A second section will include tips for buying meats and a recipe for an easy vegetarian dinner. This would be a good lesson for you to choose if you eat least one serving of high-fat meat during each meal or if cutting back on meat is a change you want to make. Do you want to stick with [prior lesson] or do you want to add a new lesson?

Met weight loss goal/Did not meet diet goal: Fantastic job losing weight this week! You are making enough changes to your diet and exercise to lose weight but you reported fewer than six changes per day. Given your weight loss, it is likely that you made changes but you may not have reported them as the total number of 100-calorie changes per week. There is a new lesson available this week: "Manage Meats." This lesson will focus on helping you manage your calorie intake from meats by reducing portions and making lower fat choices. A second section will include tips for buying meats and a recipe for an easy vegetarian dinner. This would be a good lesson for you to choose if you eat least one serving of high-fat meat during each meal or if cutting back on meat is a change you want to make. Do you want to stick with [prior lesson] or do you want to add a new lesson?

Did not meet weight loss goal/Did not meet diet goal: Thanks for reporting your progress this week. Working towards weight loss is challenging but it's important to stick with it. This program will help you find the strategies that work for you. This past week, you didn't meet the goal to make six 100-calorie changes to your diet. This may be because you haven't yet identified enough areas where you can make changes or you faced barriers to making changes. If you are having trouble finding areas of your diet that you can change, go back to your self-monitoring records from week 1 and think back to the discussion from the second group session. Do you remember any areas that you wanted to change? Your REFIT lessons are designed to give you ideas of places you can make changes to your day. Make an honest effort to set specific goals and follow through on them in the coming week. Keep working towards weight loss by adding a new lesson. There is a new lesson available this week: "Manage Meats." This lesson will focus on helping you manage your calorie intake from meats by reducing portions and making lower fat choices. A second section will include tips for buying meats and a recipe for an easy vegetarian dinner. This would be a good lesson for you to choose if you eat least one serving of high-fat meat during each meal or if cutting back on meat is a change you want to make. Which lesson do you want to add this week?

Did not meet weight loss goal/Did meet diet goal: Great job working to make the six changes per day to your diet. Making changes to long-standing habits isn't easy but you are making progress. If you aren't seeing the scale move for more than a couple of days, consider either adding two to three more changes to your day or change the type of change you are making. If you have been focused on cutting portions, consider focusing more on replacing (or vice versa, depending on your situation). Keep up the hard work. If you are consistent in your six

100-calorie changes each day, the scale will eventually move! There is a new lesson available this week: "Manage Meats." This lesson will focus on helping you manage your calorie intake from meats by reducing portions and making lower fat choices. A second section will include tips for buying meats and a recipe for an easy vegetarian dinner. This would be a good lesson for you to choose if you eat least one serving of high-fat meat during each meal or if cutting back on meat is a change you want to make. Which lesson do you want to add this week?

APPENDIX E: TEXT FROM BASELINE ELECTRONIC QUESTIONNAIRES

Welcome to the REFIT Questionnaire. This survey will take you approximately 60 minutes to complete. You DO NOT need to complete this survey all at one time. Your answers are saved each time you move to a new page. You can always return to where you left off by clicking on the link in the email sent to you. If you have any questions or encounter any problems, please email refitstudy@unc.edu.

DEMOGRAPHICS

- Q1.2 What is the highest grade in school you finished?
- **O** Finished some high school (1)
- **O** High school graduate or G.E.D. (2)
- Technical school or vocational training (after high school) (3)
- Some college (less than 4 years) or associate degree (4)
- College graduate or baccalaureate degree (5)
- **O** Masters or doctoral degree (6)

Q1.3 Are you currently: (Please check all that apply)

- □ Working full-time (1)
- □ Working part-time (2)
- □ A full-time student (3)
- □ A part-time student (4)
- $\Box \quad \text{Retired (5)}$
- □ Not working (6)
- □ Looking for work (7)

Q1.4 What is the total income of your household? Include all sources of income like your (and your partner's) wages or salary, child support, and government assistance.

- **O** Less than \$10,000 (1)
- \$10,000 or more, but less than \$20,000 (2)
- \$20,000 or more, but less than \$30,000 (3)
- **O** \$30,000 or more, but less than \$40,000 (4)
- **O** \$40,000 or more, but less than \$50,000 (5)
- **O** \$50,000 or more, but less than \$75,000 (6)
- **O** 75,000 or more, but less than \$100,000 (7)
- **O** \$100,000 or more (8)
- **O** Prefer not to answer (9)

Q1.5 Do you think of yourself as heterosexual or straight; homosexual or gay; bisexual; something else; or you are not sure?

- **O** Heterosexual or straight (1)
- **O** Homosexual or gay (2)
- **O** Bisexual (3)
- **O** Something else (4)
- **O** Not sure (5)

Q1.6 What is your current relationship status?

- O Married (1)
- O Separated (2)
- O Divorced (3)
- O Widowered (4)
- O Single (5)
- **O** Living with partner (6)

Q1.7 Do you currently live with a romantic partner or spouse?

- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To Do you live with any friends or room...

- Q1.8 Is your romantic partner or spouse:
- **O** Underweight (1)
- Normal Weight (2)
- O Overweight (3)
- **O** Obese (4)

Q1.9 Do you live with any friends or roommates?

- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To Do you currently live with children?

Q1.10 How many friends or roommates do you live with?

- **O** 0(5)
- **O** 1(1)
- **O** 2 (2)
- **O** 3 (3)
- **O** 4+ (4)

	Underweight (1)	Normal Weight (2)	Overweight (3)	Obese (4)
Friend/Roommate #1 (1)	0	0	0	О
Friend/Roommate #2 (2)	О	О	О	О
Friend/Roommate #3 (3)	0	0	0	О
Friend/Roommate #4 (4)	0	0	0	Ο

Answer If How many friends or roommates do you live with? 4+ Is Selected O1 14 Please indicate their weight status below

- Q1.15 Do you currently live with children?
- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To Do you live with any other family mem...

Q1.16 Please indicate the age and weight status of the children you live with below.

	Underweight (1)	Normal Weight (2)	Overweight (3)	Obese (4)
Child #1 (Enter age in years) (1)	0	0	0	О
Child #2 (Enter age in years) (2)	0	0	0	O
Child #3 (Enter age in years) (3)	0	0	О	O
Child #4 (Enter age in years) (4)	0	0	0	O

Q1.17 Do you live with any other family members?

- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To End of Block

	Underweight (1)	Normal Weight (2)	Overweight (3)	Obese (4)
(1)	О	Ο	О	Ο
(2)	0	Ο	Ο	Ο
(3)	O	Ο	Ο	Ο

Q1.18 Please indicate your relationship to other family members you live with and their weight status.

Q2.1 Do you currently use chewing tobacco, snuff, snus, pipes, cigars, or any other tobacco product other than cigarettes?

- **O** Yes (1)
- **O** No (2)

Q2.2 Do you currently smoke cigarettes every day, some days, or not at all?

- O Every day (1)
- O Some days (2)
- **O** Not at all (3)

If Not at all Is Selected, Then Skip To During the past 12 months, have you s...

Q2.3 On average, how many cigarettes do you smoke each day?

- I did not smoke cigarettes during the past 30 days (1)
- **O** 1 cigarette or less per day (2)
- \bigcirc 2 to 5 cigarettes per day (3)
- **O** 6 to 10 cigarettes per day (4)
- 11 to 20 cigarettes per day (5)
- More than 20 cigarettes per day (6)

If I did not smoke cigarettes ... Is Displayed, Then Skip To Do you think you will gain weight if ...

Q2.4 Have you smoked cigarettes in the past, but no longer smoke?

- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To Q3.1

Q2.5 How long has it been since you last smoked cigarettes regularly?

- **O** Within the past month (less than 1 month ago) (1)
- Within the past 3 months (1 month but less than 3 months ago) (2)
- Within the past 6 months (3 months but less than 6 months ago) (3)
- **O** Within the past year (6 months but less than 1 year ago) (4)
- Within the past 5 years (1 year but less than 5 years ago) (5)
- Within the past 10 years (5 years but less than 10 years ago) (6)
- **O** 10 years or more (7)

Q2.6 Did you gain any weight when you quit smoking?

• Yes. If so, how much weight did you gain, in pounds? (1)

O No (2)

Answer If Do you now smoke cigarettes every day, some days, or not ... Not at all Is Not Selected

Q2.7 Do you think you will gain weight if you quit smoking?

- **O** Yes (1)
- **O** No (2)

WEIGHT HISTORY

Q3.1 What is your current weight? (in pounds)

Q3.2 What do you consider to be your ideal weight? (in pounds)

Q3.3 How much weight do you expect you will lose during the 6 month REFIT program? (in pounds)

Q3.4 On a scale of 1-10, how confident are you that you will lose this amount of weight? (with 1 being "Not at all Confident" and 10 being "Very Confident")

- 1- Not at all confident (1)
- **O** 2 (2)
- **O** 3 (3)
- **O** 4 (4)
- **O** 5 (5)
- **O** 6(6)
- **O** 7 (7)
- **O** 8 (8)
- **O** 9 (9)
- **O** 10- Very Confident (10)

Q3.5 What is the highest weight you have ever been as an adult? (in pounds)

Q3.6 How old were you then? (in years)

Q3.7 What is the lowest weight you have ever been as an adult? (in pounds)

Q3.8 How old were you then? (in years)

Q3.9 Currently, how often do you weigh yourself? (Select the answer that best applies.)

- O Several times/day (1)
- One time/day (2)
- O Several times/week (3)
- One time per week (4)
- **O** Less than one time/week (5)
- **O** Less than one time per month (6)
- **O** I never weigh myself (7)

Q3.10 Have you ever tried to lose weight in the past (i.e., purposefully or intentionally lost weight)?

- **O** Yes (1)
- **O** No (2)

If No Is Selected, Then Skip To What have you done to try and lose we...

Q3.11 Choose the number of times in your life you have intentionally lost the number of pounds shown below. NOTE: Please respond for each intentional weight loss episode based on the total amount lost during that episode, and only pick one category for each episode (e.g., If you lost 25 pounds over the course of 6 months, you would only count that in the 20-29 pounds category, not also in the 5-9 and 10-19 pounds categories).

	Never (1)	1-2 (2)	3-4 (3)	5-6 (4)	More than 7 (5)
a. How often have you lost 0-5 pounds? (1)	О	0	О	0	o
b. How often have you lost 5-9 pounds? (2)	О	0	0	0	O
c. How often have you lost 10-19 pounds? (3)	0	Ο	О	Ο	o
d. How often have you lost 20-29 pounds? (4)	О	О	О	О	O
e. How often have you lost 30-39 pounds? (5)	О	О	О	О	O
f. How often have you lost 40-49 pounds? (6)	О	Ο	О	ο	O
g. 50 or more pounds? (7)	Ο	Ο	О	Ο	0

- Q3.12 What have you done to try and lose weight? (check all that apply)
- Commercial program (e.g., Weight Watchers / Jenny Craig / NutriSystem) (1)
- Support Group (e.g., Overeaters Anonymous / TOPS) (2)
- □ Individual counseling with a nutritionist, physician, or psychologist (3)
- □ Structured exercise program (e.g., classes or trainer) (4)
- □ Weight loss surgery. If yes, enter type: (ex: liposuction, gastric bypass, gastric banding, etc.) (5) _____
- □ Medication (e.g., prescription or over-the-counter) (6)
- □ Followed a diet from a book (e.g., Atkins, Zone) (7)
- Used my own approach without following any published diet (e.g., decreased calories)
 (8)
- Tried to lose weight with a friend or family member (9)
- \Box Used an Internet weight loss site (10)

Q3.13 Which of the following do you believe best describes your mother while you were growing up?

- **O** Underweight (1)
- O Normal Weight (2)
- O Overweight (3)
- O Obese (4)
- O Don't Know (5)

Q3.14 Which of the following do you believe best describes your father while you were growing up?

- **O** Underweight (1)
- Normal Weight (2)
- **O** Overweight (3)
- O Obese (4)
- O Don't Know (5)

Q3.15 Which of the following do you believe best describes your three closest male friends?

	Underweight (1)	Normal Weight (2)	Overweight (3)	Obese (4)
Friend #1 (1)	Ο	Ο	Ο	Ο
Friend #2 (2)	Ο	Ο	Ο	Ο
Friend #3 (3)	Ο	Ο	Ο	Ο

	Not At All Important (1)	Somewhat Unimportant (2)	Neither Important nor Unimportant (3)	Somewhat Important (4)	Extremely Important (5)
Health concerns (1)	О	О	0	О	О
Improving your appearance (2)	О	0	0	О	О
Social pressure (3)	Ο	О	0	Ο	О
Wanting to feel better about yourself (4)	0	0	0	0	О
An event such as wedding, reunion, or birthday (5)	0	0	O	0	0
Improved energy (6)	О	О	0	О	О
Improved social life (7)	О	0	0	О	О
Improved work performance (8)	Ο	0	0	О	О
Feeling physically uncomfortable (9)	0	0	0	0	О

Q3.16 Listed below are reasons why people try to lose weight. Please rate how important each of these reasons is for you at this time.

TREATMENT SELF-REGULATION QUESTIONNAIRE:WEIGHT LOSS PROGRAM

Q4.1 There are a variety of reasons why a person may decide to enter a weight-loss program such as this and follow its procedures. Please read the statement at the beginning of each group and then consider the reasons that follow it in terms of how true that reason is for you.

	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
I won't like myself very much until I lose weight. (1)	О	0	0	0	0	0	О
People will like me better when I'm thin. (2)	О	o	ο	О	o	ο	0
It feels important to me personally to be thinner. (3)	О	Ο	О	0	О	О	o
I really want to make some changes in my life. (4)	Ο	Ο	О	0	ο	О	О

Q4.2 I decided to enter this weight-loss program because:

Q4.3 If I remain in treatment it will probably be because:

	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
I'll feel like a failure if I don't. (1)	О	ο	ο	0	ο	ο	Ο
People will think I'm a weak person if I don't. (2)	О	o	o	О	o	o	O
I'll feel very bad about myself if I don't. (3)	О	o	o	О	o	o	O
Others will be angry at me if I don't. (4)	0	o	o	0	o	o	О
I feel like it's the best way to help myself. (5)	Ο	ο	ο	0	ο	ο	Ο

Q4.4 I plan to lose weight because:

	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
I'll be ashamed of myself if I don't. (1)	0	o	o	0	o	o	О
I'll hate myself if I can't get my weight under control. (2)	О	o	o	0	o	o	o
My friends/family don't like the way I look. (3)	О	o	o	0	o	o	o
Being overweight makes it hard to do many things. (4)	О	Ο	Ο	0	Ο	Ο	О

Q4.5 I have agreed to follow the procedures of the program because:

	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
I am worried that I will get in trouble with the staff if I don't follow all the guidelines. (1)	0	0	0	О	0	О	0
I'll feel guilty if I don't comply with all the procedures. (2)	0	O	o	О	О	О	0
I want others to see that I am really trying to lose weight. (3)	0	0	ο	0	О	О	О
I believe they will help me solve my problem. (4)	0	0	ο	0	О	О	О
It's important to me that my efforts succeed. (5)	0	o	o	•	Ο	Ο	О

WEIGHT LOSS STRATEGIES

Q5.1 Over the past 3 months, how often have you used the following strategies to try to manage your weight?

	Never or hardly ever (1)	Some of the time (2)	About half the time (3)	Much of the time (4)	Always or almost always (5)
Reduced your calorie intake by 500-1000 per day (1)	О	0	О	O	О
Cut out/reduced sweets or junk food (2)	О	О	О	0	O
Cut out/reduced between meal snacks (3)	О	O	О	0	O
Cut out/reduced late night snacking (4)	О	O	О	0	O
Ate less meat (5)	Ο	Ο	Ο	0	О
Ate less carbohydrates (6)	Ο	Ο	О	0	0
Ate less fat (7)	Ο	Ο	О	0	0
Reduced portion sizes (8)	Ο	Ο	О	0	0
Decreased the number of times that you ate out at fast food restaurants (9)	О	О	0	0	о
Decreased the number of times that you ate out at other restaurants (10)	0	0	0	0	•

Q5.2 Over the past 3 months, how often have you used the following strategies to try to manage your weight?

	Never or hardly ever (1)	Some of the time (2)	About half the time (3)	Much of the time (4)	Always or almost always (5)
Changed food preparation techniques (1)	О	О	0	Ο	O
Drank less alcohol or changed type of alcoholic drink to reduce calories (2)	0	О	О	0	О
Decreased how much or how often you drank sweetened beverages (e.g., soda, sweet tea) (3)	O	О	0	0	О
Decreased how much or how often you drank other sweetened beverages (e.g.,	0	О	0	ο	О

sweetened fruit juice) (4)					
Decreased how much or how often you drank high calorie coffee drinks (e.g., caramel macchiato) (5)	0	0	0	0	0
Increased fruits and vegetables (6)	0	О	О	О	O
Increased water consumption (7)	0	О	0	О	O
Used frozen entrees such as Lean Cuisine or Smart Ones (8)	0	0	0	О	O
Increased your daily steps (9)	Ο	Ο	Ο	О	О
Left a few bites of food on your plate (10)	О	0	О	О	О

	Never or hardly ever (1)	Some of the time (2)	About half the time (3)	Much of the time (4)	Always or almost always (5)
Followed a structured meal plan that limited your choices for breakfast, lunch, and dinner (1)	O	0	0	0	О
Used meal replacement bars such as Power Bars or Zone Bars (2)	0	0	О	0	o
Decreased frequency or portion sizes of desserts (3)	ο	0	О	0	Ο
Skipped meals (4)	0	0	0	0	Ο
Make one or two small changes to your activity every day (5)	0	О	О	О	o
Used the stairs instead of the elevator (6)	О	О	О	0	Ο
Wore a pedometer (7)	0	0	О	0	Ο
Reduced the amount of time spent watching TV (8)	О	О	О	О	O
Used home exercise equipment (9)	О	Ο	О	Ο	O
Exercised at a gym or participated in an exercise class (10)	0	0	0	0	О

manage your weight:	Never or hardly ever (1)	Some of the time (2)	About half the time (3)	Much of the time (4)	Always or almost always (5)
Worked out with a personal trainer (1)	О	О	0	О	О
Exercise for periods of 30 minutes or more (2)	О	О	О	О	O
Recorded or wrote down the type and quantity of food eaten (3)	0	О	0	О	О
Recorded or graphed your physical activity (4)	О	О	О	О	Ο
Recorded or graphed your weight (5)	О	О	0	О	O
Weighed yourself daily (6)	Ο	Ο	Ο	О	Ο
Shopped from a list (7)	О	Ο	Ο	О	Ο
Kept healthy ready-to-eat or portion controlled snacks for yourself (8)	О	О	О	О	О
Removed high calorie foods from your home, office, or room (9)	О	О	О	О	О
Avoided eating while watching TV (10)	О	О	О	О	Ο
Attended or participated in a structured weight loss group or program (e.g., Weight Watchers, Jenny Craig) (11)	0	0	0	0	O
Followed a specific weight loss diet (e.g., Atkins) (12)	О	О	О	О	Ο
Used an Internet diet, exercise, or weight loss program (13)	О	О	О	О	Ο
Made one or two small changes to your diet every day (14)	О	О	О	О	Ο
Used liquid meal replacements, such as Slim Fast (15)	О	О	0	О	О

Q5.4 Over the past 3 months, how often have you used the following strategies to try to manage your weight?

TREATMENT SELF-REGULATION QUESTIONNAIRE: DIET

Q6.1 The following question relates to the reasons why you would either start eating a healthier diet or continue to do so. Different people have different reasons for doing that, and we want to know how true each of the following reasons is for you. All 15 responses are to the same question. Please indicate the extent to which each reason is true for you, using the following 7-point scale:

Q0.2 The reason I would car a heart	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
Because I feel that I want to take responsibility for my own health. (1)	0	o	o	0	o	o	O
Because I would feel guilty or ashamed of myself if I did not eat a healthy diet. (2)	О	o	o	0	o	o	О
Because I personally believe it is the best thing for my health. (3)	О	0	o	О	0	0	О
Because other would be upset with me if I did not. (4)	О	o	o	О	ο	0	0
I really don't think about it. (5)	Ο	0	0	Ο	0	0	0
Because I have carefully thought about it and believe it is very important for many aspects of my life. (6)	О	•	0	О	•	o	О
Because I would feel bad about myself if I did not eat a healthy diet. (7)	0	o	o	О	o	o	O
Because it is an important choice I really want to make. (8)	O	o	o	О	o	o	0
Because I feel pressure from others to do so. (9)	O	o	o	О	o	o	0
Because it is easier to do what I'm told than think about it. (10)	O	o	o	О	o	o	0
Because it is consistent with my life goals. (11)	O	o	o	О	o	o	0
Because I want others to approve of me. (12)	O	o	o	О	o	o	0
Because it is very important for being as healthy as possible. (13)	0	0	0	О	0	0	0
Because I want others to see I can do it. (14)	О	0	o	0	0	0	О

Q6.2 The reason I would eat a healthy diet is:

I don't really know why. (15)	О	0	0	О	0	0	Ο
				l			<u> </u>

CENTER FOR EPIDEMIOLOGIC STUDIES DEPRESSION SCALE

Q7.1 Below is a list of the ways you might have felt or behaved. Please tell indicate how
often you have felt this way during the past week

onen you have leit uns wa	ty during the pus			
	Rarely or none of the time (less than 1 day) (1)	Some or a little of the time (1-2 days) (2)	Occasionally or a moderate amount of time (3-4 days) (3)	Most or all of the time (5-7 days) (4)
I was bothered by things that usually don't bother me. (1)	0	0	O	О
I did not feel like eating; my appetite was poor. (2)	0	O	Ο	o
I felt that I could not shake off the blues even with help from my family or friends. (3)	O	O	O	0
I felt I was just as good as other people. (4)	О	0	Ο	О
I had trouble keeping my mind on what I was doing. (5)	О	О	Ο	О
I felt depressed. (6)	0	Ο	О	Ο
I felt that everything I did was an effort. (7)	О	0	0	О
I felt hopeful about the future. (8)	О	0	0	О
I thought my life had been a failure. (9)	О	О	O	О
I felt fearful. (10)	0	0	0	0

	Rarely or none of the time (less than 1 day) (1)	Some or a little of the time (1-2 days) (2)	Occasionally or a moderate amount of time (3-4 days) (3)	Most or all of the time (5-7 days) (4)
My sleep was restless. (1)	Ο	0	Ο	О
I was happy. (2)	Ο	Ο	О	0
I talked less than usual. (3)	0	О	О	О
I felt lonely. (4)	Ο	Ο	Ο	Ο
People were unfriendly. (5)	О	0	О	О
I enjoyed life. (6)	0	0	0	O
I had crying spells. (7)	0	О	О	О
I felt sad. (8)	Ο	Ο	О	0
I felt that people dislike me. (9)	0	0	0	C
I could not get "going." (10)	0	0	0	С

Q7.2 Below is a list of the ways you might have felt or behaved. Please tell indicate how often you have felt this way during the past week.

TREATMENT SELF REGULATION QUESTIONNAIRE: EXERCISE

Q8.1 The following question relates to the reasons why you would either start to exercise regularly or continue to do so. Different people have different reasons for doing that, and we want to know how true each of the following reasons is for you. All 15 response are to the one question. Please indicate the extent to which each reason is true for you:

Q0.2 The reason I would excreme te	1: Not at all true (1)	2 (2)	3 (3)	4: Somewhat true (4)	5 (5)	6 (6)	7: Very true (7)
Because I feel that I want to take responsibility for my own health. (1)	o	o	o	O	o	o	o
Because I would feel guilty or ashamed of myself if I did not exercise regularly. (2)	•	0	О	0	o	o	O
Because I personally believe it is the best thing for my health. (3)	0	0	o	О	0	0	0
Because other would be upset with me if I did not. (4)	O	0	Ο	О	0	0	0
I really don't think about it. (5)	Ο	0	0	О	0	0	0
Because I have carefully thought about it and believe it is very important for many aspects of my life. (6)	О	0	0	O	•	o	О
Because I would feel bad about myself if I did not exercise regularly. (7)	o	o	O	O	o	o	O
Because it is an important choice I really want to make. (8)	0	0	ο	О	0	0	О
Because I feel pressure from others to do so. (9)	0	0	ο	О	0	o	О
Because it is easier to do what I'm told than think about it. (10)	O	0	ο	О	o	o	0
Because it is consistent with my life goals. (11)	0	0	ο	О	0	o	О
Because I want others to approve of me. (12)	0	o	ο	О	o	o	0
Because it is very important for being as healthy as possible. (13)	Ο	0	Ο	О	0	0	0
Because I want others to see I can do it. (14)	О	o	o	0	o	o	О

Q8.2 The reason I would exercise regularly is:

I don't really know why. (15)	Ο	0	Ο	Ο	0	0	Ο
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CONFORMITY TO MASCLINE NORMS INDEX-46

Q9.1 The following pages contain a series of statements about how men might think, feel, or behave. The statements are designed to measures attitudes, beliefs, and behaviors associated with both traditional and non-traditional masculine gender roles. Thinking about your own actions, feelings and beliefs, please indicate how much you personally agree or disagree with each statement by selecting "Strongly Disagree", "Disagree", "Agree," or "Strongly agree" to the left of the statement. There are no right or wrong responses to the statements. You should give the responses that most accurately describe your personal actions, feelings and beliefs. It is best if you respond with your first impression when answering.

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)
In general, I will do anything to win (1)	0	Ο	0	O
If I could, I would frequently change sexual partners (2)	0	О	О	O
I hate asking for help (3)	0	Ο	Ο	0
I believe that violence is never justified (4)	0	О	0	O
Being thought of as gay is not a bad thing. (5)	0	О	0	O
In general, I do not like risky situations (6)	0	О	0	O
Winning is not my first priority (7)	Ο	О	Ο	0
I enjoy taking risks (8)	Ο	Ο	Ο	0
I am disgusted by any kind of violence (9)	0	О	0	O
I ask for help when I need it (10)	Ο	Ο	0	0
My work is the most important part of my life (11)	0	О	0	O
I would only have sex if I was in a committed relationship (12)	0	О	O	O
I bring up my feelings when talking to others (13)	O	О	0	O
I would be furious if someone thought I was gay (14)	0	О	0	0
I don't mind losing (15)	О	0	0	0

Q9.2				
	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)
I take risks (1)	Ο	Ο	Ο	Ο
It would not bother me at all if someone thought I was gay (2)	0	О	0	O
I never share my feelings (3)	Ο	Ο	Ο	0
Sometimes violent action is necessary (4)	О	О	O	O
In general, I control the women in my life (5)	О	О	O	O
I would feel good if I had many sexual partners (6)	О	О	O	O
It is important for me to win (7)	0	Ο	Ο	Ο
I don't like giving all my attention to work (8)	О	О	O	O
It would be awful if people thought I was gay (9)	О	О	O	O
I like to talk about my feelings (10)	Ο	О	Ο	0
I never ask for help (11)	Ο	О	Ο	0
More often than not, losing does not bother me (12)	0	О	O	O
I frequently put myself in risky situations (13)	О	О	0	O
Women should be subservient to men (14)	О	О	0	O
I am willing to get into a physical fight if necessary (15)	0	О	0	O

Q9.3

	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)
I feel good when work is my first priority (1)	0	О	0	О
I tend to keep my feelings to myself (2)	О	О	0	O
Winning is not important to me (3)	Ο	Ο	Ο	Ο
Violence is almost never justified (4)	Ο	Ο	Ο	Ο
I am happiest when I'm risking danger (5)	0	О	ο	О

It would be enjoyable to date more than one person at a time (6)	О	О	O	O
I would feel uncomfortable if someone thought I was gay (7)	О	О	O	O
I am not ashamed to ask for help (8)	Ο	О	Ο	0
Work comes first (9)	Ο	Ο	Ο	0
I tend to share my feelings (10)	Ο	Ο	Ο	0
No matter what the situation I would never act violently (11)	О	О	0	O
Things tend to be better when men are in charge (12)	0	О	O	O
It bothers me when I have to ask for help (13)	0	О	0	O
I love it when men are in charge of women (14)	0	О	О	O
I hate it when people ask me to talk about my feelings (15)	0	Ο	0	O
I try to avoid being perceived as gay (16)	0	О	0	O

EATING BEHAVIOR INVENTORY

Q10.1 Directions: Select the option that best describes your behavior during the last three months.

	Never or hardly ever (1)	Some of the time (2)	About half of the time (3)	Much of the time (4)	Always or almost always (5)
I carefully watch the quantity of food that I eat. (1)	0	0	0	0	О
I eat foods that I believe will aid me in losing weight. (2)	0	О	0	О	О
I keep 1 or 2 raw vegetables available for snacks. (3)	0	О	0	О	О
I record the type and quantity of food which I eat. (4)	O	О	О	О	О
I weigh myself daily. (5)	О	О	О	О	Ο
I refuse food offered to	Ο	Ο	Ο	Ο	Ο

me by others. (6)					
I eat quickly compared to most other people. (7)	О	О	Ο	О	0
I consciously try to slow down my eating rate. (8)	О	О	О	О	0
I eat at only one place in my home. (9)	О	0	О	0	0

Q10.2 Directions: Select the option that best describes your behavior during the last three months.

	Never or hardly ever (1)	Some of the time (2)	About half of the time (3)	Much of the time (4)	Always or almost always (5)
I use the same place mat and other utensils for each meal. (1)	0	О	0	0	0
I eat and just can't seem to stop. (2)	О	0	Ο	О	O
I eat in the middle of the night. (3)	О	О	О	О	O
I snack after supper. (4)	Ο	Ο	Ο	Ο	0
My emotions cause me to eat. (5)	О	0	О	0	O
I buy ready-to-eat snack foods for myself. (6)	О	0	О	0	O
I shop when I'm hungry. (7)	О	О	О	О	O
I shop from a list. (8)	Ο	Ο	Ο	Ο	0
I leave food on my plate. (9)	Ο	О	0	О	O

Q10.3 Directions: Select the option that best describes your behavior during the last three months.

	Never or hardly ever (1)	Some of the time (2)	About half of the time (3)	Much of the time (4)	Always or almost always (5)
I serve food family style (serve from bowls on table). (1)	О	0	О	0	О
I watch TV, read, work, or do other things while I eat. (2)	О	О	О	О	o
If I'm served too much, I	Ο	Ο	Ο	Ο	Ο

leave food on my plate. (3)					
Generally, when I'm at home, I leave the table as soon as I finish eating. (4)	О	0	0	0	О
I keep a graph of my weight. (5)	Ο	0	Ο	О	O
I eat when I'm not really hungry. (6)	О	O	О	О	O
I store food in containers where it is not readily visible or in a closed cupboard. (7)	0	0	O	O	О
I decide ahead of time what I will eat for meals and snacks. (8)	0	0	0	0	•

SELF-EFFICACY FOR EXERCISE

Q11.1 Below is a list of things people might do while trying to increase or continue regular exercise. We are interested in exercises like running, swimming, brisk walking, bicycle riding, or aerobics classes. Whether you exercise or not, please rate how confident you are that you could really motivate yourself to these consistently, for at least six months.

How sure are you that you can do these things?

	I know I cannot 1 (1)	2 (2)	Maybe I can 3 (3)	4 (4)	I know I can 5 (5)	Does not apply (6)
Get up early, even on weekends, to exercise. (1)	0	0	0	0	О	О
Stick to your exercise program after a long, tiring day at work. (2)	O	0	О	0	О	О
Exercise even though you are feeling depressed. (3)	O	0	О	0	О	О
Set aside time for a physical activity program, that is, walking jogging, swimming, biking, or other continuous activities for at least 30 minutes 3 times per week. (4)	O	O	0	0	0	0
Continue to exercise with other even though they seem too fast or too slow for you. (5)	0	o	0	o	0	O
Stick to your exercise program when	0	0	0	0	0	Ο

undergoing a stressful life change (e.g., divorce, death in the family, moving). (6)						
Attend a party only after exercising. (7)	О	0	O	o	0	o
Stick to your exercise program even when your family is demanding more time from you. (8)	0	0	0	0	О	O
Stick to your exercise program when you have household chores to attend to. (9)	0	0	0	0	О	O
Stick to your exercise program even when you have excessive demands at work. (10)	0	0	0	0	О	O
Stick to your exercise program when social obligations are very time consuming. (11)	0	0	0	0	0	O
Read or study less in order to exercise more. (12)	O	0	0	0	0	ο

WEIGHT LOSS PROGRAM PREFERENCES

Q12.1 The next section of questions focuses on your preferences for weight loss treatment. Please rate each item for how appealing a program with this feature would be to you.

Q1212 How appointing	Not at all appealing (1)	2 (2)	3 (3)	4 (4)	5 (5)	6 (6)	Very Appealing (7)
Commercial setting (1)	О	0	0	0	0	0	o
Medical setting (2)	Ο	0	0	0	0	0	Ο
Psychology clinic (3)	0	o	o	o	o	O	O
Gym/Fitness center (4)	0	o	O	o	o	O	О
Home (5)	Ο	0	0	0	0	0	Ο
Church (6)	Ο	0	0	0	0	0	Ο
Work-site (7)	Ο	0	0	0	0	0	Ο
On-line (8)	Ο	0	0	0	0	0	0

Q12.2 How appealing would weight loss program delivered the following setting be to you?

Q12.5 How appealing wo			weig	, int ito	35 P.	iogia	1	1	icu u	·y
		ot at all ealing (1)	2 (2)	3 (3		4 (4)	5 (5		6 (6)	Very appealing (7)
A personal trainer (1)		0	0	0		0	0	(C	Ο
A dietitian/nutritionist (2)		0	О	0		0	0	(c	O
A doctor/nurse (3)		o	О	0		О	$ \circ$		c	0
A peer (4)		0	О	0		0	0		c	Ο
An exercise physiologist (5)		0	О	0		0	0	(c	О
A man (6)		0	О	0		0	0	(c	Ο
A woman (7)		0	О	0		0	0		C	О
Q12.4 How appealing are	the foll		1		1			_	-	
		Not at all appealing (2 (2)	3 (3		4 4)	5 (5)	6 (6)	Very appealing (7)
Focus on managing emote eating (1)	tional	0		0	0	C	>	0	0	O
Focus on improving spor athletic performance (О		0	\circ		>	0	0	o
Group exercise sessions	s (3)	О		0	0		>	0	0	0
Exercise planning (4)	О		0	0		>	0	0	0
Meal planning (5)		О		0	0		>	О	0	0
Healthy food preparation	n (6)	О		0	0		>	О	0	0
Program provides a deta meal plan for you to follo		О		О	\circ		>	0	0	o
Program allows you to s your own foods (8)	elect	0		0	\circ		>	0	0	o
Treatment delivered in g sessions (9)	roup	0		0	\circ		>	0	0	o
Treatment delivered i individual sessions (1		O		0	0		>	0	0	o
Group sessions with sn groups (12 or fewer gro members) (11)		О		0	0	C	>	0	0	0
Group sessions with la groups (up to 100 grou members) (12)	0	О		0	0)	0	o	o

Q12.3 How appealing would it be to have the weight loss program delivered by...

OUTCOME EXPECTANCY: HEALTHY DIET

Q13.1 Now, tell us what you expect will happen when you eat healthier foods. Use the scale shown to tell us if you agree the following will happen. If I eat healthier foods every day, I expect:

	1 Strongly Disagree (1)	2 (2)	3 (3)	4 (4)	5 Strongly Agree (5)
I will have more energy. (1)	Ο	0	0	Ο	Ο
I will lose weight. (2)	О	0	0	0	Ο
I will feel healthier and happier. (3)	0	o	o	o	О
I will live longer. (4)	О	0	0	0	Ο
I will feel better in my clothes. (5)	О	0	0	0	Ο
I will be hungrier. (6)	О	0	0	0	Ο
I will be unhappy and irritable. (7)	О	0	0	0	Ο
My health will improve. (8)	О	0	0	0	Ο
I will miss eating the foods I love. (9)	0	o	ο	o	O
I will have healthier skin, hair, or teeth. (10)	0	o	O	ο	•
I will be less likely to get cancer or heart disease. (11)	0	o	0	0	О

	1 Strongly Disagree (1)	2 (2)	3 (3)	4 (4)	5 Strongly Agree (5)
Shopping for healthy foods will be a lot of trouble. (1)	О	O	0	o	О
I will be bored with what I have to eat. (2)	0	o	o	o	O
I will have to change a lot of my favorite foods. (3)	0	o	o	o	Ο
I won't be able to eat the same foods as the rest of my family. (4)	О	o	0	o	Ο
I will have to spend too much time keeping track of what I eat. (5)	О	o	0	o	Ο
The food I eat will not taste good. (6)	Ο	0	0	0	0
It will take too long to prepare meals and snacks. (7)	Ο	o	o	o	O
I will have to plan my meals too far in advance. (8)	0	o	o	o	О

I will be more attractive. (9)	0	0	Ο	0	Ο
I will be doing what I know I should. (10)	Ο	0	o	o	o
I won't be able to stick with itI'll just go back to my old habits. (11)	Ο	0	0	o	o

WEIGHT EFFICACY LIFESTYLE QUESTIONNAIRE

Q14.1 Read each situation listed below and decide how confident (or certain) you are that you will 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 the number that reflects how confident you feel now about being able to successfully resist the desire to eat.

Q14.2 I can resist eating when I am anxious (or nervous).

- **O** Not confident at all 0 (1)
- **O** 1 (2)
- **O** 2 (3)
- **O** 3 (4)
- **O** 4 (5)
- **O** 5 (6)
- **O** 6(7)
- **O** 7 (8)
- **O** 8 (9)
- Very confident 9 (10)

Q14.3 I can control my eating on weekends.

Q14.4 I can resist eating even when I have to say "no" to others.

Q14.5 I can resist eating when I feel physically run down. $\$

Q14.6 I can resist eating when I am watching TV.

Q14.7 I can resist eating when I am depressed (or down).

Q14.8 I can resist eating when there are many different kinds of foods available.

Q14.9 I can resist eating even when I feel it's impolite to refuse a second helping.

Q14.10 I can resist eating even when I have a headache.

Q14.11 I can resist eating when I am reading.

Q14.13 I can resist eating when I am angry (or irritable).

Q14.14 I can resist eating even when I am at a party.

Q14.15 I can resist eating even when others are pressuring me to eat.

Q14.16 I can resist eating when I am in pain.

Q14.17 I can resist eating just before going to bed.

Q14.18 I can resist eating when I have experienced failure.

Q14.19 I can resist eating even when high-calorie foods are available.

Q14.20 I can resist eating even when I think others will be upset if I don't eat.

Q14.21 I can resist eating when I feel uncomfortable.

Q14.22 I can resist eating when I am happy.

OUTCOME EXPECTATIONS: EXERCISE

Q15.1 These questions ask about what you expect will happen if you were to take a walk or do other exercise most days of the week. They also ask about how much it would matter to you for these things to happen. Using first scale, tell us if you agree the following will happen. Using the second scale, tell us how much it will mater. Please ensure you have provided one answer in each column. If I slowly and steadily build up to walking or doing other exercise most days of the week, I expect I will...

			you ag	-		Will	it ma	tter?		
	Strongly Disagree 1 (1)	2 (2)	3 (3)	4 (4)	Strongly Agree 5 (5)	It will not matter at all 1 (1)	2 (2)	3 (3)	4 (4)	It will matter very much (5)
1. decrease my chance of becoming ill or disabled. (1)	0	0	O	O	0	0	0	0	O	0
2. have to give up some of my normal activities (2)	0	o	o	o	0	0	o	o	o	О
3. have to take more time than usual to plan my day. (3)	O	0	0	0	0	O	O	0	0	О
4. have one more thing to worry about getting done. (4)	O	0	0	0	О	O	0	0	0	О
5. not have enough time for other things I want to do. (5)	O	0	0	0	O	O	0	0	0	О
6. have to change my normal routine. (6)	O	0	•	•	О	O	•	0	0	О
7. sleep better. (7)	O	o	0	0	О	О	o	0	0	0

8. have less time to spend with my family. (8)	O	o	O	О	0	О	0	0	0	О
9. have less time to spend with my friends. (9)	0	0	•	0	0	О	0	0	0	О
10. fit into my clothes better. (10)	О	o	o	О	О	О	o	o	ο	О

		ree?	Will it matter?							
	Strongly Disagree 1 (1)	2 (2)	3 (3)	4 (4)	Strongly Agree 5 (5)	It will not matter at all 1 (1)	2 (2)	3 (3)	4 (4)	It will matter very much (5)
11. manage my weight better. (1)	O	0	o	o	0	О	o	ο	ο	O
12. feel less stress. (2)	О	o	0	0	О	О	0	0	0	Ο
13. be less irritable. (3)	О	o	0	0	О	О	0	0	0	О
14. enjoy it. (4)	О	o	0	0	О	О	0	0	0	Ο
15. feel bored. (5)	О	o	0	0	О	О	0	0	0	Ο
16. dislike it. (6)	О	o	0	0	О	О	0	0	0	О
17. find it pleasurable. (7)	О	o	o	o	0	О	o	o	ο	O
18. be no fun at all. (8)	О	o	0	0	О	О	0	0	0	О
19. be very energized. (9)	О	o	0	0	О	О	0	0	0	О
20. feel depressed. (10)	0	o	o	o	0	О	0	o	o	О

		Do y	you ag	gree?		Will	it ma	atter?		
	Strongly Disagree 1 (1)	2 (2)	3 (3)	4 (4)	Strongly Agree 5 (5)	It will not matter at all 1 (1)	2 (2)	3 (3)	4 (4)	It will matter very much (5)
21. be happier. (1)	0	o	o	o	0	0	o	o	o	О
22. feel good physically. (2)	0	0	0	o	0	O	0	0	o	О
23. feel very invigorated. (3)	0	0	0	0	0	0	0	0	0	o
24. be frustrated. (4)	0	0	0	0	0	0	0	0	0	o
25. be gratified. (5)	О	o	0	0	Ο	0	0	0	0	o
26. feel exhilarated. (6)	О	o	0	0	О	0	0	o	0	O
27. feel a strong sense of accomplishment. (7)	0	0	0	o	0	0	0	0	o	O
28. not want to do anything else. (8)	0	0	0	0	0	0	0	0	0	o
29. be very absorbed by it. (9)	О	o	0	0	О	0	0	o	0	О
30. feel refreshed. (10)	О	o	o	0	О	0	o	o	0	О

PERCEIVED STRESS SCALE

Q16.1 The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by choosing how often you felt or thought a certain way.

a certain way.	Never (1)	Almost Never (2)	Sometimes (3)	Fairly Often (4)	Very Often (5)
In the last month, how often have you been upset because of something that happened unexpectedly? (1)	О	0	0	О	O
In the last month, how often have you felt that you were unable to control the important things in your life? (2)	О	0	0	0	О
In the last month, how often have you felt nervous and "stressed"? (3)	О	0	О	0	0
In the last month, how often have you felt confident about your ability to handle your personal problems? (4)	О	0	0	О	О
In the last month, how often have you felt that things were going your way? (5)	О	0	О	О	0
In the last month, how often have you found that you could not cope with all the things that you had to do? (1)	О	0	0	0	О
In the last month, how often have you been able to control irritations in your life? (2)	О	0	0	О	O
In the last month, how often have you felt that you were on top of things? (3)	О	0	0	О	O
In the last month, how often have you been angered because of things that were outside of your control? (4)	О	0	0	0	О
In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? (5)	О	0	0	0	о

MEDICATION USE

Q17.1 Are you currently taking any of the following types of medications? if YES, list the name of the medication you take.

Q17.2 Weight loss pill O No (1)
• Yes (2)
Q17.3 Antidepressants O No (1)
• Yes (2)
Q17.4 Diuretics (water pill) O No (1) O Yes (2)
Q17.5 Laxative O No (1) O Yes (2)
Q17.6 Steroid (e.g., Prednisone) O No (1) O Yes (2)
 Q17.8 Are you taking medications to control a thyroid disorder? O No (1) O Yes (2)
 Q17.9 Are you taking medications to control diabetes (e.g., insulin or oral pills)? O No (1) O Yes (2)
 Q17.10 Are you taking medications to control your cholesterol? O No (1) O Yes (2)
 Q17.11 Are you taking medications to control high blood pressure? O No (1) O Yes (2)

APPENDIX F: PROGRAM EVALUATION QUESTIONNAIRES

Intervention Group Only

The next set of questions focuses on your experience with the weight management program you received from REFIT. When answering these questions, please rate only the program itself, not the research measures you were asked to complete (e.g., assessment visits, online questionnaires, etc.). During the REFIT program, there were:

- Two group sessions
- 10 weekly online check-ins
- 3 monthly online check-ins

Q123 How satisfied are you overall with the weight management program you received from REFIT?

- **O** Very Dissatisfied (1)
- **O** Somewhat Dissatisfied (2)
- Somewhat Satisfied (3)
- Very Satisfied (4)

Q127 If you were "Very dissatisfied" or "Somewhat dissatisfied" with the program, please tell us why:

Q129 Would you recommend the weight management program you received from REFIT to other men?

- O Definitely Not (1)
- Probably Not (2)
- **O** Probably Would (3)
- **O** Definitely Would (4)

Q131 If you would "Definitely not" or "Probably not" recommend the program to others, please tell us why:

Q133 Given the effort you put into following the weight management program you received from REFIT, how satisfied are you with your progress over the past 6 months?

- Very Dissatisfied: -4 (1)
- **O** -3 (2)
- **O** -2 (3)
- **O** -1 (4)
- **O** 0(5)
- **O** 1 (6)
- **O** 2(7)
- **O** 3 (8)
- **O** Very Satisfied: 4(9)

Q135 Please rank the following program features on how much they helped you to reach your weight loss goals. Please assign values from 1 (most helpful) to 7 (least helpful). Assign each value to only one item.

- _____ Group sessions (1)
- _____ Exercise plans (2)
- _____ Online check-ins (overall) (3)
- _____ Feedback during check-ins (4)
- _____ REFIT Lessons (5)
- _____ Recommendation to make 100-calorie changes to diet (6)
- _____ REFIT "Aim for 6" tracking forms (7)

Q162 Please think about your participation in REFIT.

	Not Confident: 1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	6 (6)	7 (7)	Very Confident: 8 (8)
How confident are you that you will continue following the approach to eating you were taught during this program? (1)	O	0	0	0	0	0	0	O
How confident are you that you will continue to follow the approach to exercise you were taught in this program? (2)	O	0	0	0	0	0	0	0

	I didn't know about or use this feature (1)	Very dissatisfied (2)	Somewhat dissatisfied (3)	Somewhat satisfied (4)	Very satisfied (5)
Initial group meetings (1)	0	•	0	•	О
Number of group meetings (2)	О	0	0	О	О
Topics covered in group meetings (3)	0	0	0	0	O
Other aspects of group meeting, please describe: (4)	0	O	O	O	О
Online check-ins (5)	О	•	0	О	O
Number of check-ins (6)	0	О	0	О	0
Amount of feedback text (7)	0	О	О	О	О
Other aspects of check-ins, please describe: (8)	0	O	O	O	O
REFIT lessons (9)	О	•	0	О	O
Topics covered by lessons (10)	0	О	0	О	О
Length of lessons (11)	О	О	О	О	О
Other aspects of lessons, please describe: (12)	0	0	O	O	О

Q139 How satisfied are you with the following features of the REFIT program?

	Very Dissatisfied - 4 (1)	-3 (2)	-2 (3)	-1 (4)	Neither Satisfied nor Dissatisfied 0 (5)	1 (6)	2 (7)	3 (8)	Very Satisfied 4 (9)
Losing weight (1)	0	О	0	0	0	0	0	О	О
Changing your dietary habits (2)	0	О	o	o	0	ο	0	О	O
Changing your physical activity habits (3)	0	0	0	o	0	0	ο	О	•

Q141 Given the effort you put into following the REFIT program over the past six months, how satisfied are you overall with your progress on...

(143 Over the	nast six	months	how	often	did	vou	do	the	foll	owing	?
~ ~		pust six	monuis,	110 **	onton	uiu	you	uo	uno	TOIL	Jung	•

	Never or hardly ever (1)	Some of the time (2)	About half the time (3)	Much of the time (4)	Always or almost always (5)
Tracked my eating using the REFIT "Aim for 6" sheet (1)	О	0	О	0	О
Reduced my intake by making 100-calorie changes to my diet (2)	О	О	О	0	О
Tracked my intake using an app or website (e.g., myfitnesspal) (3)	О	О	О	0	О
Recorded my exercise (4)	О	Ο	О	Ο	O
Set weekly goals related to my diet (5)	Ο	О	О	0	O
Set weekly goals related to my exercise (6)	О	ο	О	0	О

Q145 Have you shared your program materials with anyone in your household? (select all that apply)

- □ Spouse/Partner (1)
- \Box Friend(s) (2)
- $\Box \quad \text{Child(ren)} (3)$
- **O** Other: (4) _____

Q147 Have you shared your program materials with anyone outside of your household? (select all that apply)

- □ Spouse/Partner (1)
- \Box Friend(s) (2)
- \Box Child(ren) (3)
- \Box Coworker(s) (4)
- □ Other (5) _____

Tonowing aspects be for helping you	Not at all important (1)	Somewhat Important (2)	Very Important (3)	Extremely Important (4)
Attend groups with a spouse or partner (1)	Ο	0	О	О
Use of a family-centered approach to weight loss that addresses parents and children (2)	0	0	0	О
Online chats or video conferences with other participants (3)	О	•	О	O
Online chats or video conferences with study staff (4)	Ο	O	О	О
More frequent face-to-face contact (5)	Ο	•	О	O
More frequent online contact (6)	Ο	Ο	О	О
Text messages sent by study staff (7)	О	•	О	O
Participation in a message board specifically for people like me (i.e., fathers, young adults, etc.) (8)	0	0	0	O
Updates on other participants' progress in diet and exercise changes to know how your progress stands in comparison to the rest of the group (9)	0	0	0	О
Competitions between you and other study participants (10)	О	0	О	O
Program for men only (11)	Ο	Ο	О	Ο
Fewer face-to-face contacts (12)	0	0	0	Ο
Program delivered at my worksite (13)	О	0	О	O

Q149 If you were to participate in another weight loss program, how important would the following aspects be for helping you to complete the program?

Q151 If you were going to participate in another weight loss program, who would you most want to participate with?

- Your spouse or romantic partner (1)
- **O** A friend/coworker (2)
- **O** Your child (3)
- **O** My whole family (including partner and children) (4)
- **O** No one--I would prefer to participate alone. (5)
- **O** Other (6) _____

Q153 Are you currently married or living with a spouse or cohabitating partner?

- **O** Yes (1)
- **O** No (2)

Questions asked of married participants only

Q157 Has your participation in the program negatively impacted your relationship with your spouse/partner (e.g., caused relationship strain)?

- **O** Yes (1)
- O No (2)
- O Unsure (3)

Q155 Has your spouse/partner made positive changes to their diet and/or physical activity as a result of your participation on the program?

- **O** Yes (1)
- O No (2)
- O Unsure (3)

Q159 How helpful might it have been to do this program with a spouse/partner?

- Not at all helpful (1)
- O Not helpful (2)
- O Somewhat helpful (3)
- Very helpful (4)

	Not at all helpful: 1 (1)	2 (2)	3 (3)	Very helpful: 4 (4)
Information on ways to exercise together (1)	Ο	0	Ο	О
Information on ways to plan meals together (2)	Ο	0	0	О
Information on ways to support each other (3)	Ο	0	0	О
Encouragement from your partner (4)	Ο	0	0	О
Partner providing information/suggestions on eating, exercise and/or losing weight (5)	0	o	o	O
Partner buying healthy food for the home or exercise equipment (6)	0	o	o	O
Partner evaluating your progress (7)	0	0	0	Ο

Q161 If you were trying to lose weight with your spouse/cohabitating partner, what would be helpful?

Question asked of all intervention group participants

Q125 Please use the box below to submit any additional feedback--positive or negative-- you have about the REFIT program.

Questions asked of all control participants

aspects be for helping you to complete the program?							
	Not at all important (1)	Somewhat Important (2)	Very Important (3)	Extremely Important (4)			
Attend groups with a spouse or partner (1)	Ο	О	О	О			
Use of a family-centered approach to weight loss that addresses parents and children (2)	0	0	0	О			
Online chats or video conferences with other participants (3)	О	•	Ο	O			
Online chats or video conferences with study staff (4)	О	•	О	O			
Face-to-face contact at the beginning of the program (5)	О	•	Ο	O			
Face-to-face contact throughout the program (6)	О	•	Ο	О			
Online contact once per week (7)	Ο	0	Ο	О			
Online contact more than once per week (8)	О	О	О	O			
Text messages sent by study staff (9)	О	•	О	O			
Participation in a message board specifically for people like me (i.e., fathers, young adults, etc.) (10)	O	O	O	О			
Updates on other participants' progress in diet and exercise changes to know how your progress stands in comparison to the rest of the group (11)	0	O	0	О			
Competitions between you and other study participants (12)	О	•	Ο	O			
Program for men only (13)	Ο	0	0	Ο			
Program delivered at my worksite (14)	О	О	О	О			

Q95 If you were to participate in a weight loss program, how important would the following aspects be for helping you to complete the program?

Q97 If you were going to participate in a weight loss program, who would you most want to participate with?

- Your spouse or romantic partner (1)
- **O** A friend/coworker (2)
- Your child (3)
- **O** My whole family (including partner and children) (4)
- **O** No one--I would prefer to participate alone. (5)
- **O** Other (6) _____

Q99 Are you currently married or living with a spouse or cohabitating partner?

- **O** Yes (1)
- **O** No (2)

Questions ask of Control Group Married Participants Only

Q101 If you were losing weight with your spouse/cohabitating partner, what would be helpful?

	Not at all helpful: 1 (1)	2 (2)	3 (3)	Very helpful: 4 (4)
Information on ways to exercise together (1)	0	0	0	0
Information on ways to plan meals together (2)	Ο	0	0	0
Information on ways to support each other (3)	O	0	0	0
Encouragement from your partner (4)	O	0	0	0
Partner providing information/suggestions on eating, exercise and/or losing weight (5)	0	o	o	O
Partner buying healthy food for the home or exercise equipment (6)	0	o	o	O
Partner evaluating your progress (7)	0	0	0	0

	Assessment Period ^a			<u>p-value^b</u>					
	Baseline	3 month				Grou p	Group	Group x Time	
				3 mo. vs. BL	6 mo. vs. BL		3 mo.	6 mo.	
Weight Loss									
REFIT	99.6 (95.7, 103.5)	94.6 (90.7, 98.5)	94.1 (90.2, 98.0)	<.001	< 0.001	0.90	<.001	<.001	
Waitlist	99.9 (96.1, 103.8)	99.4 (95.5, 103.2)	99.3 (95.4, 103.2)	0.30	0.27				
Percent weight	loss								
REFIT	Ref	-5.0 (-5.9, -4.0)	-5.4 (-6.3, -4.4)	<.001	<.001	0.99	<.001	<.001	
Waitlist	Ref	-0.6 (-1.5, 0.4)	-0.7 (-1.6, 0.3)	0.30	0.22				
Waist Circumfe	erence								
REFIT	109.0 (106.1, 111.9)	105.0 (102.1, 107.8)	104.1 (101.3, 107.0)	<.001	<.001	0.80	<.001	<.001	
Waitlist	108.5 (105.6, 111.3)	107.7 (104.9, 110.6)	107.4 (104.5, 110.2)	0.10	0.02				
Percent Body F	at								
REFIT	34.5 (32.8, 36.3)	31.5 (29.7, 33.2)	30.3 (28.5, 32.1)	<.001	<.001	0.75	<.001	<.001	
Waitlist	34.1 (32.4, 35.9)	33.7 (32.0, 35.5)	33.0 (31.2, 34.8)	0.34	0.01				
Caloric Intake									
REFIT	2333 (2168, 2497)	1883 (1708, 2059)	1894 (1721, 2068)	<.001	<.001	0.27	0.23	0.07	
Waitlist	2461 (2297, 2625)	2187 (2019, 2356)	2286 (2116, 2456)	0.007	0.09				
% Calories from									
REFIT	35.8 (34.0, 37.7)	35.4 (33.4, 37.4)	36.3 (34.3, 38.2)	0.70	0.70	0.25	0.48	0.43	
Waitlist	37.4 (35.5, 39.2)	35.8 (33.9, 37.7)	36.5 (34.6, 38.4)	0.16	0.46				
Caloric Expend	iture*								
REFIT	718.0 (492.8, 1440.2)	1440.2 (1106.9, 1816.5)	1319.1 (997.9, 1685.1)	<.001	<.001	0.76	<.001	.001	
Waitlist	773.4 (539.6, 1048.5)	715.6 (489.2, 984.6)	766.1 (528.9, 1047.2)	0.60	0.95				

APPENDIX G: UNADJUSTED DATA ANALYSIS

Note. ^aValues are model estimated means and 95% Confidence Interval ^bLinear mixed model analysis all available data. *Analysis performed on square root transformed values

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