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The Effect of Depression and Adherence in a Dietary and Physical Activity Intervention for Overweight and Obese Adults

A dissertation submitted in partial satisfaction of the requirements for the degree

Doctor of Philosophy

in

Clinical Psychology

by

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Twenty years from now you will be more disappointed by the things that you didn't do than by the ones you did do. So throw off the bowlines. Sail away from the safe harbor. Catch the trade winds in your sails. Explore. Dream. Discover.

Mark Twain

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ABSTRACT OF THE DISSERTATION

The Effect of Depression and Adherence

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by

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Overweight and obesity result in serious medical, economic, and psychological consequences. A better understanding of factors that lead to successful weight loss treatment is needed, including mediators and moderators of treatment effects. This study investigated the effect of depression on adherence to a dietary and physical activity behavior change intervention in a sample of overweight and obese men and women.

The PACEi Men in Motion (n=441) and Women in Balance (n=401) on-line interventions used similar randomized controlled designs with data collected at baseline, 6, and 12 months. Outcomes included BMI, depression, dietary quality, physical activity and sedentary behavior. Adherence scores reflected the percentage of potential intervention activities completed. Moderator and mediator analyses were performed as described by Baron and Kenny (1986) and Kraemer et al. (2002).

A mediating relationship among depression, adherence, and outcome was supported for dietary quality in men; no relationship was found for women. In addition, baseline depression in men was related to lower adherence rates, and, in turn, lower adherence rates predicted poorer outcome for BMI, physical activity, sedentary behavior, and dietary quality. For women, adherence was not affected by baseline depression but lower adherence did predict poorer dietary quality outcomes. However, baseline level of depression in women was found to moderate the intervention effect on dietary changes, where women in the intervention group improved their dietary quality more than the control group, with greater improvements seen in the depressed intervention women. Depressed women in the control group had a slight decrease in diet quality. Baseline level of depression was also found to moderate the intervention effect on sedentary behavior for men. Men in the intervention group reduced their sedentary behavior about the same amount, regardless of depression status at baseline, while in the control group, depressed men decreased their sedentary behavior and non-depressed men had a slight increase.

This study provided further evidence for the relationship between adherence and outcome. The relationship between depression and adherence was supported only for men. Overall, the study provided evidence that participating in a dietary and physical activity intervention while experiencing depressive symptoms is not harmful, and may be beneficial in some cases. Screening out participants who are similarly depressed due to concern for their ability to participate may not be warranted. Future studies should investigate strategies to promote adherence to weight loss interventions as a method of enhancing outcomes in addition to examining the effects of treating depression either before or concurrently with weight loss interventions.

Introduction

Prevalence of Obesity

Obesity is a major health concern in the United States. The prevalence of overweight and obesity has been increasing dramatically in the last 25 years. Overweight is defined as a body mass index (BMI) of 25.0 to 29.9 kg/m^2 and obesity is defined as a BMI of $\geq$ 30 kg/m^2 (CDC, n.d.) Data obtained as part of the 2003-2004 National Health and Nutrition Examination Survey, a representative sample of the U.S. population, indicate that approximately 66.3% of adults 20 years or older are overweight or obese (Ogden et al., 2006). This represents an increase from data obtained in 1976-1980 where 47.1% of adults were overweight or obese (Flegal, Carroll, Ogden, & Johnson, 2002). Since 1976, the greatest increase in prevalence occurred in the obese category where the prevalence increased from 15% to 32.9% (Flegal et al., 2002; Ogden et al., 2006). The recent data indicate that among men, the prevalence of obesity increased significantly from 27.5% (1999) to 31.1% (2004) while the prevalence among women appeared to be leveling off (33.4% and 33.2%, respectively) but still high (Ogden et al., 2006).

Medical Consequences of Obesity

Overweight and obesity result in serious medical consequences. Cardiovascular disease, hypertension, diabetes, dyslipidemia, metabolic syndrome, gallstones, osteoarthritis, sleep apnea, and certain forms of cancer have all been associated with overweight and obesity (Wyatt, Winters, & Dubbert, 2006). Two large ongoing prospective cohort studies, the Nurses' Health Study and the Health Professionals Follow-up Study, examined the 10-year associated risks of developing high cholesterol, hypertension, gallstones, type 2 diabetes, heart disease, stroke, and colon cancer with overweight and obesity (Field et al., 2001). The results indicate that the risks of

developing diabetes, gallstones, hypertension, and heart disease increased with severity of overweight among both women and men. Specifically, adults who were overweight were more than 3 times as likely as their leaner peers to develop diabetes during 10 years, and those with a BMI of 35.0 or more were approximately 20 times more likely to develop diabetes (Field et al., 2001). Adults who were overweight were also significantly more likely than their leaner peers to develop gallstones, hypertension, high cholesterol and heart disease, and obese men were significantly more likely to have a stroke during the 10 years of follow-up (Field et al., 2001). Obesity and overweight in adulthood were also found to be associated with large decreases in life expectancy in two large epidemiologic studies (The Framingham Heart Study and NHANES data) (Fontaine, Redden, Wang, Westfall, & Allison, 2003; Peeters et al., 2003).

Economic Consequences of Obesity

Estimates of the economic consequences of obesity are considerable. A review paper by Thompson & Wolf (2001) estimates that obesity accounts for 5.5-7.0% of health expenses in the United States. The direct costs of obesity have been reported to range from $51.64 to $70 billion (Thompson & Wolf, 2001; Wolf & Colditz, 1998). These costs are greater than those associated with coronary heart disease ($50.8 billion), hypertension ($15.6 billion), stroke ($18.1 billion), and diabetes ($53.2 billion) (Thompson & Wolf, 2001). Another recent review, found that expenditures related to overweight and obesity accounted for 9.1% of total annual U.S. medical expenditures in 1998 which may have been as high as $78.5 billion (Finkelstein, Fiebelkorn, & Wang, 2004). A review examining the economic burden of diabetes estimated the direct medical expenditures as $91.8 billion, comprised of $23.2 billion for diabetes care, $24.6 billion for chronic complications attributable to diabetes, and $44.1 billion for the excess prevalence of general medical conditions (Hogan, Dall, & Nikolov, 2003). It is important

to note that these estimates are based on direct costs which refer to preventive, diagnostic, and treatment services related to overweight and obesity (e.g., physician visits, hospital and nursing home care) and do not include indirect costs such as the value of wages lost by people unable to work because of illness or disability, as well as the value of future earnings lost by premature death (Wolf & Colditz, 1998).

Psychosocial Consequences of Obesity

Two reviews by Puhl and Brownell (2001; 2003) have documented well the stigmatization and discrimination experienced by those who are overweight and obese. In employment settings, obese individuals with identical qualifications are less likely to be hired than thin people, and obese employees are viewed as less competent, lazy, and lacking in self-discipline. There is evidence that weight discrimination has a negative impact on wages, promotions, and decisions about employment status. In health care settings, negative attitudes about overweight patients have been reported by physicians, nurses, psychologists, and medical students, even those specializing in the treatment of obesity. In educational settings, overweight and obese children have experienced harassment and rejection from peers and negative teacher attitudes. As obese students approach college, they have been shown to experience lower college acceptances and wrongful dismissals from college. Shockingly, one study reported that parents of overweight children provided them with less financial support for college than parents of thin children, regardless of factors like family size, income, and education (Crandall, 1995).

Overweight and obesity have also been linked to negative mental health consequences, specifically depression. McElroy and colleagues (2004) performed an extensive review of the literature examining the relationship between mood disorders and obesity. From clinical studies they concluded that children and adolescents with

major depressive disorder may be at increased risk for developing overweight at a later time. Clinical studies also revealed that there was a positive relationship between obesity and major depressive disorder and bipolar disorder in adults. Community studies found the same positive relationship between obesity and major depressive disorder in women but for men, both positive and negative relationships were found. The largest of the community studies which included over forty thousand adults aged 18 and older in the United States found that obesity was associated with a 37% increased risk of depression for women, but for men, obesity was associated with a decreased risk of depression of similar magnitude (Carpenter, Hasin, Allison, & Faith, 2000). Prevalence rates for past-year depression in the overweight category were reported as 4.7% for women and 1.2% for men (Carpenter et al., 2000). Results from the Third National Health and Nutrition Examination Survey, which included over eight thousand people from 15 to 39 years old, found that obesity (BMI ≥ 30) was associated with past-month depression in women but not in men, with prevalence rates reported as 6.7% for women and 2.85% for men (Onyike, Crum, Lee, Lyketsos, & Eaton, 2003). Yet, severe obesity (BMI ≥ 40) was associated with past month depression in both men and women, with prevalence rates reported as 13.0% for women and 11.5% for men (Onyike et al., 2003). Other community studies have confirmed the association between obesity and depression but did not find gender differences. A study of almost two thousand adults aged 50 and older who were evaluated in 1994 and again in 1999 found that obesity was associated with current major depressive episodes at both time points (Roberts, Deleger, Strawbridge, & Kaplan, 2003). Obesity in 1994 was also associated with increased risk of depression in 1999 (Roberts et al., 2003). The reported prevalence rates in 1994 of current depression in the obese category were 15.5% in comparison to 7.4% in the normal weight category (Roberts, Kaplan, Shema, & Strawbridge, 2000).

Johnston and colleagues (2004) examined the link between obesity and self-reported depressive symptoms in 2,482 Canadian men and women and found that participants who were obese were 41% more likely to be depressed than those who were not (Johnston et al., 2004). Differing prevalence rates of comorbid depression and obesity reported in the literature are often attributed to methodological issues regarding the assessment of depression and the definition of obesity (Carpenter et al., 2000; Onyike et al., 2003).

In examining the gender differences reported in the relationship between obesity and depression, it is important to note the differing rates of depression in men and women. The National Comorbidity Survey of over eight thousand participants reported the prevalence of major depressive disorder to be 21.3% in women and 12.7% in men (Kessler, McGonagle, Swartz, Blazer, & Nelson, 1993).

These differences begin in adolescence and continue into midlife (Kessler et al., 1993). Likewise, results from the National Epidemiologic Survey on Alcoholism and Related Conditions reported lifetime prevalence of depression at 17% for women and 9% for men (Hasin, Goodwin, Stinson, & Grant, 2005). Similar prevalence rates among men and women have been found consistently, including across different countries and ethnic groups (Grigoriadis & Robinson, 2007; Weissman et al., 1996).

These data indicate that the relationship between depression and obesity may be different for men and women and deserves further inquiry.

Treatment of Overweight and Obesity

A modest amount of weight loss can improve health factors associated with obesity. A weight reduction of as little as 5 –10% has been associated with improvements in cardiovascular risk factors, fasting glycaemia, HBA1c, blood pressure, and plasma lipid profile (NIH, 1998; Vidal, 2002).

Weight loss treatments can generally be divided into 3 types: behavioral treatment, pharmacotherapy, and surgical treatments. Behavioral treatments typically include intervention components that address diet, physical activity, and behavioral change techniques to help patients adopt new habits (Wadden, Crerand, & Brock, 2005). These techniques include self-monitoring, stimulus control, social support, cognitive restructuring, problem-solving skills, and relapse prevention (Wadden, McGuckin, Rothman, & Sargent, 2003). Treatments combining diet, physical activity, and behavior change have been shown to be more effective than diet or physical activity alone. Interventions which focus only on physical activity have been shown to be minimally effective in weight loss but instrumental in helping to *maintain* weight loss (Wadden et al., 2003). The addition of physical activity components to diet interventions not only increased initial weight loss, the results were sustained for a longer amount of time (Avenell et al., 2004; Curioni & Lourenco, 2005). Adding behavioral techniques to interventions also resulted in improved outcomes (Avenell et al., 2004; McTigue et al., 2003). In the short term, behavioral treatments result in a weight loss of 3-5kg (McTigue et al., 2003), or the equivalent of 0.4 to 0.5 kg per week (Wadden et al., 2005). Unfortunately weight loss typically reported with behavioral treatment is not maintained well. Reviews of long-term studies have found that 30% to 50% of lost weight is regained in the year after treatment (Curioni & Lourenco, 2005; Wadden et al., 2005) and that in 5 years, more than half of patients are likely to have returned to their baseline weight (Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989).

Behavioral treatments can be delivered in a variety of ways, including print materials, face-to-face individual contact, or group contact. With the advent of the World Wide Web, Internet based delivery of interventions has become more popular. Yet, Internet based weight loss studies have met with limited success. Some report

approximately the same weight loss results as non-Internet based interventions (Weinstein, 2006) while others have reported them to be not as effective although still resulting in clinically significant weight loss (Wadden et al., 2005). There is some evidence showing higher attrition with online studies and the preference for face-to-face contact (Wadden et al., 2005; Weinstein, 2006). Despite this, there are many advantages to using online interventions. Most behavioral treatments are currently only available through research facilities (Wadden et al., 2005) which do not have the capacity to provide programs for all those in need. The internet has the ability to reach more people at lower cost. Programs delivered online can be tailored to individual needs and also can be used to augment face-to-face interventions.

Pharmacotherapy has also shown some short term success. Drugs like sibutramine and orlistat are approved for use in combination with lifestyle change for people with BMIs ≥ 30 or BMIs ≥ 27 with other risk factors (McTigue et al., 2003). The use of these drugs typically results in an average weight loss of 3-5 kg (McTigue et al., 2003). A recent meta-analysis reported a mean difference in weight loss of 4.45 kg with sibutramine and 2.89 kg with orlistat at 12 months (Li et al., 2005). There has been some success in maintaining weight loss with longer drug courses but patients tend to regain weight when treatment is discontinued (McTigue et al., 2003). One review of sibutramine trials reported regain of up to 25% of previously lost weight within 1-6 weeks of stopping treatment (Arterburn & Noel, 2001). One trial even reported weight regain of up to 80% within three months of stopping medication (Apfelbaum et al., 1999). Excess regain after discontinuation has also been observed with orlistat (Karhunen et al., 2000). Patients using weight loss drugs have reported adverse side effects, including insomnia, nausea, dizziness, increased heart rate, gastrointestinal problems, and in some cases, significantly increased blood pressure (McTigue et al., 2003). The data are currently

limited due to shorter-term trials; additional research is needed regarding the long-term effectiveness and safety of weight loss drug interventions (Li et al., 2005).

Surgical treatments for weight loss have shown dramatic results with patients losing on average 61% of excess weight (Buchwald et al., 2004). Over 1-5 years, weight losses of 10-159 kg have been reported (McTigue et al., 2003). Surgical treatments are either malabsorptive or restrictive, and include gastric bypass, adjustable gastric banding, or vertical banded gastroplasty. Gastric bypass produces a small upper pouch in the stomach with a narrow outlet where food bypasses much of the stomach and part of the small intestine, while gastroplasty also produces a small upper pouch but the natural passage of food is maintained (Glenny, O'Meara, Melville, Sheldon, & Wilson, 1997). Adjustable gastric banding involves placing an inflatable band around the stomach that can be adjusted to different diameters (McTigue et al., 2003). Since surgical procedures offer the greatest risks and side effects, these treatments have only been recommended for patients who are severely obese (BMI>40) or patients who are obese (BMI>35) with severe health complications and have not responded to other forms of treatment (McTigue et al., 2003). Complications of surgery include the need to operate again, wound infection, gastric leaks, pouch dilations and death, with mortality rates observed between 0-1.5% (McTigue et al., 2003). Surgical treatment also requires extensive follow-up care and management of ongoing issues like “dumping syndrome” and vitamin and mineral deficiencies due to restricted absorptions (Glenny et al., 1997).

In summary, long-term studies of weight loss have found weight loss of less than 5 kg after 2-3 yrs for behavioral treatments, weight loss of 5-10 kg after 1-2 years for pharmacologic therapy, and weight loss of 25-75 kg 2-4 years post surgery (Douketis, Macie, Thabane, & Williamson, 2005).

The limited success of weight loss interventions and the propensity for regain highlight the need to better understand what factors lead to success in weight loss treatments. As Kraemer and colleagues state (2002), much more can be learned from randomized controlled trials than is currently learned. They suggest information on possible moderators and mediators of treatment outcomes be provided from randomized controlled trials in order to guide the next generation of studies and inform clinical applications (Kraemer et al., 2002). If mediators were routinely reported, interventions could be developed to be more efficient and effective by using the mediators supported consistently in the literature (Judd & Kenny, 1981; MacKinnon & Dwyer, 1993). In addition, these interventions could potentially yield larger effect sizes, or at the very least, yield the same effect size but be delivered at lower cost or risk to participants (Kraemer et al., 2002). Those intervention components identified as effective could be intensified and refined, while those identified as ineffective or redundant could be discarded (Kraemer et al., 2002). Besides improving interventions, identifying moderators and mediators can also improve and strengthen our understanding of the process of behavior change (Kraemer et al., 2002).

Depression, Adherence and Weight

One factor which has received interest in its effect on intervention outcome is depression. The relationship between depression and weight is complicated and potentially bidirectional. As reviewed earlier, depression is a risk factor for later development of overweight (McElroy et al., 2004) and obesity is a risk factor for later development of depression (Roberts et al., 2003). The two are positively related in adulthood (McElroy et al., 2004). Research has also shown that weight loss can improve depressive symptoms. Dixon (2003) found that in 487 weight-loss surgery patients, those who lost more weight had predictably greater reductions in their Beck

Depression Inventory scores. Similar improvements in depressive symptoms have been reported from other weight loss surgery studies (Dymek, le Grange, Neven, & Alverdy, 2001; Karlsson, Sjostrom, & Sullivan, 1998; van Gemert, Severeijns, Greve, Groenman, & Soeters, 1998). Improvement in mood has also been seen with behavioral interventions for weight loss (Bryan & Tiggemann, 2001; Gladis et al., 1998). Additionally, physical activity interventions have shown improvement of depressive symptoms and mood states in both healthy and clinical populations (Brosse, Sheets, Lett, & Blumenthal, 2002; Dunn, Trivedi, & O'Neal, 2001; Penedo & Dahn, 2005).

Notwithstanding the support in the literature for the positive effects of weight loss and increased physical activity on depressive symptoms, how depression may affect participation in and success in a weight loss intervention is less clear. A meta-analysis examining depression as a risk factor for noncompliance with medical treatment, including dietary regimens and other health behaviors, found that in comparison with non-depressed patients, the odds were 3 times greater that depressed patients were noncompliant with treatment recommendations (DiMatteo, Lepper, & Croghan, 2000). Recent studies also confirm that greater depressive symptoms predict lower adherence (Gehi, Haas, Pipkin, & Whooley, 2005; Kalsekar et al., 2006; Morgan et al., 2006). Data from the National Weight Control Registry indicate that continued adherence to diet and exercise strategies is associated with low levels of depression (Wing & Phelan, 2005).

Decreased adherence has been shown to result in suboptimal outcome. A meta-analysis of 63 studies assessing adherence and outcome of medical treatment found that adherence reduced the risk for a null or poor treatment outcome by 26% compared with non-adherence (DiMatteo, Giordani, Lepper, & Croghan, 2002). The adherence-outcome relationship was stronger for chronic diseases and non-medication treatments.

Although there is a relationship between depression and adherence as well as adherence and outcome, Wing and colleagues (2002) point out that further research is needed to understand the potential mediating role of adherence between depression and outcome. They suggest that known methodological approaches be used for testing adherence as a mediator, like the approach proposed by Baron and Kenny (1986), and emphasize the importance of using objective measures of adherence in future research.

Study Aims

The aim of the present study is to investigate the effect of depression on adherence to a dietary and physical activity behavior change intervention in a sample of overweight and obese men and women. Specifically, using the framework of Baron and Kenny (1986) and Kraemer et al. (2002) the following will be examined:

1. **Does baseline level of depression moderate the intervention effect on outcome (Dietary behaviors, physical activity, sedentary behavior, and BMI)?**

Rationale: Determining if the intervention is as effective for those who are depressed at baseline versus those who are not can help inform development and tailoring of the intervention as well as participant selection.

Hypothesis: It is hypothesized that greater improvements in outcome will be observed in participants exhibiting fewer depressive symptoms.

2. **Does adherence mediate baseline depression on outcome?**

Rationale: Depressed participants have been shown to have poorer adherence, and poorer adherence has been linked to poorer outcome. This aim explores the effect of depressive symptoms on outcome in the intervention group and tests if this relationship is mediated by (or due to) level of adherence.

Hypothesis: It is hypothesized that participants with greater depressive symptoms will have poorer outcomes, and that this relationship is at least partially explained by poorer adherence to the intervention.

3. **Is the effect of change in depression mediated by change in adherence on outcome?**

Rationale: Weight loss and physical activity have been shown to improve depressive symptoms. This aim explores if changes in depressive symptoms result in changes in adherence, and this, in turn, leads to improved outcomes.

Hypothesis: It is hypothesized that participants whose depressive symptoms improve will have more positive outcomes, and that this relationship is at least partially explained by improved adherence to the intervention.

4. **Does treatment condition affect depression?**

Rationale: Improved depressive symptoms have been observed in weight loss and physical activity interventions that do not explicitly focus on depression. This aim determines if improvements in depressive symptoms are observed in the intervention group in comparison to the control group.

Hypothesis: It is hypothesized that a greater improvement of depressive symptoms will be observed in the intervention group.

Methods

Study design

The PACEi Men in Motion and Women in Balance studies were funded by the National Cancer Institute as companion studies to evaluate a behavioral intervention on diet and physical activity behaviors. Each study employed a randomized controlled design with data collected from March 2004 to April 2006 and July 2002 to January 2005, respectively. Both sets of data are used in the current study. The interventions were similar in that they both aimed to improve diet and exercise behavior and were conducted by the same team. However, the women's study focused on diet quality and the men's study focused more on creating a caloric deficit and weight loss. Body mass index was the primary outcome for the men's study while diet and physical activity behaviors were the primary outcomes for the women's study. Each intervention was tailored to gender. Identical assessments and measurement time points were used. Because these studies were so similar, they provided an opportunity to explore the moderational and mediational relationships for both men and women in parallel. Corresponding analyses were performed on the Men in Motion and Women in Balance data sets.

Participants

Men

Four hundred and forty-one men were recruited and randomized to the PACEi Men in Motion intervention or control group. Participants for the PACEi men's study were recruited from the greater San Diego area. Criteria for participation included being 18-55 years, BMI: 25.0-34.9, having access to the Internet at home or work, and being able to engage in moderate physical activity. Participants could have one or more risk

factors for cardiovascular disease (CVD), including uncomplicated type 2 diabetes or mild-moderate hypertension but were excluded if they had diagnosed CVD.

Women

Four hundred and one women were recruited through their primary care provider at five clinics in the San Diego area and randomized to the PACEi Women in Balance intervention or delayed treatment control. Criteria for participation included being 18-55 years, BMI: 25.0-39.9, having Internet computer access, not being pregnant or planning to become pregnant in the next 2 years, and being able to engage in moderate physical activity. Potential participants were also screened for eating disorders; those screening positive were not enrolled.

Intervention

Men

The PACEi Men in Motion was a 12-month intervention designed to promote adoption and maintenance of improved eating and physical activity behaviors through an integrated web-based intervention. The intervention was tailored to men by including short sessions, the use of a pedometer, work related language and graphics, and little extraneous information. Participants completed monthly web-based activities which included learning about and applying new behavioral skills, and reading diet and physical activity topics. Tip sheets, topical news items, and archived content were all available online and content was updated weekly. Participants were encouraged to log on weekly to report their weight, progress on their goals, and to set new goals. The men set weekly goals through the web-based program to improve (1) fruit & vegetable intake, (2) dietary fat (3) fiber intake, (4) physical activity, and (5) strength. Men were given pedometers to assess daily steps and were encouraged to input the data on the website for tracking purposes. Physical activity goals included increasing steps per day to at

least 10,000 (5-7 d/wk) and participating in strength training two times per week. Health counselors had occasional e-mail and phone contact with the participants to facilitate interaction with the website and troubleshoot technical difficulties.

Men randomized to the wait list control condition were given access to an alternate website and encouraged to log on monthly. The control website contained general health information of interest to men but not likely to lead to changes in diet or physical activity behaviors. At the end of the 12 months, waitlisted men were given the option to cross over to the weight loss intervention.

Women

The PACEi Women in Balance was a 12-month intervention aimed at improving the physical activity and nutrition behaviors of overweight women. The intervention focused on diet quality rather than weight loss, per se. The intervention included an initial web-based assessment, health behavior counseling from the participants' doctor based on the assessment, follow-up intervention via the web, and periodic phone and e-mail interaction with a health counselor. Target behaviors for the intervention included increasing physical activity (30-60 minute goal), fruit and vegetable intake, fiber intake, and decreasing dietary fat. Participants logged on to a secure website and completed monthly modules that included goal setting for target behaviors, behavior change skills, and educational topics on physical activity and nutrition. Trained health counselors sent individualized monthly e-mails and made quarterly counseling phone calls.

The wait list control group received usual-care which consisted of previously scheduled provider visits without health behavior counseling and a standard set of materials summarizing diet and activity recommendations. At the end of the 12 months, waitlisted women were also given the option to cross over to the intervention.

Assessment

Data were collected at baseline, 6 months, and 12 months in the PACE study office. All self-report measures were completed as part of a battery of computer administered assessments and height and weight was measured in person by a trained research assistant.

Measures

Body Mass Index (BMI)

BMI was calculated from height and weight as kilograms per squared meters (kg/m^2). Height (without shoes) was measured using a stadiometer with the subject standing erect against a wall with heels close to the wall. Weight was measured using a calibrated digital scale.

Center for Epidemiological Studies Depression Scale (CESD-10)

The Center for Epidemiological Studies Depression Scale (CESD-10) (Andresen, Malmgren, Carter, & Patrick, 1994) is a 10-item short form of a scale which asks participants to report how often they felt specific symptoms of depression during the previous week from rarely or none of the time (0) to all of the time (3). The scoring for positive items is reversed so that higher scores indicate more depressive symptoms. The authors of the CESD-10 suggest that a score of 10 or greater be considered as a cutoff for probable depression. The 10-item scale has been shown to have good internal consistency (Cronbach α = 0.92) and test-retest reliability (r = 0.83) (Irwin, Artin, & Oxman, 1999). The 10 items were also separated into 3 somatic and 7 mood items (Knight, Williams, McGee, & Olaman, 1997) for separate analysis, since changes in physical activity may have affected reporting on the somatic items. Physical activity may be associated with an increase in energy and improved sleep, and at the same time be associated with fatigue and muscle soreness.

Physical activity

Physical activity was measured with the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003). Total minutes of moderate and vigorous physical activity per day were calculated. The initial validation of the IPAQ showed good test-retest repeatability (repeatability coefficient for the pooled data from all study centers was 0.81) (Craig et al., 2003). The criterion validity against accelerometer was modest, with a pooled coefficient of 0.33. Reliability and criterion validity against accelerometer for a computerized version of the IPAQ long format were comparable to those reported earlier for the "paper and pencil" format (Vandelanotte, De Bourdeaudhuij, Philippaerts, Sjöström, & Sallis, 2005). For these analyses, the data were combined into one variable representing average moderate activity, vigorous activity, and walking MET minutes per day.

The ActiGraph accelerometer (AGA) is a small, lightweight, unidirectional accelerometer that measures accelerations in the vertical plane, recording activity counts in a given time interval. Minutes of light, moderate and vigorous activity are then estimated from the activity counts (Treuth et al., 2004; Trost et al., 1998). The monitor has been successfully used with adults in field settings (Nichols, Morgan, Chabot, Sallis, & Calfas, 2000). For these analyses, the data were combined into one variable representing moderate and vigorous activity minutes per day.

S*edentary behavior*

The Sedentary Behaviors Inventory (SBI) is a 7-item inventory which assesses amount of time spent in sedentary behavior (e.g., watching TV, reading, and driving). Items range from 0 (no time) to 8 (> 6 hours) and assess separately for a typical weekday and weekend day. Initial evaluation provides evidence for the reliability and validity of the SBI. Two-week test-retest correlation coefficients ranged from .64 to .90

for weekday and.51 to .93 for weekend. Concurrent validity coefficients when comparing SBI summary scores to the IPAQ sitting time estimate were small but statistically significant [weekday sedentary time ($r = .36$, $p < .001$), weekend sedentary time ($r = .26$, $p < .001$), and sedentary hours per week ($r = .36$, $p < .001$)] (Rosenberg et al., 2007).

Dietary Behaviors.

The Fred Hutchinson Cancer Research Center Food Frequency Questionnaire (FFQ) was originally developed and used in the Women's Health Initiative (WHI) Study (Rossouw et al., 1995). The FFQ has been shown to be useful in deriving estimates of total fruit, vegetable, fiber, and fat intake similar to those of 4-day food records and short-term dietary recalls (Kristal, Feng, Coates, Oberman, & George, 1997; Patterson et al., 1999). It has also been tested and used among multiethnic and mixed gender populations (Kristal et al., 1997). Data from the FFQ was summarized into daily servings of fruits, vegetables, and daily grams of dietary fiber per 1000 kilocalories. In addition, a daily percent of energy from total fat was computed.

The Healthy Eating Index (HEI) was utilized to create a composite outcome variable representing diet quality (Basiotis, Carlson, Gerrior, Juan, & Lino, 2002) in order to reduce the number of dependant variables. The index is comprised of 10 components consisting of grains, vegetables, fruit, milk, meat, total fat, saturated fat, cholesterol, sodium, and diet variety reflecting recommendations of the U.S. Department of Agriculture Food Guide Pyramid and the U.S. Dietary Guidelines for Americans. Scores for each component range from 0 to 10 with a possible total score of 100. Since servings of grains were not available from the FFQ data, grams of fiber were substituted as a component. The Institute of Medicine (IOM, 2002) recommends that men and women 50 years and younger consume 38 and 25 grams per day, respectively, while for those over 50, 30 and 21 grams per day is recommended due to decreased food

consumption. Reflecting the intervention targets, only the components of fiber, vegetables, fruit, and total fat were used, resulting in a possible total score of 40.

Adherence

Measurement of adherence to an intervention or treatment may involve a variety of methods depending on the type of intervention. Objective measurement of adherence may include pill count, physical tests, blood work, electronic monitoring, or observation, while subjective measurement of adherence may include self report, collateral or proxy report, or medical record review (DiMatteo, 2004). Some objective measures may be invasive to the participant like biological markers found in blood, urine or stool, or physical tests (Windhauser et al., 1999). Self report is less invasive but relies on the accuracy and honesty of reports (Windhauser et al., 1999). In a meta-analysis of patient adherence to medical treatment outcome (including behavioral outcomes), Dimatteo et al. (2002) conclude that adherence measures should be continuous instead of dichotomous, multiple adherence measurement methods should be utilized, and measures should include self report.

Several large studies of dietary and physical activity interventions have combined objective and subjective methods of adherence measurement. The Diabetes Prevention Program (DPP) used self-reported records and objective measures of adherence to their lifestyle intervention. Adherence was measured by the number of self-monitoring dietary records completed by participants and the number of sessions attended during the program (Wing et al., 2004). In the Dietary Approaches to Stop Hypertension (DASH) trial (Windhauser et al., 1999), a subjective adherence score was calculated based on the amount of deviation from the prescribed study diet as reported by the participant's daily diaries. This adherence score was used to calculate mean adherence per week and determine the percentage of adherent days per participant. In addition, an

anonymous post-study survey was used for retrospective evaluation of overall dietary study adherence. Objective measures included meal attendance and consumption at the study's center as well as urinary analysis. The Freedom from Fat program (Streit, Stevens, Stevens, & Rossner, 1991) subjectively measured adherence by the number of self-monitoring dietary records completed by participants during intervention. A randomized trial comparing four popular diets used two subjective techniques to measure dietary adherence to the prescribed diet (Dansinger, Gleason, Griffith, Selker, & Schaefer, 2005). Participants completed 3-day food records at various measurement time points which were then used to compute a 10-point score to reflect dietary adherence. In addition, participants were asked monthly to rate their level of dietary adherence during the previous 30 days using a similar 10-point scale. The Women's Health Initiative Dietary Modification study measured adherence as the percentage of sessions attended out of those assigned and the percentage of self-monitoring records submitted out of those assigned (Tinker et al., 2002).

Internet-based studies allow for objective adherence data to be collected by computer. For example, adherence is typically measured with "hit" rates or webpage clicks, log-on rates, modules completed, and usage patterns (Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004; Zabinski, Norman, Adams, & Rosenberg, 2006). One study examining web-based nutrition counseling and social support used number of times the site was visited and visit duration to measure adherence (Verheijden et al., 2004). Another study comparing human e-mail counseling, computer-automated tailored counseling, and no counseling in an Internet weight loss program measured adherence by number of log-ons and number of online diary submissions (Tate, Jackvony, & Wing, 2006).

As the PACEi Men in Motion and the PACEi Women in Balance interventions are web-based, objective adherence data was collected. Type and frequency of potential participation activities reflecting what was expected of participants in each study are outlined in Table 1. For men, the possible activities include 36 readings and 52 weekly goal setting sessions. For women, the possible activities include 36 readings, 4 phone calls, 12 goal setting sessions, and 12 counseling e-mails. Adherence data to counseling phone calls and e-mails for the women was entered into the database by case managers. Adherence to online readings and goal setting for both men and women were recorded automatically through the website into a case management database. Online readings were recorded as "webpage clicks" in the database. Since participants were able to review pages multiple times, as well as explore other website content in addition to the online readings, there was no upper limit to the number of page clicks possible, preventing calculation of percent completed. Therefore, for women, the adherence score used in the analyses was calculated based on percent of returned e-mails and percent of goals set. Goals set and e-mails returned were selected because they were both viewed as being important clinically, both had an upper limit allowing for percent calculations, and both required more participation from the women in comparison to page clicks, thereby representing greater involvement in the program. In addition, goals, e-mails, page clicks, and phone calls were all significantly correlated ($p < .0005$), so the two thought to be most important clinically were used. For men, goals and page clicks were also significantly correlated ($p < .0005$). For similar reasons, an adherence score was calculated based on percent of goals set.

Table 1. Type and frequency of potential participation activities.

	Men	**Women**
Intervention modules	12 monthly possible consisting of 3 online readings each	12 monthly possible consisting of 3 online readings each
Phone calls	---	4 quarterly counseling calls
Goals	52 weeks of online goal setting	12 monthly online goal setting
Counseling E-mails	---	12 e-mails received from health counselor and responded to by participant

Statistical analyses

Preliminary analysis plan:

1. Conduct a power analysis to determine if sufficient power exists in the present study to detect an effect for change in dietary behaviors, physical activity, and BMI.
2. Calculate descriptive statistics including sample size, number of subjects per condition, age, BMI, ethnicity, number of children, marital status, and level of education.

Mediator analysis

Mediators of an intervention identify possible causal links between the treatment and outcome. An intervention mediator has to be a variable indicating change during the intervention, must correlate with the treatment, and also be related to the outcome. Thus, the change in the mediator may be a result of the intervention (Kraemer et al., 2002). According to Baron and Kenny (1986), a given variable may be said to function

as a mediator to the extent that it accounts for the relationship between the predictor and the criterion. The following conditions must be met for mediation:

1. Variations in levels of the independent variable significantly account for variations in the presumed mediator (Path A)
2. Variations in the mediator significantly account for variations in the dependent variable (Path B)
3. When Paths A and B are controlled, a previously significant relation between the independent and dependent variables (Path C) is no longer significant. If the residual Path C is not zero, this indicates the operation of multiple mediating factors. If there is partial mediation, the relationship would still be significant between the independent and dependent variables, but there would be a reduced effect (Baron & Kenny, 1986).

Kraemer et al. (2001) proposed an operational definition of mediators which is consistent with Barron and Kenny's conceptual definition but which help clarify some points. Building on the definitions, they show the necessity of establishing temporal precedence of the intervention before the mediator. Specifically, to show that a variable is a mediator of an intervention, the mediator would have to measure an event or change occurring *during* treatment, not something that is measured retrospectively at post-treatment time points (Kraemer et al., 2002). Kraemer et al. (2002) additionally point out the importance of measuring potential mediators several times during the intervention, not just at midpoint, as mediators may operate early and intensively.

Moderator analysis

A moderator is a variable that affects the direction and/or strength of the relationship between an independent and a dependent variable (Baron & Kenny, 1986). Treatment modifiers specify for whom or under what conditions the treatment works

(Baron & Kenny, 1986). Moderator analysis can help clarify which participants might be most responsive to a particular treatment or if another treatment might be more appropriate (Kraemer et al., 2002). This informs whether tailoring of an intervention for a population or subset of population might be appropriate.

A moderator effect is tested by the presence of an interaction between the moderator and treatment condition (Baron & Kenny, 1986). Kraemer et al. (2002) additionally specify that a moderator must be a baseline or pre-randomized characteristic (and uncorrelated with treatment).

Specific Aim I

Does baseline level of depression moderate the intervention effect on outcome at 12 months (dietary behaviors, physical activity, sedentary behavior, and BMI)? (Figure 1)

Analysis plan:

1. A regression analysis was performed examining if treatment predicted outcome and interacted with baseline depression.

Model: $O = \beta_0 + \beta_1 T + \beta_2 M + \beta_3 TxM$

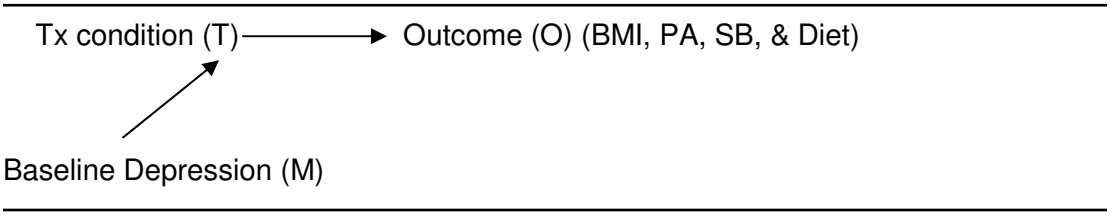

Figure 1. Model: Baseline depression moderates the effect of treatment on outcome.

Specific Aim II

Does adherence (0 -12 months) to the intervention mediate baseline depression on outcome? (Figure 2)

Analysis plan:

1. An adherence score was computed reflecting the percentage of the intervention completed over the course of 12 months.
2. A series of regressions were performed to determine if depression and adherence were significantly related, if adherence and outcome were significantly related, and if depression and outcome were significantly related.
3. Where appropriate, a regression analysis was performed where outcome was regressed on adherence and depression.

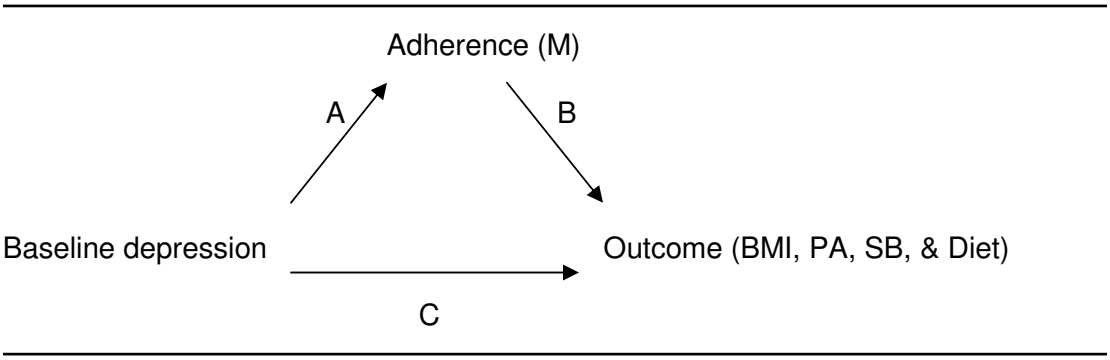

Figure 2. Model: Adherence mediates baseline depression on outcome.

Specific Aim III

Is the effect of change in depression (from 0 - 6 months) mediated by change in adherence (change in rate from 0-6 – 7-12) on outcome? (Figure 3)

Analysis plan:

1. A change score for depression was computed from 0 to 6 months.
2. A change score for adherence was computed by subtracting the 7 to 12 month adherence score from the 0 to 6 month adherence score.
3. A series of regressions were performed to determine if change in depression and change in adherence were significantly related, if change in adherence and

outcome were significantly related, and if change in depression and outcome were significantly related.

4. Where appropriate, a regression analysis was performed where outcome was regressed on changes in adherence and depression.

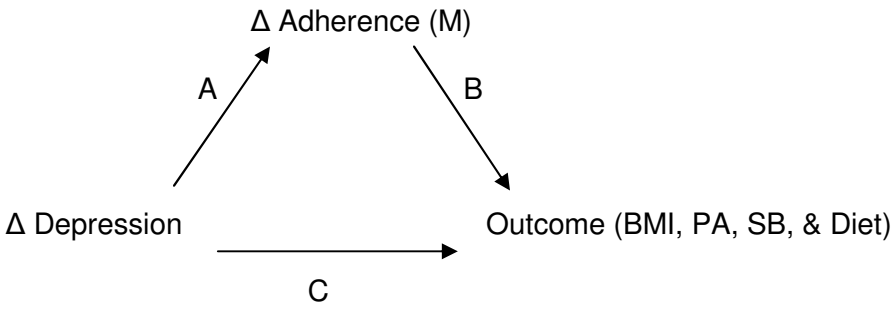

Figure 3. Model: Change in adherence mediates the change in depression's effect on outcome.

Specific Aim IV

Does treatment condition affect depression?

Analysis plan:

1. Analysis of covariance was used to analyze the effect of the intervention versus control condition on depression at 12 months while controlling for baseline depression.

Results

Power Analysis

The purpose of the power analysis was to determine if sufficient power existed in the present study to detect potential effects. A review of the literature was conducted to locate diet and physical activity intervention studies that were similar to the Men in Motion and Women in Balance interventions in terms of study design (randomized trial), outcome measures, mode of delivery, and participant sample. Effects sizes were calculated from the studies that met the criteria and provided sufficient data for the calculations. These effect sizes from the literature and the 12-month intervention sample sizes from Men in Motion and Women in Balance (men n = 155, women n = 146) were used in the power analysis. Power was calculated separately for the men's and women's samples but the results were nearly identical so one set of numbers is presented. All power analyses were conducted using G*power software (Faul, Erdfelder, Lang, & Buchner, in press).

For the dietary variables, 3 studies were located (Havas et al., 2003; Stevens, Glasgow, Toobert, Karanja, & Smith, 2003; Tate et al., 2006). Effect sizes ranged from d = .24 to .72 for dietary fat, d = .12 to .49 for fruits and vegetables, and d = .14 for fiber. For both men and women, calculated power ranged from .99 to 1.0 for dietary fat, .97 to 1.0 for fruits and vegetables, and .99 for fiber.

For the physical activity variables, 3 studies were located (Fahrenwald, Atwood, & Johnson, 2005; Hurling et al., 2007; Tate et al., 2006). Effect sizes for self-reported physical activity varied greatly, where d = .00, .27, and 1.82. For both men and women, calculated power was found to be .05, .99, and 1.0. The effect size for accelerometer physical activity was calculated as .19, resulting in calculated power = .99, for both men and women.

Two studies were located reporting weight and/or BMI changes (Tate, Jackvony, & Wing, 2003; Tate et al., 2006). Effect sizes were found to be d = .21 and .37. For men and women, calculated power = .99 and 1.0.

The results of these power calculations indicate that the present study has sufficient power to detect similar effect sizes of diet, physical activity and weight should they exist.

A recent article by Fritz and MacKinnon (2007) outlines the required sample sizes needed to detect a medicated effect for several tests of mediation including Baron and Kenny's (1986). Sample sizes necessary to achieve .8 power to detect complete mediation were quite large, ranging from 20,886 to 92, depending on the sizes of Paths A and B in the mediation model. However, sample sizes needed to detect partial mediation ranged from 562 to 36, also depending on the sizes of Paths A and B in the mediation model. For example, for moderately sized Paths A and B, the sample sizes necessary to detect partial mediation range from 224 to 158. Using these estimates as a guide, the analyses in the present study are likely to have sufficient power to detect partial mediation with even moderately sized Paths A and B.

Missing Data

Missing data in each analysis was handled using the listwise deletion option in SPSS. This ensured that all cases included had data available for each time point of the variables in the analysis.

Residualized Change Scores and Data Transformations

Residualized change scores were used in the regression analyses where appropriate as recommended for randomized trials (Van Breukelen, 2006). This allowed changes in variables to be examined while controlling for baseline values. In

addition, use of raw change scores would have resulted in increased problems with non-normality.

For the moderation and mediation analyses, several of the variables needed to be transformed due to non-normality. In the men's data, the baseline and 12-month CESD and SBI data were transformed using a log transformation. In the women's data, baseline and 12-month CESD, AGA accelerometer physical activity, and IPAQ physical activity data were transformed using a log transformation.

Demographics

Men in Motion

At baseline, the sample included 441 men with a mean age of 43.9 (sd = 8.0) years and BMI of 34.2 (sd = 4.1). Seventy-one percent of the sample identified themselves as white, non-Hispanic; 18.1% as Latino/Hispanic; 5.2% as African-American, non-Hispanic; 1.6% as Asian/Pacific Islander; 0.5% as Native American; 2.0% as multi-racial or multi-ethnic; and 1.6% as other or declined to state. Seventy percent of the sample reported that they were married or living with a partner and 65% reported they had at least one child. Approximately 63% of participants indicated having at least a college degree, some graduate education, or a graduate degree. There were no statistically significant differences between conditions at baseline on demographic variables except for age (p=.006). At baseline, 27% of the men in the intervention group and 22% of men in the control group met the cutoff for depression (χ^2= 1.3, p < .26). See Table 2 for general demographics.

Over the course of the intervention, mean percent adherence (goal setting) was 37% (sd = 31.2) for the intervention group. Thirty percent of the intervention group completed more than half of the intervention modules. Adherence data is presented in Table 3.

At 12-month follow up, a total of 308 men were available for measurement, representing 70% of the sample (68% of the intervention group, n = 153; 71% of the control group n = 155; χ^2= .51, p < .48). An analysis of variance was performed to determine if there was differential drop out in the intervention and control groups. In the intervention group, men who dropped from the study were significantly heavier (BMI: 35.2 vs. 33.7, p < .01) and had significantly poorer diet quality (HEI: 17.7 vs. 20.4, p < .02) at baseline than those who remained in the study. In the control group, men who dropped from the study were also significantly heavier (BMI: 35.3 vs. 33.9, p < .02) and were significantly more depressed (CESD: 7.5 vs.6.3, p < .03) at baseline than those who remained in the study. Additional descriptives of baseline and 12-month measures can be found in Tables 4 and 5.

Women in Balance

At baseline, the sample included 401 women with a mean age of 41.2 (sd = 8.7) years and BMI of 32.3 (sd = 4.5). Sixty-one percent of the sample identified themselves as white, non-Hispanic; 20.4% as Latino/Hispanic; 7.2% as African-American, non-Hispanic; 5.2% as Asian/Pacific Islander; 0.2% as Native American; 3.5 % as multi-racial or multi-ethnic; and 2.5% as other or declined to state. Sixty-seven percent of the sample reported that they were married or living with a partner and 70% reported they had at least one child. Approximately 46% of participants indicated having at least a college degree, some graduate education, or a graduate degree. There were no statistically significant differences between conditions at baseline on demographic variables except for BMI (p = .03). At baseline, 24% of the women in the intervention group and 30% of women in the control group met the cutoff for depression (χ^2 = 1.7, p < .20). See Table 6 for general demographics.

Over the course of the intervention, mean percent adherence (goal and e-mails) was 42% (sd = 26.0) for the intervention group. Thirty-six percent of the intervention group completed more than half of the intervention modules. Adherence data is presented in Table 7.

A total of 286 women were available for measurement at 12-month follow up representing 71% of the sample (68% in intervention group, n = 140; 75% in the control group n = 146; $\chi^2 = 1.9$, $p < .17$). An analysis of variance was performed to determine if there was differential drop out in the intervention and control groups. In the intervention group, women who dropped from the study reported engaging in significantly more physical activity at baseline (IPAQ (MET-min/day): 498.5 vs. 335.8, $p < .02$) than those who remained in the study. Also in the control group, women who dropped from the study reported engaging in significantly more physical activity at baseline (IPAQ (MET-min/day): 530.4 vs. 352.1, $p < .05$) than those who remained in the study. Additional descriptives of baseline and 12-month measures can be found in Tables 8 and 9.

Specific Aims

Specific Aim I

Does baseline level of depression moderate the intervention effect on outcome at 12 months? (Includes entire sample)

Regression analyses were used to test moderation effects. An interaction term was computed for group by baseline depression. Twelve-month outcome data were regressed on group, baseline depression, the interaction term, and baseline outcome.

Men

Baseline depression (log) did not moderate the intervention effect on the outcomes of BMI, HEI, IPAQ and AGA (log). However, baseline depression (log) did moderate the differential intervention effect on SBI (log) with a significant interaction of

group*depression(log) (β = -.70, p < .0005) (see Table 10). Since baseline depression was a continuous measure, SBI values were plotted to explore the nature of the interaction. Using the regression equation, four SBI data points were calculated. Values entered in the equation were treatment condition (intervention, control) and CESD score (one standard deviation above the mean, one standard deviation below the mean). Results indicate that SBI scores did not vary much by baseline depression in the intervention group, but did vary for men in the control group, where men with low baseline depression scores had much higher SBI scores compared to men with high baseline depression scores (see Figure 4). Further post hoc analyses using the suggested CESD >= 10 score as a cutoff for depression found that for men in the intervention group, depressed participants reduced their SBI score by 1.2 and non-depressed participants reduced their score by 1.3. For men in the control group, depressed participants reduced their SBI score by 2.8 while the non-depressed participants increased their score by 0.1. Additionally, baseline SBI scores were significantly higher for the men in the control group who were depressed at baseline in comparison to any other group (contrast p's all < .02). Significantly greater improvements in CESD scores were also found in the control group men who were depressed at baseline in comparison to any other group (contrast p's all < .005) (see Table 11). For all men, over the course of 12 months, improvements in CESD scores were significantly correlated with reduction in SBI scores (r = .115, p < .04).

Women

Baseline depression (log) did not moderate the intervention effect on the outcomes of BMI, SBI, IPAQ(log), and AGA (log). However, baseline depression did moderate the intervention effect on HEI with a significant interaction of group*depression(log) (β = -.62, p < .003) (see Table 12). Since baseline depression

was a continuous measure, HEI scores were plotted to explore the nature of the interaction. Using the regression equation, four HEI data points were calculated. Values entered in the equation were treatment condition (intervention, control) and CESD score (one standard deviation above the mean, one standard deviation below the mean). Results indicate that women in the control group had lower 12-month HEI scores than the intervention women, with the lowest values being among women with high depression scores. In the intervention group, women with higher depression scores had higher HEI scores at 12 months (see Figure 5). Further post hoc analyses using the suggested CESD >= 10 score as a cutoff for depression found that for women in the intervention group, depressed participants increased their HEI score by 8.1 and the non-depressed participants increased their score by 6.0. For the control group, non-depressed women increased their HEI score by .81 and depressed women decreased their score by 1.3. Additionally, depressed women in the intervention group had the lowest HEI scores at baseline (this difference was only significant between the depressed intervention and the control non-depressed women, $p < .01$) (see Table 13).

Specific Aim II

Does adherence to the intervention mediate baseline depression on outcome? (Includes intervention participants only, 12-month n for men = 153; 12-month n for women = 140)

A series of regression analyses were performed to test the significance of paths A, B, and C utilizing residualized change scores. For Path A: Adherence was regressed on baseline depression. For Path B: Twelve-month outcome data was regressed on adherence and baseline outcome. For Path C: Twelve-month outcome data was regressed on baseline depression and baseline outcome. If Paths A, B, and C were found significant, a regression analysis was run to determine if the previous significant Path C remained significant while controlling for Paths A and B.

Men

Path A: Baseline depression (log) was significantly related to the percent of goals set (β = -.15, p < .02), where as depression scores increased, adherence decreased (see Table 14).

Path B: Percent of goals set was significantly related to BMI (β = -.11, p < .0005), HEI (β = .28, p < .0005), SBI (log) (β = -.16, p < .02), and AGA (log) (β = .22, p < .02) at 12 months while controlling for baseline. While adherence increased, BMI and SBI decreased, and HEI and AGA increased. Percent of goals set was not significantly related to IPAQ physical activity (see Table 15).

Path C: Baseline depression (log) was significantly related to 12-month outcome of HEI (β = -.19, p < .003) while controlling for baseline, where as depression scores increased, healthy eating decreased. Baseline depression was not significantly related to 12-month outcomes of BMI, IPAQ, AGA (log), and SBI (log) while controlling for baseline (see Table 16).

To test mediation, 12-month HEI was regressed on baseline depression (log) and baseline HEI while controlling for adherence. The previous significant relationship between baseline depression (log) and HEI remained significant (β = -.14, p < .02), but the effect was reduced, indicating that partial mediation may be present (see Table 17). The difference in coefficients was computed as a measure of the indirect effect of the mediating variable adherence (c – c' = -6.3 – (-4.8) = -1.5) (Baron & Kenny, 1986; Judd & Kenny, 1981). The Aroian version of the Sobel test equation as recommended by Baron and Kenny (1986) was used to test the indirect effect of mediation on HEI and was found to be significantly different than zero (z = -1.99, p < .05).

Post hoc analyses revealed that men who were not depressed at baseline had significantly higher adherence rates (41% vs. 25%, F[1,222] = 11.7, p = .001) and

significantly increased their HEI score in comparison to those who were depressed at baseline (m = 6.3 vs. m = 2.5, respectively, F[1,151] = 7.8, p < .006) (see Table 18).

Women

Path A: Baseline depression (log) was not significantly related to the average percent adherence (see Table 19).

Path B: Average adherence was significantly related to HEI at 12 months (β = .24, p < .001) while controlling for baseline, where as adherence increased so did HEI. Average adherence was not significantly related to BMI, SBI, IPAQ (log), and AGA (log) physical activity (see Table 20).

Path C: Baseline depression (log) was not significantly related to 12-month outcomes of BMI, HEI, IPAQ (log), AGA (log), and SBI while controlling for baseline (see Table 21). Further analyses were not performed since Path A and Path C were found not significant.

Specific Aim III

Is the effect of change in depression (from 0 to 6 months) mediated by change in adherence (change in rate from 0-6 to 7-12) on outcome? (Includes intervention only, 12-month n for men = 153; 12-month n for women = 140)

A series of regression analyses were performed to test the significance of paths A, B, and C utilizing residualized change scores. A change score was computed reflecting the change in adherence from the first 6 months of the intervention (0-6) to the last 6 months (7-12) by subtracting the 0-6 adherence rate from the 7-12 adherence rate. In addition, to simplify analyses, a change score was computed reflecting the change in depression scores from 0 to 6 months. For Path A: Change in adherence rate was regressed on change in depression. For Path B: Twelve-month outcome data was regressed on change in adherence and baseline outcome. For Path C: Twelve-

month outcome data was regressed on change in depression and baseline outcome. If Paths A, B, and C were found significant, a regression analysis was run to determine if the previous significant Path C remained significant while controlling for Paths A and B.

Men

Path A: Change in adherence was not significantly related to change in depression from 0 to 6 months (see Table 22).

Path B: Change in adherence was significantly related to BMI ($\beta = -.07$, $p < .03$) at 12 months while controlling for baseline, where as adherence increased, BMI decreased. Change in adherence was not significantly related to HEI, SBI (log), IPAQ, and AGA (log) (see Table 23).

Path C: Change in depression was significantly related to SBI (log) ($\beta = .19$, $p < .02$) and AGA (log) ($\beta = -.23$, $p < .02$) at 12 months while controlling for baseline, where as depression improved, SBI decreased and AGA increased. Change in depression was not significantly related to BMI, HEI, and IPAQ physical activity (see Table 24). Further analyses were not performed since Path A was found not significant.

Women

Change in depression from 0 to 6 months was transformed with a log transformation to help correct for non-normality. Path A: Change in adherence was not significantly related to change in depression from 0 to 6 months (see Table 25).

Path B: Change in adherence was not significantly related to BMI, HEI, IPAQ (log), AGA (log), and SBI (see Table 26).

Path C: Change in depression was not significantly related to BMI, HEI, IPAQ(log), AGA (log), and SBI (see Table 27). Further analyses were not performed since Paths A, B, and C were found not significant.

Specific Aim IV

Does treatment condition affect depression? (Includes entire sample)

Men

Analysis of covariance of CESD 12-month scores (log) by group while controlling for baseline revealed that men in the intervention group had significantly different reductions in their depressive symptom scores than those in the control group ($p < .04$). Men in the intervention group reduced their CESD scores from m = 7.4 at baseline to m = 6.6 at 12 months, while men in the control group stayed about the same m = 6.3 at baseline to m = 6.6 at 12 months. When mood and somatic items were analyzed separately, no group differences were found. See Table 28. Post hoc analyses of the 12-month completers revealed that in the intervention group 26% of the sample was depressed at baseline and 22% was depressed at 12 months, using the CESD >= 10 cutoff. In the control group, 21% was depressed at baseline and 29% was depressed at 12 months.

Women

Analysis of covariance of CESD 12-month scores (log) by group while controlling for baseline revealed that women in the intervention group had significantly different reductions in their depressive symptom scores than those in the control group ($p < .007$). Women in the intervention group reduced their CESD scores from m = 7.1 at baseline to m = 5.3 at 12 months, while women in the control group reduced from m = 7.3 at baseline to m = 6.5 at 12 months. When mood and somatic items were analyzed separately, significant group differences were also found. Analysis of covariance of 12-month CESD scores by group while controlling for baseline revealed that women in the intervention group had significantly different reductions in their mood (log) and somatic scores than those in the control group ($p < .008$ and $p < .03$, respectively). For the

mood items, women in the intervention group reduced their scores from m = 4.5 at baseline to m = 3.0 at 12 months, while women in the control group reduced from m = 4.4 at baseline to m = 3.7 at 12 months. For the somatic items, women in the intervention group reduced their scores from m = 2.9 at baseline to m = 2.3 at 12 months, while women in the control group reduced from m = 3.1 at baseline to m = 2.8 at 12 months. See Table 29. Post hoc analyses of the 12-month completers revealed that in the intervention group 23% of the sample was depressed at baseline and 13% was depressed at 12 months, using the CESD >= 10 cutoff. In the control group, 30% of participants were depressed at baseline and 19% were depressed at 12 months.

Discussion

This study investigated the effect of depression on adherence to a dietary and physical activity behavior change intervention in a sample of overweight and obese men and women. Since the Men in Motion and Women in Balance studies were independent of each other, analyses were performed in parallel. A discussion of the results of each specific aim follows.

Moderation Analyses

Aim 1

Moderator analysis can help clarify which participants might be most responsive to a particular treatment (Kraemer et al., 2002). Baseline depression, as a potential moderator, may affect the direction and/or strength of the effect of treatment on outcome. For Aim 1, it was hypothesized that greater improvements in outcome would be observed in participants exhibiting fewer depressive symptoms at baseline. Determining if the intervention is as effective for those who are depressed at baseline versus those who are not can help inform development and tailoring of the intervention as well as participant selection.

Men

Baseline level of depression was found to moderate the differential intervention effect on sedentary behavior for men. Men in the intervention group reduced their sedentary behavior about the same amount regardless of depression status at baseline. This pattern was not seen in the control group. Non-depressed men in the control group slightly increased their sedentary behavior while depressed men decreased their sedentary behavior time. This result is surprising and in contrast to the hypothesis because one might expect depressed participants to have greater difficulty in reducing their sedentary behavior than non-depressed participants. One explanation may be that

men in the control group who were depressed at baseline improved their depression over the 12 months and in the process reduced sedentary time. Post hoc analyses did reveal significantly greater improvements in depression in this group in comparison to any other group. In addition, sedentary behavior scores at baseline were significantly higher for the men in this group in comparison to any other group. While greater reductions in sedentary behavior in the intervention group would have been ideal, they were in the expected direction and not affected by depression status at baseline. Overall, improvement in depression over the 12 months was significantly correlated with reduction in sedentary behavior. It should also be noted that reduction of sedentary behavior was not an explicit target of the intervention.

Women

Baseline level of depression was found to moderate the intervention effect on dietary changes for women. Women in the intervention group improved their dietary quality more than the control group, with greater improvements seen in intervention women with higher baseline depression. Depressed women in the control group had a slight decrease in diet quality. Since the depressed women in the intervention group had the lowest diet quality at baseline it is not surprising that the greatest increases were seen in this group. The results of these analyses indicate that the women in the intervention group benefited from improved diet quality and that those who were depressed at baseline may have improved the most.

For both men and women, in contrast to the hypothesis, baseline depression did not decrease the benefits to participating in the program. In fact, the current analyses provide some evidence for increased benefit to those who were depressed at baseline, at least for the women. As baseline depression did not interfere with treatment effect, the interventions may be appropriate for those who are similarly depressed. Screening

out those participants who are most depressed due to concern for their ability to participate may not be warranted.

Mediation Analyses

Aim 2

A given variable may be said to function as a mediator to the extent that it accounts for the relationship between the predictor and the criterion. Depressed participants have been shown to have poorer adherence, and poorer adherence has been linked to poorer outcome. For Aim 2, it was hypothesized that participants with greater depressive symptoms would have poorer outcomes, and that this relationship would be at least partially explained by poorer adherence (the mediator) to the intervention.

Men

The hypothesis was confirmed for dietary quality. Adherence was found to partially mediate baseline depression on dietary quality for men. The significant relationship between depression and dietary quality was at least partially explained by lower adherence rates in the depressed at baseline men, and lower adherence rates resulting in poorer dietary outcomes.

The hypothesis was not confirmed for BMI, physical activity (AGA or IPAQ), or sedentary behavior. Although baseline depression was significantly related to adherence (Path A), and adherence was significantly related to BMI, AGA physical activity, and sedentary behavior (Path B), baseline depression was not directly related to BMI, AGA physical activity, and sedentary behavior (non-significant Path C). Several researchers have questioned the need to show an association in Path C (Kraemer et al., 2002; MacKinnon, Krull, & Lockwood, 2000; Shrout & Bolger, 2002) implying that a significant Path A and Path B may by sufficient to show mediation. Following these

guidelines, adherence also partially mediated baseline depression on BMI, AGA physical activity, and sedentary behavior for men where baseline depression predicted lower adherence rates and lower adherence rates predicted poorer outcome for BMI, AGA physical activity, and sedentary behavior.

Women

The hypothesis was not confirmed for women. Baseline depression did not predict adherence rates. Post hoc analyses showed that there were no significant differences between non-depressed and depressed participants in adherence rates (42% vs. 42%, $F[1,178] = .001$, $p = .97$). Adherence was only related to changes in dietary quality in the expected direction, but not to changes in BMI, physical activity, or sedentary behavior. In addition, baseline depression was not related to changes in BMI, dietary quality, physical activity, and sedentary behavior.

For both men and women, adherence was related to improved outcome on some of the measures. The finding that adherence was significantly related to dietary quality in men is consistent with the main treatment effects of the Men in Motion intervention (Calfas et al., 2007). Similarly, the finding that adherence was significantly related to dietary quality in women is consistent with the main treatment effects of the Women in Balance intervention (Calfas et al., 2005). Surprisingly, depression was only related to adherence for men and not for women. This is in contrast to previous research (DiMatteo et al., 2000; Gehi et al., 2005; Kalsekar et al., 2006; Morgan et al., 2006), which found depression and adherence to be related for men and women. The Women's Health Initiative (WHI) Dietary Modification Trial (Tinker et al., 2002), the only other study located examining a mediational relationship with emotional state, adherence, and dietary outcome, found that mental health (as measured by the SF-36) was significantly related to program participation. In fact, the WHI Trial found that

program participation partially mediated the relationship between mental health and dietary changes (Tinker et al., 2002).

It is unclear why no significant relationship between baseline depression and adherence was found for women in the current analysis. One hypothesis is that it may have been related to the type of intervention. The Women in Balance intervention included personal contact through monthly individualized e-mails and quarterly counseling phone calls. Anecdotally, women frequently reported that they enjoyed the personal contact. It is plausible that women in the intervention who were more depressed responded in a positive way to the personal contact. This may have contributed to the comparable adherence rates in the depressed and non-depressed groups. Additionally, the personal contact may also have contributed to the improved depression scores seen in the intervention group in comparison to the control.

No studies were located examining the mediational relationship of depression, adherence, and outcome with a sample of men. While the relationship between depression and adherence as well as between adherence and outcome have been previously established (DiMatteo et al., 2002; DiMatteo et al., 2000), this is the first study to examine the mediational relationship among the three variables. The current analysis found that adherence partially mediated the effect of baseline depression on dietary quality for men. In addition, adherence was found to also partially mediate the effect of baseline depression on BMI, physical activity, and sedentary behavior changes (with the exclusion of a significant Path C requirement). These findings confirmed that depression can affect adherence which in turn can affect outcome.

Aim 3

Weight loss and physical activity have been shown to improve depressive symptoms. For Aim 3, it was hypothesized that participants whose depressive

symptoms improved over the first six months of the intervention would have more positive outcomes, and that this relationship would be at least partially explained by improved adherence to the intervention.

Men & Women

For men and women, this hypothesis was not supported. Change in adherence and change in depression were related to improved outcomes for some of the measures for men, but not for women. Yet no significant relationship was found between change in depression and change in adherence. One potential explanation for this non-significant finding is that changes in depression from 0 to 6 months may have had longer lasting effects, or delayed effects, than what was observed in this study over the course of 12 months. Improved depression may indeed contribute to improved adherence but perhaps the effect occurs with greater lag time than what was tested. More frequent measurement time points and longer follow-up may be necessary to test for effects. In addition, adherence rates declined over the 12 months for all participants regardless of depression condition. Subtle changes in <u>rate</u> of decline as a result of improved depression may not be easy to detect. Post hoc analyses were used to examine the relationship between change in depression from 0-6 months and adherence during the last half of the intervention (7-12 months), instead of rate of decline of adherence. A significant relationship was found for men only ($\beta = -.22$, $p < .008$), where improvement in depression in the first half of the intervention predicted higher adherence in the last half of the intervention, offering some support for this explanation. These post hoc results are consistent with the results in Aim II where depression was related to adherence for men only but not for women.

Effect of Treatment on Depression

Aim 4

Improved depressive symptoms have been observed in weight loss and physical activity interventions that do not explicitly focus on depression. For Aim 4, it was hypothesized that a greater improvement of depressive symptoms would be observed in the intervention group in comparison to the control group.

Men & Women

This hypothesis was supported for men and women, where the respective intervention groups had significantly greater improvements in their depression scores compared to the control groups. It should be noted that the improvements for men in the intervention group, although statistically significant and in the expected direction, were small (an improvement of less than 1 point on the CESD). Improvements for women were a little larger compared to the men, with a mean improvement of 1.8.

These findings for men and women are consistent with previous research where depression improved as a result of weight loss or participating in a weight or physical activity intervention program (Brosse et al., 2002; Bryan & Tiggemann, 2001; Dunn et al., 2001; Gladis et al., 1998; Penedo & Dahn, 2005). These findings are notable because depression improved despite the fact that it was not an intervention target. As discussed previously, women reported enjoying the personal contact with the case manager through phone and e-mail which may have contributed to improved depression scores. Although men did not have the same level of personal contact, their scores improved as well, which could be attributed to an increased sense of belonging to a group. Both men and women may have experienced increased feelings of well-being as a result of the attention of being in a study, as well as a result of taking care of one's self and mastery of health. Moreover, they may have experienced improved mood as a

result of the positive effects of physical activity and weight loss. Although the changes in depression observed fall short of what might be considered clinically meaningful change [change of 2.5 points, interpolated based on 5 points for the long form (Beekman et al., 2002)], they were in the expected direction and resulted from participation in an intervention not targeting depression. In addition, since the participants were recruited for their overweight status and not depression status, average baseline scores were sub-clinical, leaving little room for improvement. This finding underscores the importance of assessing related outcomes of an intervention as the intervention may affect areas outside of what is explicitly targeted. In addition, as people who are depressed are often reluctant to begin medication or talk therapy; this type of intervention could improve their symptoms enough to engage in other forms of treatment. It should also be noted that depression did not worsen as a result of participating in the study, whether in the intervention or control group. This is an important finding as some may argue that having overweight people focus on their overweight status may lead to increased depressive symptoms.

Study Limitations

There are several limitations to the present study. First, participants in both studies were only eligible if they had access to the Internet. In addition, the majority of participants were married or living with a partner (men 70%; women 67%), had at least one child (men 65%; women 70%) and had a college degree or higher (men 63%; women 46%). Although these factors may limit the generalizability of the findings to other populations, the sample still represents a large part of the population. In addition, there are increasing numbers of households with Internet access from 26% of U.S. households in 1998 to 54% in 2003 (U.S.CensusBureau, 2007). Some report numbers as high at 3 out of 4 Americans with home Internet access (Nielsen/NetRatings, 2004).

Another limitation of this study is the measurement frequency. Although outcome measures were obtained at baseline, 6 months, and 12 months, changes could have occurred in a non-linear fashion. More frequent measurement time points could aid in detecting changes in outcome variables and inform the process of behavior change.

In this study, depressive symptoms were assessed by the CESD-10, a self-report instrument, rather than by a structured clinical interview like the SCID. The CESD-10 asks a participant to endorse symptoms experienced over the last 7 days from a list and does not directly address clinical diagnostic criteria. While a structured clinical interview is the gold standard, the amount of time and resources involved in assessment can be prohibitive. An advantage to a self-report scale like the CESD-10 is that it is inexpensive and user-friendly. Thus, it should be noted that in this study level of depression relates to the level of self-reported depressive symptoms and not directly to a clinical diagnosis of depression. In addition, assessment of antidepressant use at baseline and changes in use over the course of the study were not reliably recorded. Understanding the effect of the intervention on changes in depressive symptoms would have been aided by this information.

In this study, sedentary behavior was assessed using a recently developed self-report measure. Unfortunately, no criterion or gold standard for measurement of sedentary behavior currently exists, limiting this area of research. As more studies include measurement of sedentary behavior, improvement and validation of self-report and objective measures are needed.

Objective measures of adherence to the web program were collected but this may have just measured “dose” of the intervention. The computer recorded how often participants visited the site, set goals, or sent e-mails but how actively participants worked on their goals on a daily basis is not known. As suggested by Dimatteo et al.

(2002), the addition of self-report measures of dietary and physical activity changes (e.g., self-monitoring records) could have strengthened the measurement of adherence to the prescribed behavioral changes. To partially address this issue, setting of goals and sending of e-mails were used as the main adherence outcome variables because they represented more involvement in the program by the participant than just pageclicks or logons.

A reduced sample size was available for 12-month measurement as some participants in both studies were lost to follow-up which could have affected power. Yet power analyses were performed using 12-month n, suggesting that the analyses had sufficient power to detect changes should they exist.

The Women in Balance study focused on dietary quality and increases in physical activity, not specifically targeting weight reduction as the Men in Motion study. Although success with these behavioral changes would likely result in weight loss, this difference prevented both samples from being combined in analyses.

Lastly, the lack of alpha control for the majority of the analyses may be considered a limitation, however, this study was exploratory by design and Type I error rates were of less relative concern.

Study Strengths

There are several strengths of this study. Both intervention studies employed a randomized design incorporating a control or waitlist group. The samples of men and women were large, diverse in ethnicity, age, and BMI range. Objective measurement of several variables helped control for self-report and social-desirability bias. Height and weight (for computing BMI) was measured objectively by a research assistant. Participants wore ActiGraph accelerometers to objectively measure physical activity in

addition to self report. Measures of adherence to the website (e.g., use, pageclicks, goals set) were automatically collected by computer.

Many weight loss studies do not include measures or analysis of adherence to behavioral interventions. In addition, depression, which has been shown to be related to weight, is often not measured in weight loss interventions or examined in relation to outcome. The analyses in this study were specifically designed to examine the relationship of depression and adherence to outcome, helping to address the limitations of the current weight loss and adherence literature (Wing et al., 2002). This is the first study to examine this relationship in men.

Another strength of this study is the contribution it makes to the moderation and mediational literature. Inclusion of moderation and mediational analyses is an important step in identifying the most effective treatments, understanding on whom treatments work, and why treatments work (Kraemer et al., 2002), yet these analyses are lacking in many reports of randomized trials (Baranowski, Anderson, & Carmack, 1998; Kraemer et al., 2002). In addition, the analyses performed in this study followed the frameworks put forth by Baron and Kenny (1986) and Kraemer et al. (2002). Because measures were taken at baseline, 6 months, and 12 months, and adherence data was collected over the course of 12 months, temporal precedence of the factors could be established for the analyses as suggested by Kraemer et al. (2002).

Both the Men in Motion and Women in Balance studies targeted multiple behaviors: dietary quality and physical activity. Treatments combining diet, physical activity, and behavior change have been shown to be more effective than diet or physical activity alone (Avenell et al., 2004; Curioni & Lourenco, 2005; Wadden et al., 2003). Each of the interventions was also tailored to gender. They were developed to be generalizable and scalable, and easily replicated and delivered as online

interventions. As the studies were similar in nature, this allowed analyses to be done in parallel to examine any gender differences.

Summary

Two main conclusions can be made from the results of this study. First, there is a clear relationship between adherence and outcome. For both men and women, adherence was related to improved outcome on at least some of the dependent measures. While the mediating relationship among depression, adherence, and outcome was confirmed for men, the relationship is less clear for women. For men, baseline depression resulted in poorer adherence, which in turn resulted in poorer outcomes. Improvement in depression also predicted higher adherence. For women, adherence rates were not affected by baseline depression, which may be attributed to the amount of contact in the intervention. The personal nature of the intervention may have helped the depressed women maintain their adherence.

Second, participating in a dietary and physical activity intervention while experiencing depressive symptoms, is not harmful, and may be beneficial. The results of the moderation analyses indicated that baseline depression did not decrease the benefits of participating in the program and provided some evidence for increased benefit in dietary quality among women. In addition, for both men and women, those in the intervention groups had significantly greater improvements in their depression scores compared to those in the control groups. Although the changes in depressive symptoms were small, they were in the expected direction and resulted from participation in an intervention not targeting depression. Screening out participants who are most depressed due to concern for their ability to participate may not be warranted. Physicians need not be reluctant to refer similarly depressed patients to a diet and physical activity program as they may benefit as well.

Future Directions

How depression may affect participation and success in a weight loss intervention needs continued investigation. As the relationship between depression and adherence was confirmed for men and not women, further research is warranted in this area. For men, the link between these variables would benefit from replication. For women, it would be important to tease out what may have contributed to the lack of relationship between depression and adherence. Based on the results of this study, where women adhered regardless of depression symptoms, increased personal contact may have reduced this discrepancy. A study experimentally examining the amount of contact with participants may be helpful. Further research could explore ways to increase personal contact in online interventions, like utilizing chat rooms, bulletin boards, and personalized e-mails. It would be important to determine if increased personal contact would increase adherence regardless of depression status for men as well. Since adherence is closely related to outcome, this may also contribute to an understanding of ways to enhance adherence in behavior change interventions.

An additional area of investigation might examine the effects of treating depression either before or concurrently with a weight loss intervention. Since in this study depressive symptoms improved without specifically targeting them, the inclusion of a treatment module addressing depression would theoretically only improve symptoms further. This may in turn improve adherence to the intervention and result in more positive outcomes. As online interventions are easy to tailor, it would be possible to screen for depression, and send those who screen positive through the depression module first or concurrently with the weight loss intervention. This framework would also allow for stratification based on severity level of depression, for example where those

reporting greater symptoms would receive an intervention targeted for their level of severity.

In further research, it would also be crucial to address adherence directly. The inclusion of a motivational interviewing module could be one way to do this. West and colleagues (2007) found that women randomized to motivational interviewing lost significantly more weight than those without that component, and that this result was mediated by enhanced adherence to the behavioral weight control program.

Weight loss intervention studies should continue to include moderation and mediational analyses as this is the best way to inform which treatments are appropriate for whom as well as what factors contribute to positive outcomes. This can lead to the development of more efficient and effective interventions and also improve and strengthen our understanding of the process of behavior change.

Table 2. Men in Motion: Baseline Characteristics.

	Total sample n=441	Intervention n=224	Control n=217
	m (sd)	m (sd)	m (sd)
Age	43.9 (8.0)	44.9 (7.8)	42.8 (8.0)
BMI	34.2 (4.1)	34.1 (4.1)	34.3 (4.0)
	%	%	%
With children	65	68	62
Depressed (CESD>=10)	25	27	22
Ethnicity			
White (non-Hispanic)	71.0	72.8	69.1
Black (non-Hispanic)	5.2	6.3	4.1
Hispanic	18.1	15.2	21.2
Asian/Pacific Islander	1.6	1.3	1.8
Native American	.5	0	.9
Multi-ethnic	2.0	2.2	1.8
Declined to state	1.6	2.2	.9
Marital status			
Single, never married	16.6	12.9	20.3
Married	65.3	68.3	62.2
Living with partner	5.0	4.5	5.5
Separated	1.4	1.3	1.4
Widowed	.5	.9	0
Divorced	11.3	12.1	10.6
Highest level of education			
Some high school	.9	1.3	.5
High school or GED	3.6	3.1	4.1
Trade or technical	3.9	5.8	1.8
Some college	28.6	30.8	26.3
College grad	29.9	25.0	35.0
Post-grad training	8.8	8.0	9.7
Graduate degree	24.3	25.9	22.6

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale.

Table 3. Men in Motion: Intervention adherence.

	Min	Max	m (sd)
Number of goals set	0	53	19.6 (16.5)
Page hits	1	425	44.0 (50.2)
Average % adherence (goals)	0	100	37.0 (31.2)
Change in adherence 0-6 to 7-12	-74.1	37.0	-16.4 (18.5)

Table 4. Men in Motion (intervention group): Outcome variable descriptives at baseline and 12 months.

	Baseline (n=224)	12 months (n=153)
	m (sd)	m (sd)
BMI	34.2 (4.1)	33.1 (4.4)
CESD	7.4 (4.9)	6.6 (5.3)
Physical activity		
IPAQ total activity +walking (MET- min/day)	708.9 (604.2)	886.6 (668.6)
AGA mod+vig activity (min/day) (n=192,91)	34.2 (19.8)	36.9 (29.9)
SBI (hours/day)	10.3 (3.7)	9.0 (3.0)
Dietary		
Fruit servings/1000cal	.5 (.4)	1.0 (.9)
Veg servings/1000cal	.7 (.6)	1.2 (.8)
Fiber gms/1000cal	9.1 (2.8)	11.6 (4.4)
% calories from fat	37.4 (6.3)	32.8 (7.3)
Healthy Eating Index	19.5 (8.1)	25.7 (9.3)

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI=Sedentary Behavior Inventory.

Table 5. Men in Motion (control group): Outcome variable descriptives at baseline and 12 months.

	Baseline (n=217)	12 months (n=155)
	m (sd)	m (sd)
BMI	34.3 (4.0)	33.7 (4.4)
CESD	6.6 (4.6)	6.6 (4.7)
Physical activity		
IPAQ total activity +walking (MET-min/day)	688.5 (581.9)	739.6 (622.9)
AGA mod+vig activity (min/day) (n=170,109)	36.0 (22.2)	35.8 (20.3)
SBI (hours/day)	10.5 (4.1)	9.9 (4.1)
Dietary		
Fruit servings/1000cal	.5 (.5)	.7 (.6)
Veg servings/1000cal	.7 (.4)	.9 (.7)
Fiber gms/1000cal	.0 (.7)	9.9 (2.7)
% calories from fat	38.0 (6.6)	36.2 (6.5)
Healthy Eating Index	18.3 (7.6)	19.4 (8.5)

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI=Sedentary Behavior Inventory.

Table 6. Women in Balance: Baseline Characteristics.

	Total sample n=401	Intervention n=205	Control n=196
	m (sd)	m (sd)	m (sd)
Age	41.2 (8.7)	40.8 (8.4)	41.6 (8.9)
BMI	32.3 (4.5)	31.9 (4.5)	32.8 (4.6)
	%	%	%
With children	70	70	70
Depressed (CESD>=10)	27	24	30
Ethnicity			
White (non-Hispanic)	60.8	58.5	63.3
Black (non-Hispanic)	7.2	8.3	6.1
Hispanic	20.4	21.5	19.4
Asian/Pacific Islander	5.2	5.4	
Native American	.2	.5	5.1
Multi-ethnic	3.5	3.4	3.6
Declined to state	2.5	2.4	2.6
Marital status			
Single, never married	18.5	18.0	18.9
Married	63.1	64.4	61.7
Living with partner	3.5	3.4	3.6
Separated	1.5	1.0	2.0
Widowed	1.0	0	2.0
Divorced	12.0	12.2	11.7
Highest level of education			
Some high school	.7	0	1.5
High school or GED	10.7	9.8	11.7
Trade or technical	4.2	4.4	4.1
Some college	37.7	34.1	41.3
College grad	24.4	27.3	21.4
Post-grad training	8.5	10.7	6.1
Graduate degree	13.2	12.7	13.8

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale.

Table 7. Women in Balance: Intervention adherence.

	Min	Max	m (sd)
Calls completed with participant	0	4	3 (1.2)
Counseling e-mails returned by participant	0	12	4.8 (3.1)
Number of months goals were set	2	12	5.8 (2.9)
Number of special topic “tip sheets” sent	1	26	7.3 (6.5)
Average % adherence (goals & e-mails)	0	100	41.7 (26.0)
Change in adherence 0-6 to 7-12	-91.7	0	-55.3 (27.2)

Table 8. Women in Balance (intervention group): Outcome variable descriptives at baseline and 12 months.

	Baseline (n=205)	12 months (n=140)
	m (sd)	m (sd)
BMI	31.9 (4.5)	31.1 (4.5)
CESD	7.4 (5.0)	5.3 (4.7)
Physical activity		
IPAQ total activity +walking (MET-min/day)	387.4 (463.8)	865.2 (728.7)
AGA mod+vig activity (min/day) (n=168,105)	21.1 (15.4)	25.5 (17.3)
SBI (hours/day)	10.3 (4.4)	9.0 (4.1)
Dietary		
Fruit servings/1000cal	.7 (.6)	1.6 (1.3)
Veg servings/1000cal	1.3 (1.0)	2.6 (1.7)
Fiber gms/1000cal	9.3 (2.8)	12.7 (4.2)
% calories from fat	36.0 (7.1)	31.7 (8.2)
Healthy Eating Index	21.0 (8.4)	27.3 (9.5)

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI=Sedentary Behavior Inventory.

Table 9. Women in Balance (control group): Outcome variable descriptives at baseline and 12 months.

	Baseline (n=196)	12 months (n=146)
	m (sd)	m (sd)
BMI	32.9 (4.6)	32.6 (5.1)
CESD	7.5 (4.4)	6.5 (4.9)
Physical activity		
IPAQ total activity +walking (MET-min/day)	397.6 (478.0)	1033.8 (906.4)
AGA mod+vig activity (min/day) (n=141, 116)	23.2 (17.9)	21.9 (16.3)
SBI (hours/day)	9.6 (4.1)	8.7 (3.7)
Dietary		
Fruit servings/1000cal	.8 (.8)	1.1 (1.0)
Veg servings/1000cal	1.4 (1.1)	1.8 (1.5)
Fiber gms/1000cal	9.7 (3.5)	10.7 (4.0)
% calories from fat	34.7 (7.2)	34.4 (9.2)
Healthy Eating Index	22.4 (8.9)	22.9 (9.6)

Note. BMI=body mass index; CESD= Center for Epidemiological Studies Depression Scale; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI=Sedentary Behavior Inventory.

Table 10. Men in Motion: Aim I: Analyses of depression moderating the intervention effect on outcome.

Outcome variables	Interaction term: group*baseline depression (log)				
	n	B	β	t	p
BMI	297	-.64	-.09	-.93	.35
HEI	308	5.0	.31	1.9	.06
IPAQ	309	176.5	.16	.84	.40
AGA (log)	174	.07	.15	.57	.57
SBI (log)	308	-.18	-.70	-3.7	.000**

Note. BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05; **=significant effect at p<.001.

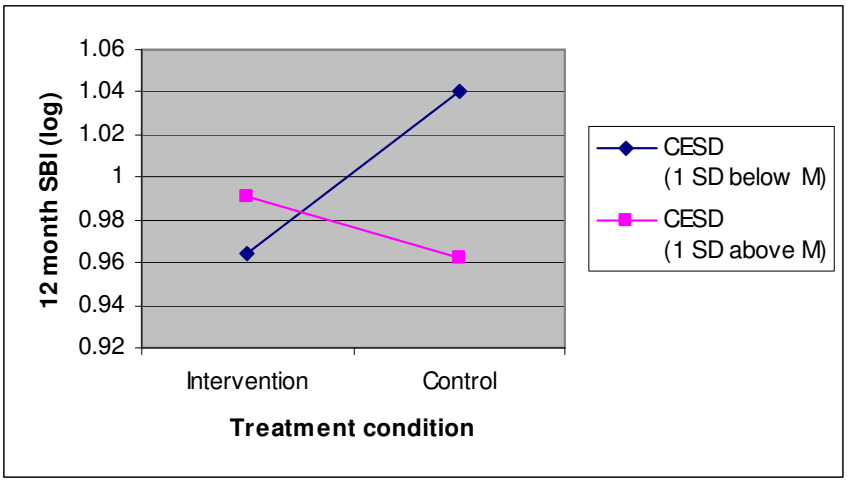

Figure 4. Men in Motion: Aim 1: Moderation interaction effect of depression on effect of treatment on sedentary behavior (SBI).

Table 11. Men in Motion: Aim I: Post hoc analysis.

		SBI Baseline	SBI 12 months	CESD Baseline	CESD 12 months
	n	m(sd)	m(sd)	m(sd)	m(sd)
Intervention group					
Depressed at baseline (CESD >= 10)	39	10.3(3.4)	9.5(2.8)	14.1(4.4)	12.6(5.5)
Not depressed (CESD < 10)	114	9.8(3.2)	8.8(3.0)	5.1(2.6)	4.6(3.4)
Control group					
Depressed at baseline (CESD >= 10)	32	12.3(3.9)	10.0(3.6)	13.1(2.8)	9.9(5.4)
Not depressed (CESD < 10)	123	9.6(3.7)	9.9(4.3)	4.5(2.7)	5.7(4.2)

Note. SBI = Sedentary Behavior Inventory; CESD= Center for Epidemiological Studies Depression Scale.

Table 12. Women in Balance: Aim I: Analyses of depression moderating the intervention effect on outcome.

Outcome variables	Interaction term: group*baseline depression (log)				
	n	B	β	t	p
BMI	283	.93	.11	1.0	.32
HEI	286	-9.8	-.62	-3.0	.003*
IPAQ (log)	256	.01	.02	.10	.92
AGA (log)	184	-.14	-.26	-.91	.37
SBI	286	1.3	.22	.97	.33

Note. BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05; **=significant effect at p<.001.

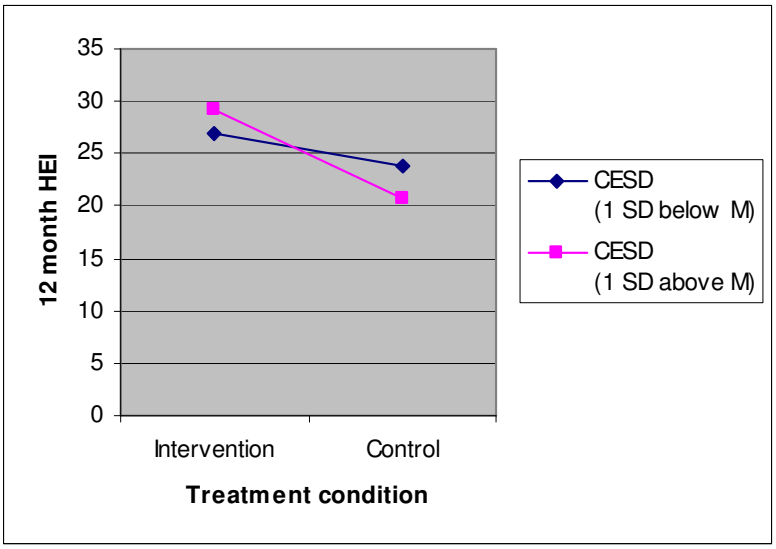

Figure 5. Women in Balance: Aim 1: Moderation interaction effect of depression on effect of treatment on dietary quality (HEI).

Table 13. Women in Balance: Aim I: Post hoc analysis.

		HEI Baseline	HEI 12 months
	n	m(sd)	m(sd)
Intervention group			
Depressed at baseline (CESD >= 10)	32	17.5(7.4)	25.7(10.3)
Not depressed (CESD < 10)	108	21.8(8.3)	27.8(9.3)
Control group			
Depressed at baseline (CESD >= 10)	44	22.4(8.4)	21.0(9.3)
Not depressed (CESD < 10)	102	22.8(9.2)	23.6(9.6)

Note. HEI= Healthy Eating Index.

Table 14. Men in Motion: Aim II Path A: Relationship of baseline depression to average adherence (mediator).

Dependent variable	CESD baseline (log)				
	n	B	β	t	p
Adherence	224	-17.7	-.15	-2.3	.02*

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05; **=significant effect at p<.001.

Table 15. Men in Motion: Aim II Path B: Relationship of average adherence (mediator) to outcome.

Dependent variables	Adherence				
	n	B	β	t	p
BMI	149	-.02	-.11	-3.6	.000**
HEI	153	.08	.28	4.6	.000**
IPAQ	153	.77	.04	.53	.60
AGA (log)	82	.002	.22	2.5	.02*
SBI (log)	153	-.001	-.16	-2.3	.02*

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; **=significant effect at p<.001.

Table 16. Men in Motion: Aim II Path C: Relationship of baseline depression to outcome.

Dependent variables	CESD baseline (log)				
	n	B	β	t	p
BMI	149	.01	.001	.03	.98
HEI	153	-6.3	-.19	-3.0	.003*
IPAQ	153	-167.5	-.07	-1.3	.30
AGA (log)	82	.02	.02	.23	.82
SBI (log)	153	.05	.10	1.5	.15

Note. CESD= Center for Epidemiological Studies Depression Scale; BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05.

Table 17. Men in Motion: Aim II: Mediation test: Relationship of baseline depression to HEI while controlling for adherence.

Dependent variable	CESD baseline (log)				
	n	B	β	t	p
HEI	153	-4.8	-.14	-2.4	.02*

Note. CESD= Center for Epidemiological Studies Depression Scale; HEI= Healthy Eating Index; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05.

Table 18. Men in Motion: Aim II: Post hoc analysis.

		HEI Baseline	HEI 12 months	Adherence rate
	n	m(sd)	m(sd)	%
Intervention group				
Depressed at baseline (CESD >= 10)	39	21.2(6.9)	23.6(8.4)	25.5
Not depressed (CESD < 10)	114	20.1(7.9)	26.4(9.5)	41.2

Note. HEI= Healthy Eating Index; CESD= Center for Epidemiological Studies Depression Scale.

Table 19. Women in Balance: Aim II Path A: Relationship of baseline depression to average adherence (mediator).

Dependent variable	CESD baseline (log)				
	n	B	β	t	p
Average adherence	180	9.4	.10	1.3	.18

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 20. Women in Balance: Aim II Path B: Relationship of average adherence (mediator) to outcome.

Dependent variables	Average adherence				
	n	B	β	t	p
BMI	132	.00	-.002	-.06	.95
HEI	134	.09	.24	3.4	.001**
IPAQ (log)	119	.00	.01	.16	.87
AGA (log)	85	.001	.10	1.01	.31
SBI	138	.007	.04	.59	.55

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; **=significant effect at p<.001.

Table 21. Women in Balance: Aim II Path C: Relationship of baseline depression to outcome.

Dependent variables	CESD baseline (log)				
	n	B	β	t	p
BMI	138	.34	.02	.57	.57
HEI	140	4.0	.11	1.6	.11
IPAQ (log)	123	-.06	-.04	-.52	.60
AGA (log)	86	-.13	-.12	-1.2	.25
SBI	140	-.32	-.02	-.29	.77

Note. CESD= Center for Epidemiological Studies Depression Scale; BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 22. Men in Motion: Aim III Path A: Relationship of change in depression to change in adherence 0-6 to 7-12 months (mediator).

Dependent variable	CESD change 0-6 months				
	n	B	β	t	p
Adherence change	146	-.31	-.06	-.68	.50

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 23. Men in Motion: Aim III Path B: Relationship of change in adherence (mediator) to outcome.

Dependent variables	Adherence				
	n	B	β	t	p
BMI	149	-.02	-.07	-2.3	.03*
HEI	153	.07	.12	1.9	.06
IPAQ	153	-2.05	-.05	-.77	.45
AGA (log)	82	.000	.01	.07	.95
SBI (log)	153	.000	.04	.58	.56

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05.

Table 24. Men in Motion: Aim III Path C: Relationship of change in depression to outcome.

Dependent variables	CESD change 0-6 months				
	n	B	β	t	p
BMI	126	.09	.07	1.9	.06
HEI	130	-.04	-.02	-.24	.81
IPAQ	130	7.56	.04	.55	.58
AGA (log)	72	-.02	-.23	-2.3	.02*
SBI (log)	130	.01	.19	2.5	.02*

Note. CESD= Center for Epidemiological Studies Depression Scale; BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level; *=significant effect at p<.05.

Table 25. Women in Balance: Aim III Path A: Relationship of change in depression to change in adherence 0-6 to 7-12 months (mediator).

Dependent variable	CESD change 0-6 months (log)				
	n	B	β	t	p
Adherence change	129	24.4	.17	.19	.06

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 26. Women in Balance: Aim III Path B: Relationship of change in adherence (mediator) to outcome.

Dependent variables	Adherence				
	n	B	β	t	p
BMI	132	-.002	-.01	-.37	.71
HEI	134	-.023	-.07	-.91	.37
IPAQ (log)	119	-.002	-.137	-1.7	.10
AGA (log)	85	.000	-..3	-.32	.75
SBI	134	-.02	-.12	-1.64	.10

Note. CESD= Center for Epidemiological Studies Depression Scale; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 27. Women in Balance: Aim III Path C: Relationship of change in depression to outcome.

Dependent variables	CESD change 0-6 months (log)				
	n	B	β	t	p
BMI	119	-.99	-.04	-1.1	.29
HEI	120	-6.7	-.13	-1.7	.10
IPAQ (log)	119	-.11	-.06	-.71	.48
AGA (log)	76	.31	.18	1.7	.09
SBI	120	1.2	.05	.65	.52

Note. CESD= Center for Epidemiological Studies Depression Scale; BMI=body mass index; HEI= Healthy Eating Index; IPAQ= International Physical Activity Questionnaire; AGA= ActiGraph Accelerometer; SBI = Sedentary Behavior Inventory; B=unstandardized beta coefficient; β=standardized beta coefficient; t=t test statistic value; p=significance level.

Table 28. Men in Motion: Aim IV: Depression by treatment condition.

	Intervention (n=153)		Control (n=155)		
	Baseline	12 months	Baseline	12 months	p
	m (sd)	m (sd)	m (sd)	m (sd)	
CESD (log)	7.4 (5.0)	6.6 (5.3)	6.2 (4.4)	6.6 (4.7)	.04*
CESD mood items (log)	4.5 (3.5)	4.0 (3.6)	3.9 (3.2)	4.0 (3.5)	.09
CESD somatic items	2.8 (1.9)	2.6 (2.0)	2.8 (1.9)	2.6 (1.8)	.40

Note. CESD= Center for Epidemiological Studies Depression Scale; p=significance level;
*=significant effect at p<.05.

Table 29. Women in Balance: Aim IV: Depression by treatment condition.

	Intervention (n=140)		Control (n=146)		
	Baseline	12 months	Baseline	12 months	p
	m (sd)	m (sd)	m (sd)	m (sd)	
CESD (log)	7.4 (5.0)	5.3 (4.7)	7.5 (4.4)	6.5 (4.9)	.007*
CESD mood items (log)	4.5 (3.5)	3.0 (3.3)	4.4 (3.3)	3.7 (3.4)	.008*
CESD somatic items	2.9 (2.0)	2.3 (1.9)	3.1 (1.9)	2.8 (2.0)	.03*

Note. CESD= Center for Epidemiological Studies Depression Scale; p=significance level;
*=significant effect at p<.05.

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