A Feasibility Study on the Effectiveness of an 8-Week Meditative Movement Intervention to Initiate Weight Loss in Female Gastric Bypass Bariatric Patients Experiencing Post-Surgical Weight Gain

by

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ABSTRACT

While obesity rates have plateaued within the last decade, two-thirds of the United States population is currently classified as overweight (defined as a body mass index [BMI] of 25–29.9 kg/m²) or obese (a BMI greater than 30 kg/m²). Bariatric surgical interventions are not only more effective than behavioral treatments in the short term but are the only form of obesity intervention with evidence of consistent long-term effectiveness. However, even among bariatric surgery patients, weight loss often stabilizes and it is estimated that more than 20% of bariatric surgery patients will regain a significant amount of weight that was initially lost long-term. Little research to date has been conducted on physical activity in post bariatric surgery patients. More specifically, there have been no studies to date examining the effects of Meditative Movement (MM) programs on body composition in bariatric patients. A study using an 8-week Tai Chi Easy program was conducted in female gastric bypass patients to explore feasibility of MM in the bariatric population as well as pre- and post-intervention changes in weight, mindfulness, eating behaviors, body awareness, physical activity patterns, dietary quality and mood. Data analysis revealed that there were no significant changes in weight or physical activity patterns; however, significant changes were observed in anxiety, overall body awareness and cognitive restraint in eating. Additionally, a significant decrease in processed meat consumption and a weak trend towards increased consumption of fruits may suggest an overall improvement in dietary quality.

DEDICATION

This dissertation is dedicated to my partner Natalie. Without her love, support and patience during this journey, I would not be where I am today. I also want to acknowledge my parents, Billy, Carol and Donn for their unwavering support and help not only during my graduate school tenure, but also throughout my entire life!

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CHAPTER 1

INTRODUCTION

Statement of the Problem

While obesity rates have plateaued within the last decade (Flegal, Carroll, Ogden, & Curtin, 2010), two-thirds of the United States population is currently classified as overweight (defined as a BMI of 25–29.9 kg/m²) or obese (a BMI greater than 30 kg/m²) (Flegal et al., 2010). Obesity is a serious issue, not only because of its impact on morbidity and mortality rates, but also due to the financial burden it puts on both the individual and society.

In 2005, an estimated $190 billion, or approximately 21% of the United States health care expenditures, was spent on obesity-related issues in the United States (Cawley & Meyerhoefer, 2012). Cawley et al. (2012) also determined that per capita medical spending was $2,741 higher for obese individuals than those of normal weight.

Obese employees take more sick days a year than their normal weight co-workers (5.9 more for men and 9.4 more days for women). The morbidly obese (those with a BMI greater than 40 kg/m²) lose approximately one month of productive work per year, costing employers an average of $3,792 per obese male and $3,037 per female, or an average of $6.4 billion dollars annually (Finkelstein, 2010).

In contrast to absenteeism, presenteesim is defined as impaired or diminished productivity while at work. Presenteeism data were collected by the National Health and Wellness Survey (NHWS) in 2008, using the Work Productivity and Activity Impairment (WPAI) questionnaire. In 2008, the total annual cost of presenteeism due to obesity was $30 billion (Finkelstein, 2010).

Obesity is associated with increases in cardiometabolic disease, certain types of cancer, premature death, osteoarthritis, and breathing problems (CDC, 2012). Additionally, obese teenage girls are more likely to start smoking and are more likely to be depressed than their normal weight peers (Ratcliff, Jenkins, Reiter-Purtill, Noll, & Zeller, 2011). Compared with healthy weight male students, male students with extreme obesity had greater odds of smoking before age 13 (Ratcliff et al., 2011). Both obese male and female youth are less likely to date and experience more bullying and less social support than the non-obese (Cawley, Joyner, & Sobal, 2006).

Morbidly obese patients lose less weight with medical therapy than with bariatric surgery. Kraschnewski et al. 2010 examined 1999-2006 National Health and Nutrition Examination Survey (NHANES) data and found that only 8.5% and 4.4% of adults who had ever been overweight and obese reported long-term weight loss (LTWL), i.e., weight loss sustained for over 1 year, of 15 and 20% of original body weight, respectively. An isolated, moderate-intensity aerobic exercise program is an ineffective weight loss intervention for overweight and obese persons (Foster-Schubert et al., 2012). However, aerobic exercise programs of 12 weeks to 12 months in length result in modest weight and waist circumference reduction for this population (Thorogood et al., 2011).

In general, participation in a lifestyle modification program results in a weight loss of 7–10% (Wadden, Butryn, & Wilson, 2007). Personal preference should dictate the choice of the dietary intervention, as adherence level rather than diet type, appears to be the key determinant of weight loss (Dansinger, Gleason, Griffith, Selker, & Schaefer, 2005). PA alone is of limited benefit in inducing weight loss (Wadden et al., 2007) but is critical for long-term weight maintenance (Wing & Phelan, 2005).

Weight regain is a problem following virtually any type of non-surgical weight loss intervention due to a complex interaction of physiological, environmental and psychological factors such as adaptive thermogenesis and decreased adherence to a calorie-restricted diet (Wadden, Brownell, & Foster, 2002). Patients treated by lifestyle modification for 20–30 weeks typically regain about 30–35% of their lost weight in the year following treatment. Weight regain slows after the first year, but more than 50% of patients are likely to have returned to their baseline weight by 5 years (Perri & Corsica, 2002).

In general, surgical interventions are more effective than behavioral treatments in both the short and long term (Buchwald & Williams, 2004; NIH, 1998). However, for certain bariatric patients, between the first and second years following surgery, weight loss often stabilizes and a substantial proportion of individuals begin to regain lost weight (Hsu, Sullivan, & Benotti, 1997; Hsu et al., 1998). It is estimated that more than 20% of bariatric surgery patients will regain a significant amount of weight that was initially lost (Meguid, Glade, & Middleton, 2008). While statistics vary per procedure and intervention, approximately 30-40% of surgically treated patients regain up to one-third of their initial weight loss at the 5-year mark (Bond et al., 2007).

Bariatric patients face many of the same challenges to weight loss maintenance as those that choose the lifestyle modification route, such as decreased metabolic rates, pre-existing negative psychosocial factors such as depression and lack of social support and continuous environmental exposure to calorie-dense, high fat foods (Alvarado et al., 2005).

Current Research Deficiencies

Although PA is recognized as an integral part of the non-surgical management of obesity for weight loss and weight loss maintenance (Jakicic et al., 2001; Wing & Phelan, 2005), the exact relationship between PA levels and weight loss following bariatric surgery is unknown. There are currently only 2 randomized controlled trials of PA and weight loss in bariatric patients, and both reported significant weight losses in the intervention arm (Egberts, Brown & O'Brien, 2011; Shah et al., 2011). A multitude of observational studies have found a dose-response relationship between post-surgical PA and weight outcomes (Livhits et al., 2010).

There are no standard post-surgical PA recommendations for bariatric patients, however walking to volitional fatigue with small increases in daily step counts is a common recommendation (Petering and Webb, 2009). Additionally, the American Society for Bariatric Surgery (ASBS) recommends walking from postoperative day one (Silver, Torquati, Jensen, & Richards, 2006). The American College of Sports Medicine (ACSM) has no specific guidelines for bariatric patients but does indicate that "aerobic exercise should be the focus of a post-bariatric surgery program, as it burns the most calories and is the best way for a previously sedentary individual to ease into physical activity" (ACSM, 2011). A more thorough review of PA and bariatric surgery is provided in Chapter 2.

Alternative Modalities of Physical Activity

Alternative forms of exercise are gaining in popularity in the general population, especially those that include a focused, meditative or mind-body component (La Forge, 2005). Meditative Movement (MM) has recently been proposed as a category of exercise

with elements of practice that differ substantially from conventional versions of exercise (Larkey, Jahnke, Etnier & Gonzalez, 2009). In contrast to most other forms of physical activities, many of the MM practices are low impact, low-to moderate-intensity activity that encourages people to move slowly and gently (although there are some exceptions with more vigorous forms). These types of activities may be beneficial and more feasible to initiate for physically de-conditioned individuals such as the overweight/obese or in bariatric patients. Additionally, MM may heighten body awareness of bariatric patients and improve maladaptive eating and coping strategies, which may be an important component of successful long-term weight loss in this population. For example, MM is associated with decreases in binge eating disorder (McIver, McGartland, & O'Halloran, 2009) and emotional eating (Tapper et al., 1998) in non-surgical obese populations. The potential impact of MM on weight outcomes will be discussed further in Chapter 2. There have been no studies to date examining the effects of MM on health and weight outcomes in the bariatric population.

Meditative Movement

The most current comprehensive definition of MM was generated by Larkey, Jahnke, Etnier, & Gonzalez in 2009 and includes four components: Some form of body movement or postural positions; focus of the mind; focus on breathing and a deep state of relaxation. Some of the most common examples of MM are Tai Chi (TC), Qigong (QG) and Yoga. Exercise intensity measures of these practices range from very low (Chao, Chen, Lan, & Lai, 2002), to moderate (Lan, Chen, & Lai, 2008; Leung, McKeough, Peters, & Alison, 2013). A few practices, such as Bikram Yoga, would probably be measured at a vigorous intensity level (based on observations of fast pace, intense

postures, and heart rate increases reported), but the research literature in this area is sparse. In a recent study examining heart rate responses to Vinyasa Yoga in healthy adults, 1 participant (out of 42) experienced heart rates of (77-93% of HR_{max}), indicating vigorous exercise (Ward, McCluney, & Bosch, 2013).

Tai Chi Easy (TCE) is a simple TC/QG form that was developed by Dr. Roger Jahnke and developed into a standardized research intervention protocol by a team of researchers (Jahnke, Larkey, & Rogers, 2010). It has been used in several prior projects (Larkey, Szalacha, Rogers, Jahnke, & Ainsworth, 2012; Larkey et al., 2009) and one recently completed NIH/NCCAM-funded randomized controlled trial (RCT) with breast cancer survivors (Larkey et al., 2014) showing reduction in fatigue and depression, and improved sleep and physical function. The TCE intervention combines simplified TC movements with QG methods that include gentle flowing movements and slow shifts of body weight while incorporating deep, soothing breathing. Given the absence of interventions using MM in the bariatric population, a feasibility study was conducted to determine the overall interest in, acceptability of and potential demand for MM programs in bariatric surgery patients.

Preliminary Studies

Feasibility study. In support of the currently reported project, a recent feasibility study in 39 bariatric patients was conducted by providing a brief experience of the practice in the context of existing post-bariatric surgery support group meetings, and then asking a series of questions to obtain responses to the experience. The questions were designed to tap into general attitudinal responses to the practice, as well as more specific Theory of Planned Behavior (TPB) related reactions. TPB questions were asked to assess

perceptions of the practice as being socially normed (e.g., do people like me do this), attitudes about the behavior (e.g., I think this is worthwhile/beneficial, and I enjoy/like this practice) and perceived behavioral control (e.g., I can do this). The result of this study was that 71% of participants indicated a positive attitude about learning more about MM and 65% reported a positive attitude about trying MM in the future. Seventy-five percent of the participants provided high scores, i.e., scores closer to 5, on the social norm questions for MM practice and questions regarding perceived behavioral control. Questions asking about intention to practice MM scored the lowest, i.e., scores closer to 1, among participants, with only 69% indicating a positive intention towards the behavior.

A standardized group of questions was developed for the post-surgical focus groups to obtain their thoughts, feelings and intentions around MM. Questions were selected to be asked based on the flow of conversation, time constraints and subject participation levels in each particular group. In terms of physical sensations, a common response of participants was that the MM exercises were "relaxing," "peaceful" and "gentle." One subject indicated that the movements were "too gentle" and that she preferred more high intensity activities after her surgery. Being physically active was a new and exciting state for her and doing low-impact activities reminded her of her "old life" that she wanted to leave behind. Many other participants, however, indicated a willingness to incorporate MM into their post surgical exercise regimes given its low impact nature. The demonstration exercises were described as "perfect" for after surgery, "very gentle" and "helpful for breathing."

To date, there have not been any MM interventions tested for effects in the bariatric population. MM is an appealing PA modality for this population that should be explored for several reasons. Immediately after surgery, patients are typically weak and frail with limited range of motion. MM, and specifically TCE, is a gentle, low impact activity suitable for deconditioned individuals in the recuperative process.

Physical activity. MM has been shown to lead to additional and more vigorous PA (Dechamps, Lafont, & Bourdel-Marchasson, 2007; Larkey, Goel, Rogers, Weihs, Lopez, & Jahnke, 2009), which can contribute to increased weight loss in the bariatric population. Additionally, PA in general has been positively associated with the successful maintenance of post-bariatric surgery weight loss (Livhits et al., 2010).

Eating patterns. In addition to the link between PA and body composition, there is evidence to suggest that obesity is associated with both emotional (internal) eating and externally-driven eating (Van Strien, Schippers, & Cox, 1995). Research shows that questionnaire measures of these types of eating behaviors are positively associated with BMI and obesity (Delahanty et al., 2002). In addition, a study by Blair et al. (1990) found significant associations between levels of emotional eating and weight loss success; successful weight control was associated with decreases in emotional eating.

Mindfulness has been shown to positively affect weight loss and maladaptive eating behaviors. Adding a 1 day mindfulness workshop to a weight loss program resulted in significant decreases in body mass index ($p<.05$) over a 3 month period (Lillis, Hayes, Bunting & Masuda, 2009). In bariatric patients, the practice of mindful eating has been shown to be effective in maintaining weight loss post surgery (Engstrom, 2007). These effects on weight loss may be due to a number of mediating factors, such

as the reduction of stress-related eating, more mindful eating, normalization of neurohormones associated with weight, as well as the caloric expenditure of the physical activity itself. The relationship between MM, eating patterns and weight outcomes will be further explored in Chapter 2.

Research Question

This study evaluated the feasibility of TCE and the effect it had on weight, eating patterns and mindfulness. Feasibility, acceptability, demand, and barriers to adherence or retention of a TCE practice were evaluated to refine the research protocol in preparation for a future larger scale randomized controlled study. The research questions that guided this research were:

1. Is TCE an exercise that is feasible for bariatric patients?
2. Will TCE facilitate a change in mindfulness, weight, eating patterns, psychosocial factors and physical activity levels?

Specific Aims

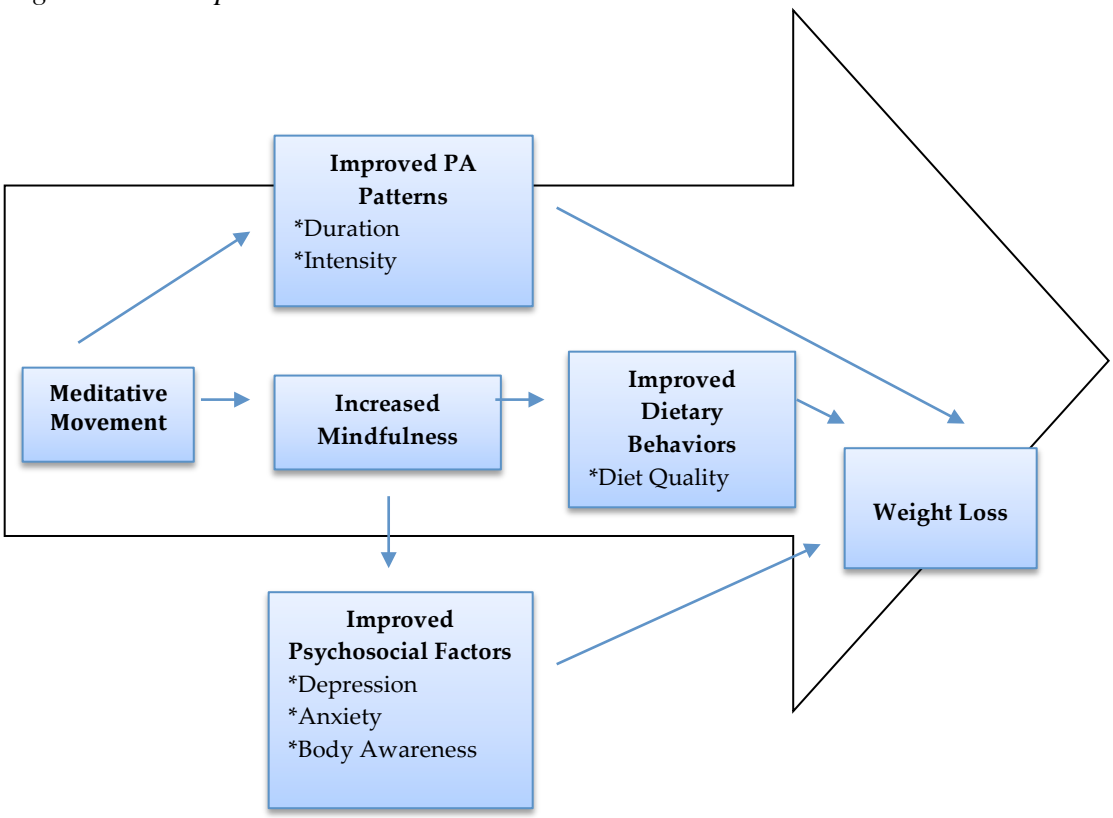
Specific aim 1. (a) Evaluate intervention feasibility, acceptability, demand, and barriers to adherence or retention of TCE among first time bariatric patients who have started to gain weight post surgery (b) Evaluate recruitment strategies and/or estimate recruitment and retention rates in the intervention.

Specific aim 2. To evaluate whether the TCE intervention is associated with weight loss, improved behavioral eating factors, mood, body awareness, measures of mindfulness or PA levels in post-surgical bariatric patients as compared to baseline measures.

Conceptual Framework

The intervention model (Figure 1) outlines the proposed mechanisms influencing weight loss as a result of practicing a MM program. The independent variable is a MM program and the dependent variable is weight loss. In the current study we will explore the relationships among these variables and in future studies, we will test for mediation and moderation.

Figure 1- Conceptual Framework



Delimitations

The intervention included females between 18-70 years of age who are first time gastric bypass bariatric patients and who have begun to re-gain weight (at least 5 pounds), 12-36 months after surgery.

Limitations

Bypass surgery in the United States and Arizona is performed predominantly in Caucasian women and results of the study may not be applicable to males and ethnic minorities. Additionally, a relatively small sample size may have resulted in a lack of power to detect true associations between the intervention and the outcomes of interest.

CHAPTER 2

REVIEW OF LITERATURE

OBESITY

Definition of Obesity

The World Health Organization (2010) classifies people with a BMI between 18.5-24.99 kg/m^2 as normal weight, a BMI ≥ 25 kg/m^2 as overweight, a BMI 30.00-34.99 kg/m^2 as obese class I, a BMI 35.00-39.00 kg/m^2 as obese class II "severe obesity," and a BMI > 40 kg/m^2 as obese class III "morbid obesity." Those individuals with a BMI ≥ 50 kg/m^2 are classified as "super obese" (Almogy, Crookes, & Anthone, 2004) and a BMI ≥ 60 kg/m^2 are considered "super-super obese" (Regan, Inabnet, Gagner, & Pomp, 2003).

Obesity Prevalence and Trends

Currently, approximately 70% of Americans are classified as overweight BMI ≥ 30 kg/m^2 and of those, 35% are considered obese (BMI ≥ 30 kg/m^2). Another 6.2% of the U.S. population (over 9 million Americans) currently suffers from morbid obesity, up from 2.9% in 1994 (An, 2014). The rate of morbid obesity is increasing roughly 2-3 times faster than the rates of class I obesity and between 2000 and 2005, the prevalence of super obesity (BMI ≥ 50) increased by 75% (Sturm, 2007). Obesity is clearly widespread in the US, affecting over 72 million adults (Bean, Stewart, & Olbrisch, 2008).

Magnitude of the Problem

Obesity is a serious issue, not only because of its impact on morbidity and mortality rates, but also due to the financial burden it puts on both the individual and society. The leading causes of death in 2010 in the US were heart disease (598,000 deaths; 25% of all deaths), cancer (575,000; 25% of all deaths) and cerebrovascular

disease (130,000 deaths; 5% of all deaths) (CDC, 2014). According to the World Health Organization, elevated BMI is a major risk factor for these primary causes of death in the US and the risk for these diseases escalates with increases in BMI (World Health Organization, 2014).

Physical morbidities associated with obesity include heart disease, type II diabetes, certain cancers (endometrial, breast, and colon), hypertension, dyslipidemia, stroke, liver and gallbladder disease, sleep apnea, respiratory issues, osteoarthritis and selected gynecological problems (abnormal menses, infertility) (CDC 2010; Mokdad et al., 2003). Numerous psychological morbidities may also be associated with obesity, including "lack of self-esteem possibly leading to social isolation, feelings of insecurity and despair, somatization, denial of emotional stress, difficulties making interpersonal contact and poor social adjustment" (van Gemert, Severeijns, Greve, Groenman, & Soeters, 1998). It has been noted in the literature that severely obese subjects, especially younger women with a negative body image, have a higher risk for depression (Dixon, Dixon, & O'Brien, 2003; Sjostrom et al., 2007). Additionally, severity, or level of obesity appears to be associated with frequency of symptoms of depression in adult women. Females with class III obesity (a BMI $\geq$ 40 kg/m^2) report a more extensive history of psychological issues and greater stress levels compared to those with only an obesity class or I or II (Wadden et al., 2006).

The obesity-related direct healthcare costs in the United States during 2010 were estimated to be $194 billion and that same year Americans spent almost $59 billion on weight-loss remedies (O'Brien, 2010). Annually, obese patients spend an average of $1500 (42%) more on their medical care than their normal-weight counterparts

(Finkelstein et al., 2009). Obesity accounts for 8.5% of total Medicare expenditures, 11.8% of Medicaid expenditures, and 12.9% of private insurance expenditures (Finkelstein et al., 2009). From 1998 to 2006, there was an almost 30% increase in costs associated with obesity reported by health insurance companies including private insurance companies, Medicaid and Medicare (Finkelstein et al., 2009). Additionally, Medicare prescription drug payments for obese recipients are approximately $600 a year more than for normal weight recipients (Finkelstein et al., 2009).

The George Washington University (GWU) School of Public Health and Health Services' Department of Health Policy released a report in 2010 titled *A Heavy Burden: The Individual Costs of Being Overweight and Obese in the United States*. This report calculated an individual's obesity cost by examining data on both direct (medical expenditures) and indirect costs (lost productivity). GWU determined that the annual individual cost of being obese in America is $4,879 for women and $2,646 for men. Adding in the value of lost wages due to disability and mortality, these numbers increase to $8,365 and $6,518, respectively (Dor, 2010). Compared to healthy-weight individuals, obese men pay up to six times and obese women pay up to nine times more for their medical care (Dor, 2010).S

Treatment of Obesity

Conventional or non-surgical treatment. PA, diets, and drugs are considered standard obesity treatments. Diets such as the Atkins and Zone (high protein/low carbohydrate), Ornish (very low fat), and Weight Watchers (calorie deficit, not macronutrient-focused), have been studied in obese populations and report similar weight losses at 1 year (Thompson, Cook, Clark, Bardia, & Levine, 2007). Dietary approaches to

weight loss typically focus on caloric reduction or restriction, high protein/low carbohydrate diets, increased intake of fruits and vegetables, and low-glycemic index diets, but none of these diets have translated into long-term successful weight loss (Thompson et al., 2007). In a meta-analysis of the literature, low-calorie or very-low-calorie (< 800 calories/day) diets resulted in the loss of 2.1% and 6.6% of total body initial weight, respectively, after 5 years (Anderson, Konz, Frederich, & Wood, 2001). In another study, at the 1 and 2 year mark, dieters lost 8% and 10%, correspondingly, of their total body weight, but returned to their baseline weight without ongoing behavioral intervention (Brethauer, Chand, & Schauer, 2006).

The long-term result of dieting thus may paradoxically be the opposite of the desired goal. Several theories explain why weight loss may become attenuated after dieting including a permanent down-regulation of resting metabolic rate (Rosenbaum, Hirsch, Gallagher, & Leibel, 2008), circulating hormones that favor weight re-gain (Sumithran et al., 2011), and adaptive thermogenesis (Tremblay & Chaput, 2009).

FDA-approved weight loss drugs have two main categories, appetite suppressants (Phentermine, Phendimetrazine) and those that impair energy absorption (Orlistat). However, not only do these medications have few positive long-term effects, they can actually cause negative health complications. Patients taking an appetite suppressant reported an increased incidence of depression and anxiety as compared to those in placebo groups and blood pressure and heart rate increased modestly in the intervention group (Thompson et al., 2007). Other data indicate that short-term weight loss by pharmaceuticals is often linked with anxiety, irritability, depressions and fixation with food (Doherty et al., 1993).

The prevalent view of public health organizations is that exercise is important for weight loss (Stiegler & Cunliffe, 2006). The actual weight loss brought about by exercise programs is usually less than expected and results are typically disappointing (Ross et al., 2004; Steiger et al., 2006). Little to no weight loss has been reported by the majority of studies with exercise alone or when added to a diet (Thompson et al., 2007). Current research would indicate that lifestyle interventions alone have not been effective in achieving significant long-term weight loss in the obese. The majority of individuals who attempt weight loss through conventional means regain most to all of the weight lost over the ensuing five years (Khwaja & Bonanomi, 2010).

Operative/surgical treatment. A third of adults are obese in the United States (Flegal et al., 2010). Surgical interventions are not only more effective than behavioral treatments in the short term but are the only form of obesity intervention with evidence of consistent long-term effectiveness (Buchwald & Williams, 2004; Bult, van Dalen & Muller, 2008; NIH, 1998).

In the first year after gastric bypass, a mean weight loss of 60–70% excess weight loss (EWL) can be expected. This effect decreases to an average 50% EWL for those still attending follow-up at 5 years (O'Brien, 2010) and 25% EWL 10 years post surgery (Sjostrom et al., 2007). Despite the variability in weight loss results between surgical procedures, approximately 30-40% of bariatric patients regain up to one-third of their initial weight lost by the 5-year mark (Bond et al., 1998).

Surgical treatment is not only the most effective method of achieving long-term weight loss, it also and reduces many medical risks for the morbidly obese (Bult et al., 2008). The most remarkable effect of bariatric surgery is the full and rapid remission of

type 2 diabetes mellitus (Pories et al., 1995; Schauer, Ikramuddin, Gourash, Ramanathan, R., & Luketich, 2000; Schernthaner & Morton, 2008; Vetter, Cardillo, Rickels, & Iqbal, 2009). Additionally, the benefits of weight loss surgery on dyslipidemia, hypertension (Schauer et al., 2000; Arterburn et al., 2009), blood glucose levels (Arterburn et al., 2009), gastroesophageal reflux disease (Schauer et al., 2000), sleep apnea (Charuzi, Lavie, & Peiser, 1992; Schauer et al., 2000), and asthma (Macgregor & Greenberg, 1993; Schauer et al., 2000) have been well documented.

While not recommended for everyone, bariatric surgery can be utilized to help severely obese people lose weight when other weight loss strategies, such as dieting, behavioral modification, psychotherapy, exercise, and/or pharmaceutical interventions, have not worked.

BARIATRIC SURGERY

Indications

The American Society for Metabolic and Bariatric Surgery (ASMBS) recommends bariatric surgery for patients with a BMI of more than 40 kg/m^2 or those with a BMI of more than 35 kg/m^2 with concomitant obesity-related conditions after failure of conventional treatment (ASMBS, 2009). Approximately 22 million people in America are projected to be medically eligible for bariatric surgery (Martin, Beekley, Kjorstad, & Sebesta, 2010). Currently, in order for bariatric surgery candidates to be approved for surgery, they must be unsuccessful in their attempts to lose weight through non-surgical approaches and many insurance providers require proof from patients that they have participated in some type of pre-surgical lifestyle modification counseling. However some data indicate that insurance-mandated pre-surgical counseling is an

obstacle to patient access for bariatric surgery and has no association with weight loss outcomes or post-surgical compliance (Jamal et al., 2006).

Surgery Rates and Statistics

The first bariatric surgery procedures were performed in 1954. By the year 2000, a total of 36,700 bariatric surgeries were completed and the next year this number increased 29% to 47,200 (ASMBS, 2013). In 2003, over 100,000 procedures were performed for an annual growth rate of 64%, the largest increase in the previous decade. Increase in the utilization of the laparoscopic techniques and a more widespread acceptance of the surgery were partly responsible for the observed increases in bariatric surgery rates during this period (Nguyen et al., 2011). The number of bariatric operations peaked at 220,000 cases in 2008 and 2009. Numbers for subsequent years are not available, but experts believe they are staying flat or even declining (ASMBS, 2013).

Surgery Types

There are three basic categories of weight loss surgery: 1) restrictive procedures; 2) malabsorptive; and 3) a combination of restrictive and malabsorptive methods. Each of the surgery types influences weight loss in different ways. Among bariatric procedures, gastric bypass results in more weight loss than gastric banding.

The most common restrictive surgeries are the adjustable gastric banding (AGB) and the vertical banded gastroplasty (VBG) procedures. AGB involves partitioning the stomach by placing an adjustable prosthetic band around the upper portion of the stomach with a port implanted under the skin on the abdomen. The tightness of the gastric band is adjusted by inserting a needle into the port and either removing or adding liquid. The AGB procedure is predominantly performed laparoscopically. The non-invasive aspect

and the convenience of band adjustment have made the LAGB an increasingly popular bariatric procedure. Weight loss post AGB is usually less than that of bypass surgery, but short- and long-term complications are reduced. (Belachew, Belva, & Desaive, 2002).

Nonadjustable gastric banding procedures, such as the vertical banded gastroplasty (VBG), also known as "stomach stapling" divide the stomach into a small proximal pouch and a large distal remnant connected by a small aperture limiting gastric volume. Food intake at each meal is limited, and weight loss is significant. Patients will often substitute solid food with frequent intake of high-caloric liquids, and a failure rate of up to 80% has been reported (Balsiger, Poggio, Mai, Kelly, & Sarr, 2000).

Currently, two techniques are recommended for gastric bypass surgery: Roux-en-Y-gastric bypass (traditional and laparoscopic) (RYGB) and biliopancreatic diversion bypass (traditional and laparoscopic) (BDP). The gold standard of bariatric surgery is the RYGB, which has been the dominant bariatric surgical procedure in the United States for the past 20 years (Thomas & Schauer, 2010). After the stomach is divided, the small upper pouch is joined to the proximal jejunum through a narrow anastomosis. After the RYGB, stomach capacity is reduced by 95%, and food bypasses the entire duodenum and part of the proximal jejunum. Not only is the stomach pouch too small to hold large amounts of food, but by skipping the duodenum, fat absorption is substantially reduced.

In the BDP, portions of the stomach are removed and the bypass is attached to the distal illium. Up to 70% of the stomach is removed, and bile and pancreatic enzymes are diverted to the distal ileum, where they mix with food in a common channel. Weight loss occurs since most of the calories and nutrients are routed into the colon where they are not absorbed.

Laparoscopic sleeve gastrectomy (LSG) can be used as a first stage operation prior to a gastric bypass or as a definite procedure itself for high-risk, super-obese patients, i.e., those with a body mass index (BMI) >50 (Ianelli, Dainese, Piche, Facchiano, & Gugenheim, 2008). The LSG is a bariatric procedure in which approximately 85% of the stomach is removed, shaping the remaining stomach into a tube or "sleeve." LSG has been shown to produce excellent excess weight loss in the short term comparable with laparoscopic Roux-en-Y gastric bypass (RYGB) and superior to laparoscopic adjustable gastric banding (LAGB) with a very low incidence of major complications and death (Moy, Pomp, Dakin, Parikh, & Gagner, 2008). However, it is not clear if weight loss following LSG is sustaiLnable given the lack of long-term follow up data.

Surgery Concerns/Risks

DeMaria and colleagues (2009) conducted an extensive analysis of the bariatric surgery outcomes longitudinal database (BOLD) for all procedures performed between 2007 and early 2009 and determined that complication rates for all types of bariatric procedures performed are approximately 10 percent, with the most common complaint being nausea/vomiting. Through May 2009, 78 deaths were reported at any point after the index procedure, for a mortality rate of .13%. The 90-day mortality rate was .11%, and the 30-day mortality rate was .09%.

Common short-term complications of bariatric surgery include surgical site infection, stomal stenosis, constipation, dumping syndrome, vomiting, and nutritional deficiencies, some of which also may continue long-term (Virji & Murr, 2006). The rapid weight loss experienced in the 3-6 months post surgery can result in symptoms that

mirror those of a very-low calorie diet, including hair loss, body aches, fatigue, and dry skin (Blackburn, Bistrian, & Hoag, 1977; Saris, 2001). The anatomic and physiological changes that result from bariatric surgery can diminish the body's ability to absorb nutrients and electrolytes, and can cause dehydration and lactose intolerance. Psychologically, mood and personality disorders, destructive eating behaviors, and poor body image can also occur post surgery for some patients (Song & Fernstrom, 2008).

Traits of Bariatric Surgery Candidates

Demographics. A survey of patient characteristics and outcomes at Bariatric Surgery Centers of Excellence (BSCOE) hospitals was conducted to determine demographic information of the bariatric surgery population (Pratt et al., 2009). Women (83%) outnumbered men (18%), by a ratio of greater than 5 to 1. The average patient age was 43±3 years, with an age range of 18 to 68. Whites represented 60% of all bariatric surgery patients, while African-Americans were the second most represented group at 11%. The remaining ethnicities by decreasing frequency were Hispanics (5%), Native Americans (0.2%), and Asians (0.1%), constituting less than 6% of all bariatric surgery patients combined. Patients for which race/ethnicity were not reported totaled 25% . Private insurance (78%) was the predominant form of payment. Other insurance (9%), uninsured/self pay (6%), Medicaid (5%), and Civilian Health And Medical Program of the Uniformed Services (CHAMPUS) (2%) were the remaining most common forms of payment (Pratt et al., 2009).

Activity Levels. Multiple studies have shown that pre-operatively, bariatric candidates engage in low levels of PA, if they are active at all. Two pedometer studies found that participants averaged between 4600-6000 steps/day, which is classified as

"sedentary" to "low active" behavior (Donnelly et al., 2009; Josbeno, Kalarchian, Sparto, Otto, & Jakicic, 2011). In the Longitudinal Assessment of Bariatric Surgery -2 study, King and colleagues (2011) utilized the Stepwatch Activity Monitor to assess activity levels and participants averaged 7700 steps/day, which was more than the pedometer studies, but still reflected "low active" levels of PA. A subsequent study by Bond et al. (2011) using the SenseWear armband reported that participants spent 79–80% of their time sedentary, considerably higher than the percentage of sedentary time (approximately 55-70%) reported in the general adult population (Matthews et al., 2008).

Psychopathologies. Studies have found that up to 84% of bariatric surgery candidates have a long history of major mental illness and approximately 40-70% have a personality disorder (Black, Goldstein, & Mason, 1992). Candidates have also been found to have higher levels of difficulties in social relationships (Herpertz et al., 2003) and nearly one-third have a history of substance abuse (Song & Fernstrom, 2008). There is also an increased incidence of childhood sexual abuse or maltreatment in bariatric patients. One study found that 69% of morbidly obese bariatric surgery candidates, both male and female, reported childhood maltreatment (Grilo et al., 2005). And sadly, research indicates that obese persons have a higher rate of suicidal ideation and actual suicide attempts (Mather, Cox, Enns, & Sareen, 2009).

Gastric bypass patients seem to suffer from high levels of low self esteem, depression and perfectionism (Glinski, Wetzler, & Goodman, 2001) as well as body image dissatisfaction, with displeasure being more prominent in women than men (Song & Fernstrom, 2008). While there are some common pre-surgical traits between genders, males and females can differ significantly on certain characteristics. Kolotkin and

colleagues (2008) found that women have higher rates of depression while males have increased rates of sleep apnea. In addition, women patients are younger, more likely to be single, with a reduced health-related quality of life, particularly in self-esteem, sexual fulfillment, and physical functioning (Kolotkin et al., 2008). Another study found similar findings surrounding rates of depression and anxiety, with females obtaining higher scores on the PsyBari Depression Index (PDI), Beck Depression Inventory II (BDI- II) scores and the PsyBari Social Anxiety Index (PSAI) than males (Mahony, 2008). PsyBari is a self-report questionnaire that detects and measures surgical motivation, disordered eating, anger, obesity-related depression, weight-related social impairment, knowledge of post-surgical dietary restrictions, substance/alcohol abuse, and surgical anxiety.

Pre-Surgical Evaluations

Prior to surgery, dietary habits and eating styles are assessed to help determine the patient's level of readiness for surgery and to identify any issues that will either support or interfere with matters of post-surgical compliance and adherence. Correctly distinguishing between maladaptive eating patterns can help delineate habits of eating guided by dieting and restriction versus those that are clearly emotionally driven.

Bariatric candidates should also demonstrate an understanding of the role of PA in lifelong weight management. It is critical to assess the patient's plan (if any) to incorporate exercise after surgery and to determine if the plan is realistic, as well as identify any barriers to activity that may be encountered. Work and family commitments as well as sedentary habits may make it difficult to initiate and sustain a post-surgical exercise routine.

The literature suggests that stress is negatively related to eating healthy, well-balanced meals and to following a consistent program of physical activity (House, Landis, & Umberson, 1988). Ideally, a pre-surgical assessment should evaluate the surgical candidate's current living situation and whether or not the candidate is experiencing any potentially undermining stressors, crises, or obvious chaos in their life.

Social support is one of the most well-documented psychosocial factors that can positively influence health outcomes (Harvey & Alexander, 2012; Uchino, 2004). Epidemiological studies reveal that persons with low levels of social support have higher mortality rates, particularly resulting from cardiovascular disease (Holt-Lunstad, Smith & Layton, 2010; Rutledge et al., 2004). Social support is also related to successful weight loss for people attending a general behavioral weight loss program (Elfhag & Rossner, 2005; Wing et al., 2005). Additionally, there have been some data to suggest that bariatric patients who regularly attend postoperative support groups are more successful in their short-term weight loss (Kaiser, Franks, & Smith, 2011; Livhits et al., 2010). No studies have looked at bariatric support group participation and long-term (>5 years) weight loss maintenance.

Patient motivations for surgery are important to evaluate and patient expectations concerning the effect of weight loss on their physical and emotional well-being should be critically assessed. Unrealistic post-surgical expectations may lead to the false perception of failure which may then result in a sense of powerlessness and the acquiescence to old habits and unhealthy choices that contributed to their obesity initially.

Pre-surgical psychological evaluation may be vital in identifying bariatric surgery patients with potential concomitant mental health issues. Some studies have found that those with a psychiatric condition such as depression, experience less post surgical weight loss and, therefore, may not be ideal candidates for surgery (Kinzl et al., 2006). Other research suggests that no clear consensus has been reached regarding mental illness as an accurate predictor of post-surgical weight outcomes, so psychiatric disorders should not be contraindicated for surgery if proper mental health management is present (Buddeberg-Fischer et al., 2004).

There appears to be significant variability in the kind, amount and importance placed on pre-surgical evaluations performed by psychologists in the United States (Walfish, Vance, & Fabricatore, 2007). While the majority of bariatric surgery candidates are cleared for surgery based on the pre-surgical evaluation processes, approximately 15% are delayed or refused surgery for psychological reasons (Walfish et al., 2007). The exact rates of surgical deferral or denial are conflicting in the research, given the wide variability of evaluation practices mentioned above. According to one researcher, "it appears that some evaluators recommend virtually all of the candidates they see for surgery, whereas others have much more stringent criteria that candidates must meet before they receive psychological clearance" (Walfish et al., 2007).

The most common reasons for postponing or preventing surgery are considerable psychopathologies (including psychosis or bipolar disorder), and undertreated or completely untreated depression, which were reported by 51% and 39% of patients, respectively (Walfish et al., 2007).

The majority of bariatric programs use pre-surgical psychological evaluations; however, as discussed, the exclusion criteria for surgery vary greatly (Bauchowitz et al., 2005). Thus, instituting standardized guidelines for the screening of bariatric surgery candidates is essential. And, perhaps more importantly, there needs to be more direction and discussion on how psychologists should make their recommendations or conclusions for surgery admission once the screening process is complete.

Effects of Bariatric Surgery

Effect of bariatric surgery on overall health. Early interventions observed a full and rapid remission of type 2 diabetes mellitus after bariatric surgery (Pories et al., 1995; Schauer, Ikramuddin, Gourash, Ramanathan, R., & Luketich, 2000; Schernthaner & Morton, 2008; Vetter, Cardillo, Rickels, & Iqbal, 2009) with remission rates more pronounced after RYGB surgery versus AGB (80-98% compared to 50-80%, respectively) (Pories et al., 1995; Vetter et al., 2009). However, more recent research has found lower overall remission rates (at the 5 year mark post surgery) of 68.2 %, which is lower than prior reports from academic bariatric centers (Arterburn et al., 2013). As part of their landmark SOS study, Sjostrom and colleagues (2014) reported that at the 15-year mark, diabetes remission rates decreased to 30.4% in their cohort of participants.

A recent prospective observational study by Pournaras and colleagues also found lower rates of remission in 1,006 patients at the 2-year mark. A total of 72 (34.4 %) of 209 patients had complete remission of diabetes, the remission rates were 41% after gastric bypass, and 7% after gastric banding (Pournaras et al. 2011). Most notably, however, longer-term follow-up in the current Arterburn intervention discovered that 35.1% of subjects who completely remitted their diabetes after surgery experienced a

relapse within 5 years (Arterburn et al., 2013). Factors associated with failed remission included treatment with insulin and longer duration of diabetes and less deterioration in β-cell function at the time of surgery. Weight re-gain was not a significant predictor of remission rates (Arterburn et al., 2013), which contradicts other interventions that showed a clear positive association between weight gain and diabetes remission (Chikunguwo et al., 2010; DiGiorgi et al., 2010).

Additionally, the criteria for remission was revised in 2012 by the American Diabetes Association and is currently defined as: 1) if HbA1c < 5.7% and 2) improvement if HbA1c 5.7-6.5%, in both cases without hypoglycemic treatment and duration of at least one years, and no remission if these criteria were not met (ADA, 2012. The prior model indicated complete remission if: 1) "normal" measures of glucose metabolism were achieved (HbA1c < 6.5% and fasting glucose 100-125 mg/dl); 2) partial remission if HbA1c < 6.5% and fasting glucose of 100-125 mg/dl), in both cases in the absence of pharmacologic therapy or ongoing procedures, for a duration of at least one year (Buse, et al., 2009). The more stringent definition of remission currently used may explain the decrease in reported remission rates in recent studies.

In addition to improvements in glycemic control, surgery has positive effects on dyslipidemia and hypertension (Arterburn et al., 2009; Bacci et al., 2002; Schauer et al., 2000). Arterburn et al. (2009) measured predicted 10-year changes in cardiovascular risk after RYGB surgery in approximately 100 patients. Their predicted baseline 10-year cardiovascular risk was 6.7%. At 6 and 12 months, their predicted risk had decreased to 5.2% and 5.4%, respectively. This reduction was significant in both men ($p<.05$) and women ($p<.02$). Schauer et al. (2000) studied the outcomes of 275 RYGB patients at the

one-year time point after surgery, and reported that hypercholesterolemia resolved in 63% of the patients, as did diabetes in 82% of the patients. No p values were reported on these changes. Bacci et al. (2002) evaluated outcomes at 1-year post AGB and observed that hypertension rates decreased by 12% and hypercholesterolemia decreased by 11%. However, no p values were given and it is unknown whether or not these changes were statistically significant.

Lastly, improvements in gastroesophageal reflux disease (Dixon & O'Brien, 1999; Schauer et al., 2000), sleep apnea (Charuzi, Lavie, & Peiser, 1992; Schauer et al., 2000), and asthma (Macgregor & Greenberg, 1993; Schauer et al., 2000) have been documented in both RYGB and AGB patients.

Effect of bariatric surgery on weight/BMI. Weight regain is a problem following virtually any type of non-surgical weight loss intervention due to a complex interaction of physiological, environmental and psychological factors such as adaptive thermogenesis and decreased adherence to a calorie-restricted diet (Wadden, Brownell, & Foster, 2002). Patients treated by lifestyle modification for 20–30 weeks typically regain about 30–35% of their lost weight in the year following treatment. Weight regain slows after the first year, but more than 50% of patients are likely to have returned to their baseline weight by 5 years (Perri & Corsica, 2002).

Surgical interventions are more effective than behavioral treatments in both the short and long term (Buchwald & Williams, 2004; NIH, 1998). Among bariatric procedures, gastric bypass results in more weight loss than gastric banding. Because of gender differences as well as the great variations in weight among the operated individuals, many prefer to express weight loss in terms of "excess weight," i.e., current

weight - ideal body weight = excess weight. The use of percentage excess weight loss (%EWL) as a measure allows some comparison between the various bariatric operations. The Swedish Obese Subjects (Sjostrom et al., 2007) study showed that the maximal percent of initial weight lost (1–2 years post-surgery) was 32% in RYBG vs. 20% in AGB and this difference was maintained at a 10 year follow up visit (25% in RYGB vs. 14% in AGB). Similarly, at 2-yr follow up, Shah and colleagues (2006) reported reductions of approximately 31% of initial body weight in RYGB vs. 24% in GB. Buchwald, Avidor, et al. (2004) used this metric in a meta-analysis of 2,738 citations from 1990 –2002 that reviewed the results of bariatric surgery in 22,094 patients. These data showed the following outcomes, expressed in % EWL: AGB, 47.5%; VBG, 68.2%; RYGB, 61.6%; and BDP, 79.1%.

While bariatric surgery has a positive impact on weight loss for many, there is a substantial subset of patients that experience post-surgical weight gain (Bond et al., 1998; Hsu, Sullivan, & Benotti, 1997; Hsu et al., 1998; Meguid, Glade, & Middleton, 2008). One possible mechanism for weight regain post-surgically is an increase in energy intake. Sjostrom et al. (2004) reported increasing daily caloric intakes beginning one year after surgery. The role of energy intake in weight regain is challenging to assess because subjects tend to over-adhere to their dietary recommendations/restrictions on the day(s) that their diet is assessed (Forster, Jeffery, VanNatta, & Pirie, 1994). A possible reason for the increase in energy intake in RYGB patients may be due to dilation of the gastric pouch and gastrojejunal anastomosis (Muller, Wildi, Scholz, Clavian, & Weber, 2006), however, these complications are uncommon, suggesting that other factors may be involved in controlling weight gain after bariatric surgery.

Bariatric patients face many of the same challenges to weight loss maintenance as those that choose the lifestyle modification route, including decreased metabolic rates and continuous environmental exposure to calorie-dense, high fat foods. However, post-surgery patients are physically able to eat less and may experience positive changes in anorectic hormone levels, which can contribute to more successful long-term weight loss (LeRoux et al., 2010; Peterli et al., 2012).

Effect of bariatric surgery on mental health. Most studies report an overall tendency for psychopathology to lessen and stabilize following bariatric surgery (Green et al., 2004; Sarwer et al., 2005). These improvements in negative self-esteem, body dissatisfaction, anxiety, disordered eating, and personality disorders are hypothesized to be directly related to weight loss (Guisado et al., 2002). However, psychological improvements have also been observed in patients who experienced little to no substantial weight loss in the weeks immediately after surgery (Quality of Life, 2001).

A review article by van Hout et al. (2006) found that while some studies observed no significant changes in psychopathology after surgery, others reported increased hypersensitivity to criticism and difficulties in the expression of aggressive feelings. This same review article conveys mixed results in relation to level of depression. Although certain studies report no difference between pre-and post-surgical depressive symptoms, others indicate persistent depression and anxiety after surgery with some patients even committing suicide. In one study, post-surgical depression appeared to be inversely associated with greater weight loss (Ryden et al., 1989), which may suggest that significant weight loss may lead to problems of adaptation, triggering depressive reactions.

Overall, research on bariatric surgery does indicate that weight-related depression decreases after surgery (Maddi et al., 2001; Masheb et al., 2007). Many psychological outcomes, including anxiety, depression and disordered eating tend to improve substantially after surgery (Thonney et al., 2010). For a percentage of depressed patients, the weight is actually a symptom of depression rather than its outcome (Alexander, 2008). For these people, weight loss may be unsatisfactory in that they may still be depressed even after surgery. Therefore, it is recommended that each patient receive information about potential depression, especially given the recent study demonstrating an elevated rate of suicide in this population (Omalu et al., 2007). And, if a bariatric candidate is severely depressed, surgery should likely be postponed until depression lessens, unless it is medically necessary (Wadden et al., 2001).

Shortly after surgery, patients report a more positive body image, but over time, some still feel overweight and are dissatisfied with the resulting post-surgical skin-folds (Dixon et al., 2002). Data provide mixed results in relation to body image and weight loss, with some studies finding that patients who were satisfied with their appearance post-surgically experienced less weight loss (due to less excess skin) while other studies describe the opposite (van Hout et al., 2006). Although the majority of data indicate broad psychological improvements after surgery, a sizeable minority of patients appears to not benefit psychologically from surgery at all. Studies reveal that up to 40% of post surgical patients can deal with psychiatric disorders and approximately 25% visit a mental health professional (van Hout et al., 2006).

Effect of bariatric surgery and cancer risks. Hundreds of epidemiologic studies of various types and in a wide range of countries and settings have provided convincing evidence of a relationship between excess adiposity and cancer risk, and for many cancer sites, the proportion of all cancers attributable to obesity is substantial (Byers & Sedjo, 2011). Even though the precise mechanisms linking obesity to cancer risk are not all known, many plausible mechanisms are related to measurable biomarkers, e.g., estradiol, C-reactive protein and TNF –α, whose changes can be assessed with intentional weight loss.

Several bariatric surgeries have observed a significant inverse association between post-surgical weight loss and cancer prevalence rates. In the Swedish Obesity Subjects (SOS) study, the overall cancer incidence was 42% lower among women, but was essentially unchanged among men (Sjostrom et al., 2007). The SOS study included ABG, RYGB and VGB, however, the cancer incidence rates were not separated by surgery type so no hypotheses can be made on which type of surgery may have the greatest impact.

The Utah Obesity Study (Adams et al., 2009) compared outcomes of 6596 Utah patients with gastric bypass to those of 9442 other severely obese persons. After a mean 12.5 years follow-up post surgery, the total cancer incidence was 24% lower in women, and cancer incidence was essentially unchanged among men. Although the apparent protective effect of surgery on risk of developing cancer was limited to cancers likely known to be obesity related, the inverse association for mortality was seen for all cancers. Christou et al., 2004 reported 78% (p=.001) lower risk of cancer incidence in RYGB patients over 5 years of follow-up, but those findings were not stratified by gender so it is unknown what differences were observed, if any.

Effect of bariatric surgery on eating behavior and patterns. Studies suggest that approximately 30% of individuals presenting for the treatment of obesity engage in binge eating (Spitzer et al., 1993). Binge eating disorder (BED) is defined as the presence of two or more binge episodes per week without associated compensatory behavior (American Psychiatric Association (APA), 1994). Binge episodes are defined as the consumption of an unusually large amount of food in a discrete period of time with associated loss of control over the behavior (APA et al., 1994).

There is a minority of bariatric patients who are not successful in achieving and maintaining their anticipated weight loss. Rusch and Andris (2007) found that problematic response to weight-loss surgery (not defined) may be due to a worsening of pre-surgical depression, binge eating, emotion-triggered eating, body image, or eating behaviors associated with specific situations such as social events. While a small stomach size may prevent individuals from objectively consuming large amounts of food, approximately 20% of VGB patients reported a subjective loss of control of food intake, despite not eating a large amount (Hsu et al., 1996 & 1997). These episodes of loss of control are associated with smaller weight loss after RYGB, as reported by Kalarchian and colleagues (2002).

Although the presence of BED may limit weight loss after bariatric surgery, it has been proposed that gastric bypass may actually improve eating-disordered behavior and appetite. In two studies by Hsu and colleagues (Hsu, Betancourt, & Sullivan, 1996; Hsu, Betancourt, & Sullivan, 1997), no patients who had BED before VGB surgery reported binge eating post-operatively.

Several studies also support the contention that binge eating, however frequent before surgery, stops after surgery (Boan et al., 2004; Dymek et al., 2001; Latner et al., 2004). The postoperative follow-up interval in these studies was unfortunately limited to 6 months.

Additionally, recent research has observed that LAGB, RYGB and BPD patients experience significant improvements in overall eating patterns post surgery (Castellini et al., 2014). While overall disordered eating decreased across surgery types, cognitive restraint and emotional eating patterns did not show significantly change in gastric bypass patients, as it did with the banding and BPD groups (Castellini et al., 2014).

Effect of bariatric surgery on gut. Post surgical changes observed in energy intake, and perhaps even energy expenditure, may be influenced by alterations in gut and adipocyte hormones. Gut hormones such as ghrelin, peptide YY (PYY), and glucagon-like-peptide (GLP)-1 have a pivotal role in regulating satiety (Murphy & Bloom, 2007). Of these, ghrelin is an orexigenic (hunger-stimulating) peptide, secreted mainly by the cells in the fundus of stomach, acting via the hypothalamus (Tschop, Smiley, & Heiman, 2000). Each type of bariatric surgery has a different effect on hormonal secretion and thus may play a significant role in the mechanism of weight loss (Vetter, Cardillo, Rickels, & Iqbal, 2009). The potential mechanisms leading to the beneficial effects of surgery are likely complex and involve a number of organs and communicating pathways.

To date, ghrelin is the only orexigenic gut hormone identified, and decreased ghrelin was the first hormonal mechanism implicated in the beneficial weight-loss effects of RYGB (Cummings et al., 2002). Several other clinical studies did not find

significantly decreased fasting ghrelin levels after RYGB compared to untreated obese subjects (Rodieux, Guisti, D'Alessio, Suter, & Tappy, 2008; Stoeckli, Chanda, Langer, & Keller, 2004). Post AGB, variability in ghrelin levels is again seen, with some studies reporting significant decreases in ghrelin (Leonetti et al., 2003) and others reporting no change (Dixon, Dixon, & O'Brien, 2005). Post-LSG, Langer et al. (2004) found decreased ghrelin levels up to 12 months after the procedure.

In previous cross-sectional studies circulating levels of several gut hormones differed in patients who had undergone AGB compared with RYGB. Post surgical levels of PYY and GLP-1 were significantly increased in RYGB as compared to LAGB patients a year after surgery (Korner, Bessler, Inabnet, & Holst, 2007; Korner et al., 2006; Korner et al., 2009). In fact, increased levels of GLP-1 have been observed up to 20 years after surgery (Naslund, Backman, & Holist, 1998). It is important to note that the surgery referenced in the Naslund (1998) article was a jejunolieal bypass (JIL), which is no longer used given the long-term side effect of chronic post-surgical malabsorption issues. More recently, increases in PYY have lasted up to 24 months post RYGB (le Roux et al., 2010) and LSG (Peterli et al., 2012). Rubino and colleagues (2004) found no significant changes in CCK levels 3 weeks post RYGB. However, Peterli et al. (2012) observed an increase in CCK at the 12-month mark, but post LSG surgery. Leptin levels similarly decrease in both AGB and RYGB proportional to the amount of weight loss post surgically (Korner et al., 2009), up to a year after the procedures were performed.

Effect of bariatric surgery on resting metabolic rates. Numerous studies have evaluated metabolic rates in bariatric surgery patients (Buscemi et al., 2006; Das et al., 2003; Flancbaum, Choban, Bradley, & Burge, 2007; & van Gemert et al., 2000). Two

(Buscemi et al., 2006 and van Gemert et al., 2000) found a decrease in resting metabolic rate in subjects who were followed up to 42 months post surgery, while others did not (Das et al., 2003; Flancbaum et al., 2007). The role of energy expenditure changes post surgery and the potential impact on weight loss and maintenance needs to be studied more thoroughly.

Predictors of Health Outcomes

Successful outcomes after bariatric surgery depend on the individual's ability to implement lifestyle changes, which is affected by personality, psychosocial functioning, and eating patterns (van Hout et al., 2009). In order to ensure optimal weight loss and other health outcomes such as psychological wellbeing, it is important to identify potential predictors of success.

Psychosocial predictors of bariatric surgery outcomes are relatively unknown. One study observed that the presence of an Axis-I disorder, defined as any acute mental disorder that needs clinical treatment, in particular, an anxiety or mood disorder, was associated with poorer weight outcomes at 6 months, after controlling for gender, age, race, and initial BMI (Kalarchian et al., 2008). A recent review looked at data published between August 2006 and August 2009 and concluded that there is a clear need for more information on reliable psychological predictors of weight loss post surgery (Pull, 2010). Another examination of the literature by van Hout (2005) also found that although predictor variables such as psychosocial functioning, personality, coping skills, self-esteem, marital satisfaction, self-criticism, and a history of sexual abuse have been studied, results are inconsistent. No one psychosocial variable has been discovered predict weight loss after surgery (van Hout et al., 2005).

Gender and age (Busetto et al., 2002; Kinzl et al., 2006; Sczepaniak et al., 2012; van Hout et al., 2005), socio-economic status (van Hout et al., 2005), and baseline weight/BMI (Kinzl et al., 2006; Sczepaniak et al., 2012) have been found to be associated with post-surgical outcomes, however, the directions of these associations have varied between studies. Decreased caloric intake (Kruseman, Leimgruber, Zumbach, & Golay, 2010) and consistent sleep patterns have also been linked to a higher degree of postsurgical weight loss (Ketchum & Morton, 2007).

Baseline BMI as a Predictor of Weight Loss

Research results on the link between pre-surgical BMI and post surgical weight loss are varied. A recent study (Sczepaniak et al., 2012) looked at race, age, gender, technique, height, and initial weight as possible predictors of weight loss after gastric bypass surgery. Baseline weight was the main predictor of weight loss after surgery, explaining 93% of the variability of average post-surgical weight loss while all other variables accounted for less than 1% of the variability.

Another group of researchers observed the same predictability. Dixon and colleagues (2001) studied 440 AGB patients to determine pre-surgical predictors of weight loss. Information was obtained on basic demographic and anthropometric information, and past medical and psychiatric history. Only pre-surgical BMI and age were significantly associated with weight loss.

In another retrospective study, 260 patients who underwent AGB surgery were studied to explore weight loss predictors (Busetto et al., 2002). The only statistically significant predictors of success (<10% weight regain) were found to be age < 40 years and a pre-surgical BMI < 50 kg/m^2. While the super-obese patients had a success rate of

about half that observed in patients with lesser BMI values, the absolute level of BMI reduction was higher in super-obese than in morbidly obese patients.

Not all of the studies observe a positive relationship between initial BMI and post surgical weight loss. A longitudinal study with 2-year follow-up (Ma et al., 2006) studied almost 500 bariatric patients to explore weight change at 1-2 years following RYGB and to evaluate predictors of post-surgical weight loss. The success rate (≥ 50 % EWL) at 1 year was 85% and a younger age and lower baseline weight were predictors of a higher % EWL.

Alvarado et al., 2005 studied 90 weight loss surgery patients to determine if pre-surgical weight was associated with positive outcomes, including increased EWL. In this study, researchers observed that initial BMI correlated negatively with EWL, i.e., an increase of 1 unit of BMI pre-surgery correlated with a decrease of approximately 1.5% of EWL post surgery. Since the patients with the highest BMIs were losing less weight, the authors suggested that lowering initial BMI through pre-surgical lifestyle modification could lead to greater post-surgical weight loss.

While the data are inconsistent, the majority of studies observed a significant positive association between higher pre-surgical BMI and post surgical weight outcomes (Branson et al., 2005; Dixon, Dixon, & O'Brien, 2001; Sczepaniak et al., 2012). Busetto and colleagues (2002) found that super obese persons (BMI > 50 kg/m^2) lost less weight than those with a BMI between 35-49 kg/m^2 but also re-gained less weight in the long term. A few interventions reported a negative association between a higher BMI at the time of surgery and corresponding weight loss (Alvarado et al., 2005; Ma et al., 2006).

Bariatric Surgery and Physical Activity

Although PA is recognized as a cornerstone in the non-surgical management of obesity for weight loss and weight loss maintenance (Jakicic et al. 2001; Wing & Phelan, 2005), the relationship between PA levels and weight loss following bariatric surgery is imprecise. Only two randomized controlled trials have been published to date examining PA and weight loss in bariatric patients. Egberts, Brown, & O'Brien (2011) randomized 50 LAGB patients to either usual care or 12 weeks of aerobic and strength building exercises with a personal trainer for 45 minutes, 3 times a week. Those in the exercise group lost more weight (37%) and body fat (3.6%) compared to the usual care group (27% and 1.6%, respectively) at the end of the intervention.

In another study, both LAGB and RYGB were allocated to either a dietary counseling only intervention or to dietary counseling plus a high volume exercise program for 12 weeks (Shah et al., 2011). Both arms of the study lost a significant amount of weight, but there were no significant differences in weight loss between the two groups.

Several literature reviews of approximately 200 observational studies (Egberts et al., 2011; Jacobi et al., 2011; Livhits et al., 2010) observed a positive relationship between increased exercise and weight loss after bariatric surgery, independent of surgery type. These studies indicated that post-surgical weight loss is greater in those patients who exercised compared to those who did not. This value was found to be a mean of 3.6 kg, which is higher than the 1.5 kg found in a similar meta-analysis of non-surgical weight loss programs conducted as a Cochrane review in 2006 (Shaw et al., 2006).

Participation in a minimum of 150 minutes per week of moderate or higher intensity PA was associated with greater weight loss at 6 and 12 months postoperatively.

In conclusion, the current body of literature supports the notion that PA has an important role in post-surgical weight outcomes. However, further evaluation appears needed and should be conducted preferentially by means of objective measures of PA, e.g., actigraphy that allows precise measurement of time partitioning between sedentary behavior and PA of different intensities.

Physical activity and metabolism. Several metabolic considerations should be considered before designing an exercise program for a bariatric surgery patient. The lean body mass, fat mass, caloric intake, and the respiratory quotient (RQ) undergo significant changes after bariatric surgery.

The RQ is the ratio of carbon dioxide expelled and the amount of oxygen consumed and is an indication of the body's substrate usage for energy. The range of respiratory coefficients for organisms in metabolic balance usually ranges from 1.0 (representing the value expected for pure carbohydrate oxidation) to 0.7 (the value expected for pure fat oxidation).

The post-bariatric surgery diet recommendation of decreased calories, decreased carbohydrates, and increased protein lowers the RQ. As RQ decreases, the body shifts into a catabolic state, breaking down glycogen and fat stores. Exercise requires a high RQ and readily available glucose to fuel the body. When there is not adequate carbohydrate or glycogen storage, the body must break down either fat or protein for energy. The breakdown products of fat, specifically glycerol and free fatty acids, are not converted easily into glucose to meet body demands for strenuous exercise. The body will break

down protein, primarily from muscle, to meet energy requirements during exercise. This leads to an undesirable decrease in lean body mass and an increase in the percentage of fat mass. A reduction in lean body mass can lead to decreased metabolic rate, weight gain, poor muscle tone, and low energy.

Physical activity recommendations. There are currently no standard PA recommendations for bariatric surgery patients. Walking to volitional fatigue with small increases in daily step counts is a common recommendation (Petering and Webb, 2009). For the general population, the American College of Sports Medicine (ACSM) encourages 30 minutes of moderate intensity activity on as many days of the week as possible. Currently, ACSM has no specific guidelines for bariatric patients but does indicate that aerobic exercise should be the focus of a post-bariatric surgery program, as it burns the most calories and is the best way for a previously sedentary individual to ease into physical activity. Additionally, the ACSM proposes that 60 min of moderate intensity exercise for at least 5 days per week, thus providing 300 min of exercise per week, is needed to achieve substantial weight loss. It would seem logical that a similar recommendation should be applied to the bariatric surgical patient pending better data.

Low-impact activities such as walking are useful and usually well tolerated in bariatric patients, even if only for brief periods. Additionally, resistance training is a crucial partner to aerobic exercise, but limitations may be prudent during the early weeks after surgery, particularly concerning the abdominal region. But strength training may increase fat-free mass (muscle) and speed loss of fat mass in post-bariatric surgery patients. And finally, flexibility exercise improves range of motion for still-obese post-surgery patients, but following precautions is important to prevent injury (ACSM, 2011).

The American Society for Bariatric Surgery (ASBS) recommends initiating walking from postoperative day one (Silver, Torquati, Jensen, & Richards, 2006). One recommendation is to use a pedometer and walking as the primary exercise for patients undergoing bariatric surgery. During the first week postoperatively, a baseline for distance walked is calculated with a pedometer by calculating the average number of steps taken daily. The second week, a daily minimum step count equal to the average daily number of steps from the first week is advised. This daily minimum step count is increased by 250-500 steps each week until reaching the goal of 10,000 steps per day. Once walking for 2 months, patients may be advanced to a more comprehensive program including stretching, increased aerobic activity, and weight training (Martin, 2004).

Bariatric Surgery and Dietary Recommendations

Following surgery, patients are encouraged to change their eating patterns. Immediately following surgery, patients are put on a liquid diet for roughly 1-2 weeks. They then transition to a pureed food diet, then a soft food diet, and eventually return to a solid food diet approximately one month after surgery.

A comprehensive nutrition assessment should be conducted preoperatively by a dietitian, physician, and/or well-informed, qualified multidisciplinary team to identify the patient's nutritional and educational needs. It is essential to determine any preexisting nutritional deficiencies, develop appropriate dietary interventions for correction, and create a plan for postoperative dietary intake that will enhance the likelihood of success (Aills, Blankenship, Buffington, Furtado, & Parrott, 2008).

The post surgical diet is generally divided into three phases. Phase 1 lasts approximately 2 weeks and consists entirely of liquids. Most non-carbonated liquid

beverages are accepwh, however caffeine, alcohol, sodas, and fruit juices are to be avoided. In Phase 1, patients should drink 64 ounces of fluids per day with a protein intake of 60-90 grams and begin taking vitamin and mineral supplements as prescribed.

Phase 2 begins 3-6 weeks after surgery and re-introduces solid foods into the body. During this phase, patients should begin the practice of eating only 3 small meals a day and avoid snacking or "grazing" throughout the day. Grazing and snacking lead to poor weight loss after surgery. Patients should continue drinking 64 ounces of fluid per day, however, they should not drink anything with meals (to allow room for food) or for 30 minutes after a meal (to prevent "washing" the food through the stomach too quickly).

During Phase 3, patients can begin to re-introduce a variety of foods back into their diet. Softer foods are recommended to start with, before graduating to harder foods or to raw fruits or vegetables. Moving forward, it is important to eat at least 4 to 6 ounces of meat (protein) every day. The total protein goal post surgery will be at least 60 grams every day. Vitamin and mineral supplementation should continue and is based on surgery type and any specific post surgical deficiencies, which are continuously monitored.

Phase 4 is the stabilization phase and allows the patient to eat food of a regular consistency three to six times a day. It is important for patients to remain vigilant with their new eating habits to avoid falling back into patterns of disordered eating, which can negatively impact post-surgical weight outcomes.

MEDITATIVE MOVEMENT

Definitions

The most current comprehensive definition of MM was proposed by Larkey, Jahnke, Etnier, & Gonzalez in 2009 and includes four components: Focus of the mind;

some form of body movement; focus on breathing and a deep state of relaxation. Some of the most common examples of MM are Tai Chi (TC), QiGong (QG) and Yoga. QG the older, more overarching discipline than TC and incorporates diverse practices designed to cultivate functional integrity and the enhancement of the life essence that the Chinese call Qi (Jahnke, Larkey, Rogers, Etnier, & Lin, 2010). Both QG and TC incorporate a wide range of physical movements, including slow, meditative, flowing, and dance-like motions. In addition, they both can include sitting or standing meditation postures as well as either gentle or vigorous body shaking. Most importantly, both incorporate the purposeful regulation of both breath and mind coordinated with the regulation of the body. This coordination of mind, body and breathing is thought to activate the body's natural self-healing capacities, according to traditional Chinese medicine (Busetto et al., 2002; Jahnke et al., 2010). Yoga has been practiced since the beginning of civilization, and the earliest written pictorial records of yogic practice are estimated to be from 3000 BC. The word yoga means to "join or yoke together" both the body and the mind and is characterized by exercise, breathing and meditation (Tran, Holly, Lashbrook, & Amsterdam, 2007).

Components

The manner in which MM works can be partially explained by examination of the intervention's key components: The meditative state, movement and breathing. The meditative state promotes calmness and alertness in the present moment. It encourages the participant to be aware of their surroundings and to experience a sense of connection with all of nature, in a positive, harmonizing manner, focusing on one's own inner energy, otherwise known as "chi". The meditative state and focus on the breath is what

separates MM from other physical exercise (Ospina et al., 2007) and is intended to clear the mind and provide the participant with a reenergized and serene psyche. For example, in a study of another form of MM, Hatha Yoga and Omkar Meditation, it was found that the psychophysiologic stimuli increased endogenous secretion of melatonin, a hormone hypothesized to improve an individual's sense of well-being (Harinath et al., 2004). A review of these components and their potential mechanisms of action on weight and other related outcomes of interest to bariatric patients follows.

Impact of Meditative State on the Brain

Physiologically, cortical thickness has been noted with regular practice of meditation in the areas of somatosensory, auditory, visual, and interoceptive processing (Lazar et al., 2005). In this study, individuals who actively meditated were compared to control individuals who did not meditate. The largest between-group difference was noted within the insula, a section of the brain that is associated with emotions, self-awareness and cognitive functioning. Lazar et al. (2005) concluded that meditation might induce changes in the areas of the brain important for cognitive, sensory, as well as emotional processing. This information is important because it indicates that meditation has an effect on the area of the brain that is associated with emotional processing, which can impact eating and PA patterns.

It is hypothesized that regular meditation practice may stimulate increased self-awareness, leading to better control over cognitive and emotional states. These changes may shift an individual to a more positive emotional state by controlling active thought processes and therefore more positively impacting bariatric outcomes.

More awareness of food intake quantity and quality can potentially attenuate post-surgical weight gain and more importantly, possibly initiate weight loss.

More recently, Desbordes et al. (2012) conducted a study on the brain effects of meditation and discovered changes in the activation of the right amygdala (an almond-shaped structure deep in the brain that has a key role in emotion, memory, and attention) during the 8-week intervention and these changes persisted even while the individuals were not in a meditative state.

Neuroscientists recently discovered that mindfulness and meditation lead to efficient modulation of cortical alpha rhythms in the brain, which facilitates optimal filtering of sensory information. Meditators learn not only to control what specific body sensations they pay attention to, e.g., hunger or stress, but also how to regulate attention so that they do not become negatively biased towards these physical sensations (Kerr, Sacchet, Lazar, Moore, & Jones (2013). By learning to ignore stressful emotions, individuals can theoretically avoid engaging in unhealthy behaviors that might normally arise from uncomfortable feelings, e.g., stress eating, as discussed further below.

After an 8-week Mindfulness Based Stress Reduction (MBSR) intervention was conducted in non-meditators, brain images revealed increases in gray matter concentration in the left hippocampus. The hippocampus is an area of the brain involved in learning, memory, and emotional control, and is suspected of playing a role in producing some of the positive effects of meditation. Mindfulness research would suggest that the physiological and emotional changes that occur as a result of MM, such as increased body awareness or emotion regulation, might positively impact post surgical weight outcomes (Fulton et al., 2011; Hearon, Quatromoni, Mascoop & Otto, 2012).

Impact of MM on Dietary Patterns

The research on MM and dietary quality is scant but promising. Researchers observed that yoga practitioners ate more fruits and vegetables in their diets than non-practitioners and experienced practitioners had ate even more of these foods than less experienced practitioners. In fact, individuals who practiced yoga for four or more years ate approximately 50% more fruits and vegetables and consumed less fat (11%) than those who didn't practice (Kristal, Littman, Benitez, & White, 2005).

Mindfulness-Based Eating Awareness Training (MB-EAT) emphasizes making conscious food choices, developing awareness of physical versus psychological hunger and satiety cues, and eating healthfully in response to those cues. In a recent randomized control trial, there were significant differences between the MB-EAT and the control group in overall dietary intake of trans fats, total fiber, and sugars (all $p<0.05$) (Miller, Kristeller, Headings, Nagaraja, & Miser, 2012).

Taetzsch and colleagues (2014) compared the effects of TC, resistance training and dietary education on diet quality and resilience in obese women versus a control group. The intervention group reported significantly higher dietary quality post study as measured by the Dietary Screener Tool. These studies suggest that mindfulness, cultivated through activities such as MM, can improve dietary quality.

In a non-obese population of adult male veterans, an MBSR program was conducted to examine the impact of mindfulness training on emotional and uncontrolled eating and dietary quality (Kearney, Milton, Malte, McDermott, Martinez, & Simpson, 2014). There were no significant changes in any of the outcomes of interest, suggesting

that for non-obese persons, mindfulness-based programs may not have the same positive impact on eating behaviors as it does in the obese population.

Impact of MM on Stress, Related Biomarkers and Inflammation

Obesity, and in particular abdominal obesity, is associated with impaired immune function and an increased risk of chronic inflammatory diseases, such as type 2 diabetes (Bray, 2004; Lee & Pratley, 2005). However, increasing evidence suggests that the stresses of modern day life could also play a significant role. Psychological stress activates the hypothalamic–pituitary–adrenal (HPA) axis, resulting in elevations in circulating glucocorticoids, and activation of the sympathetic nervous system (SNS), leading to increased blood pressure (BP), heart rate and circulating catecholamines (Black, 2006).

Evidence suggests that people who are more responsive to psychological stress are at an increased risk of developing obesity, and particularly abdominal obesity (Bjorntorp, 2005). For example, an elevated cortisol waking response has been consistently associated with abdominal adiposity in healthy men (Therrien et al., 2007). Disturbances in sympathetic responsiveness to psychological stress have also been linked to abdominal obesity. Waist–hip ratio was associated with heightened stress-related increases in diastolic BP and total peripheral resistance in a study of pre-menopausal women (Davis, 2009), and waist circumference correlated with greater systolic and diastolic BP and heart rate reactivity to mental stress in older African men and women (Waldstein, Burns, Toth, & Poehlman, 2009). Chronic stress exposure has been associated with a dysregulated HPA and/or SNS response, and there is growing evidence for an association between chronic stress and abdominal adiposity (Bjorntorp et al.,

2005). In humans, chronic work stress and low socioeconomic status are associated with an increased risk of developing abdominal obesity, overall obesity and the metabolic syndrome, independent of traditional risk factors such as smoking, diet and exercise (Brunner, Chandola, & Marmot, 2007).

Obesity is associated with a state of chronic systemic low-grade inflammation, and because adipose tissue is source of several pro-and anti-inflammatory cytokines, obese individuals have elevated circulating levels of leptin, interleukin-1 receptor antagonist (IL-1Ra) and interleukin-6 (IL-6) (Lee et al. 2005). Leptin is significantly elevated (approximately fourfold) in obese people and positively correlates with percentage body fat (Considine et al., 2006). The sustained high concentrations of leptin from the enlarged adipose stores result in leptin desensitization. The pathway of leptin control in obese people might be flawed at some point, so the body does not adequately receive the satiety feeling subsequent to eating.

The effect is also striking for IL-1Ra; serum IL-1Ra levels are sevenfold higher in morbidly obese patients, where they are positively correlated with BMI (Meier et al., 2002). Excess levels of the protein IL-1Ra are associated with both leptin and insulin resistance in the obese (Juge-Aubry et al., 2004).

In contrast, moderately elevated circulating IL-6 levels have been reported in some groups of obese patients but not others (Meier et al., 2002). Cross-sectional studies have also demonstrated a positive association between circulating levels of leptin, IL-1Ra and IL-6 and measures of central and total adiposity in healthy non-obese people whereas weight loss induced by gastroplastic surgery or dieting in morbidly obese patients leads to parallel reductions in circulating levels of these cytokines (Considine et al., 2006).

PA modulates levels of inflammation both locally by regular muscle movement, which may suppress inflammation, and systemically via muscle-derived cytokines or leptin, which may be reduced with PA. Activity is also associated with improved endothelial function and nitric oxide (NO) synthesis and has been recently found to increase endothelial progenitor cell activation and mobilization (Kasapis & Thompson, 2005).

NO has been found to be involved in a number of regulatory functions in inflammation. These include infection control, regulation of signaling cascades and transcription factors, regulation of vascular responses, and regulation of leukocyte rolling, migration, cytokine production, proliferation and apoptosis (Cross & Wilson, 2003; Rawlingson & Burns, 2003).

Research examining the effects of MM on stress and the immune system is growing with mounting evidence that both the detrimental physiological and emotional outcomes of stress can be ameliorated by MM practice. In a recent randomized controlled trial (RCT), Irwin & Olmstead (2012) observed improvements in IL-6 levels after a TC intervention in older adults. IL-6 is a cytokine primarily produced at sites of acute and chronic inflammation. In a similar intervention, regular TC exercise for 12 weeks significantly enhanced functional mobility and regulatory T-cell function of normal adult volunteers (Yeh et al., 2007). Qigong practice by cancer patients was shown to significantly decrease levels of the inflammatory biomarker c-reactive protein (CRP) (Oh et al., 2011) as compared to a non-active control group. MM post surgery may help ameliorate obesity-related inflammatory processes and improve long-term weight outcomes.

Impact of MM on Physiological Outcomes

Regular physical activity is positively associated with decreases in hypertension, hypercholesterolemia, hyperglycemia, type 2 diabetes, stroke and myocardial infarction rates, and some cancers, such as colorectal. PA is also improves balance and muscle strength, performance of activities of daily living and mortality rates (CDC, 2013).

Research of MM practices is finding similar positive physiological benefits. The four leading morbidity and mortality risk factors of overweight, hypertension, high blood glucose and hypercholesterolemia are significantly reduced by MM (Janhke et al., 2010). Other indicators of cardiac health have also been evaluated. Reduced heart rate is reported as a result of TC (Wolf et al., 2006) as well as an increased in heart rate variability (HRV) (Audette, Jin, Newcomer, & Stein, 2006). MM can also attenuate the rate of bone loss (Chan et al., 2004), increase bone mineral density (Woo, Hong, Lau, & Lin, 2007) and decrease the rate falls in the elderly (Li, Fisher, Harmer, & Shirai, 2003; Tsang, Orr Lam, Comino, & Singh, 2007). MM is associated with improved physical functioning, (Li, Fisher, Harmer, & Shirai, 2003) sleep quality, (Irwin, Olmstead, & Oxman, 2007) and has led to promising results for people with conditions such as arthritis, lupus, and fibromyalgia (Centers for Disease Control, 2010).

Because MM includes some level of movement similar to conventional exercise, those aspects of the practice may have possible mediating effects on outcomes. These include the level of aerobic activity or exertion and strength building activities. The few studies that compare MM to an active control have observed similar improvements in both groups, making it challenging to tease out the true impact of the meditative components on physiological outcomes. However, deconditioned individuals such as

bariatric patients may gain similar health benefits from MM, a gentle exercise modality, as from conventional activity. Studies using doubly labeled water indicated that overweight and obese individuals have high absolute total energy expenditure (TEE) compared with individuals of lower BMI (Prentiss, Black, Coward, & Cole, 2006). So, while MM is experienced as low-to-moderate intensity for many individuals, bariatric patients may expend more energy during MM activities. Research has shown a significant inverse relationship between PAEE and blood glucose levels (Ekelund et al., 2005, 2007), coronary heart disease (Lee, Sesso, Oguma, & Paffenbarger, 2003) and mortality rates (Manini et al., 2006).

Impact of MM on Psychological/Emotional Outcomes

In addition to its positive impact on physiological outcomes, MM also positively influences psychological and emotional states. Anxiety decreased significantly for participants practicing TC (Lee, Soo Lee, Kim, & Moon, 2003; Tsai et al., 2003). Depression was shown to improve significantly in depressed elderly patients who practiced QG (Cheung et al., 2007; Tsang, Fung, Chan, Lee, & Chan, 2006). General measures of mood (e.g., the Profile of Mood States questionnaire) were improved significantly for participants practicing TC (Jin, 1992) and QG (Lee, Lim, & Lee, 2004). Reports of self-esteem significantly improved (Lee, Lee, & Woo, 2007) and fear of falling decreased significantly in subjects practicing TC (Zhang et al., 2006).

In a comprehensive review of the literature, Faith et al. (2011) discovered that there was good evidence that obesity is prospectively associated with increased depression. This supports earlier research that revealed that patients suffering from obesity, have an increased risk for symptoms of anxiety and depression (Sarwer,

Wadden, & Fabricatore, 2005). Overweight and obesity is also negatively associated with measures of quality of life, including self-esteem, especially in women (Kolotkin, Head, Hamilton, & Tse, 2012). By potentially improving these psychosocial outcomes through MM practice, surgical weight loss results may be also improved.

Impact of MM on Eating Patterns

There are data that suggest that obesity is associated with both emotional and external eating patterns. Emotional eating refers to an inclination to overeat in response to negative emotions such as boredom or stress, while external eating signifies a tendency to overeat in response to food-related stimuli, including the smell or taste of food (Van Strien, Schippers, & Cox, 1995). Research shows that questionnaires that capture these types of maladaptive eating behaviors are positively associated with BMI and obesity (Delahanty, Williamson, Meigs, Nathan, & Hayden, 2002). A study by Blair et al. (1990) found significant associations between the degree of emotional eating and weight loss success. Those who maintained successful long-term weight maintenance reported decreases in emotional eating between baseline and a 1-year follow-up. In contrast, subjects who lost less weight had increases in emotional eating during the same time points of the study.

It is likely that experiential avoidance is involved in both emotional and external eating behaviors. Emotional eating occurs in response to negative emotions and there is evidence to suggest that it may be an attempt to distract attention from, or alleviate, these feelings (Tice & Bratslavsky, 2000). In contrast, external eating occurs in response to food cues and is therefore not necessarily prompted by an attempt to avoid or control negative feelings. However, where an individual is trying to lose weight, or eat healthily,

and is attempting to resist overeating in response to these cues, it is likely that he or she will experience difficult thoughts, feelings and/or bodily sensations. For example, attempting to resist dessert at a restaurant may elicit uncomfortable cravings. Failure to resist dessert may therefore be viewed as an attempt to avoid or control these cravings and thus also a form of experiential avoidance (Tapper et al., 2008). Mindfulness directly targets experiential avoidance. Thus, it may be effective in bringing about reductions in emotional and external eating behaviors.

Research suggests that successful weight loss is positively associated with internal disinhibition eating factors, such as eating in response to internal emotional cues (Livhits et al., 2010; Neimeier, Phelan, Fava, & Wing, 2007). Mindfulness and meditation techniques may modify the dysregulated processes associated with emotional eating in several ways. Although there are many variations, the basic elements are to maintain a relaxed focus on a single object of attention, and when that attention shifts to another object, to simply return it to the original object. Mindfulness meditation techniques, as used here, emphasize the ability to bring focused, yet detached, awareness to all objects of attention, while maintaining a non-judgmental, self- accepting attitude. As a relaxation technique, meditation may decrease both emotional (Beauchamp-Turner & Levinson, 1992) and physiological reactivity in such disorders as essential hypertension (Sothers & Anchor, 1989). By promoting a heightened bodily awareness of physiological signals, meditation may increase the ability to recognize and respond to normal satiety cues. As a way of improving self-acceptance, it may decrease the relative appeal of binge eating as an escape mechanism (Heatherton & Baumeister, 1991) and facilitate general therapeutic change.

Mindfulness has been shown to positively affect weight loss and maladaptive eating behaviors. A 12-week yoga program reduced incidences of binge eating disorder in a group of obese females (McIver, McGartland, & O'Halloran, 2009). Specifically, women perceived an overall reduction in the quantity of food they consumed, decreased eating speed, and an improvement in food choices throughout the program. A meditation-based intervention also found significant decreases ($p<.001$) in binge eating disorder in obese females and time spent meditating was significantly associated ($p<.01$) with less binge eating episodes (Kristellar & Hallett, 1999). Adding a 1 day mindfulness workshop to a weight loss program resulted in significant decreases in body mass index ($p<.05$) over a 3 month period (Lillis, Hayes, Bunting & Masuda, 2009). In bariatric patients, the practice of mindful eating has been shown to be effective in maintaining weight loss post-surgery (Engstrom, 2007).

Binge eating disorder is one of the most commonly studied eating disorders in the overweight and obese population and is clearly improved through mindfulness-based practices such as yoga. In addition, other disorders such as emotional eating and/or external eating, have been observed to significantly decrease after mindfulness training (Alberts, Thewissen, & Reis, 2012; Dalen et al., 2010; Daubenmier et al., 2011).

Impact of MM on Weight Outcomes

There have been few studies to date that have examined the impact of MM on weight outcomes. There is a large body of evidence of the health benefits associated with MM (Jahnke, Larkey, Rogers, Etnier, & Lin, 2010), but to date, there has been limited focus on weight loss or management of weight relative to these practices. A review of the MM literature discovered a total of 31studies that examined the association between MM

and weight; of which only three included weight and/or body composition as the primary outcome. A total of 11 out of the 31 studies found significant changes in weight and/or body composition measures. The literature suggests that longer durations of yoga may lead to larger positive changes in weight, body composition and waist circumference. No such association between practice minutes and significant results was observed in the TC/QG studies examined.

In 18 of the 31 studies that were included in the literature review, there were no significant differences in weight outcomes between the MM group and the control group. This may be due to a number of factors. Research comparing MM and other actual physical activity is limited; much of the research to date examines MM in relation to education, stretching or usual/standard of care protocols. When comparing MM to a mostly sedentary activity or actual non-activity, one might argue that it is the actual energy expenditure of MM, and the resulting energy deficit that causes the improvements and positive changes in weight and/or body composition. None of the studies measured degrees or states of mindfulness or other potential mediators of weight loss. MM interventions of 12 weeks duration in obese patients have shown significant improvements in body composition measures including weight in kgs and percent body fat (Chen, Ueng, Lee, Sun, & Lee, 2010; Dechamps, Gatta, Bourdel-Marchasson, Tabarin, & Roger, 2009). Interventions of shorter duration, e.g., 6-10 weeks unequivocally resulted in non-significant weight changes (Gallantino et al., 2003; Madanmohan et al., 2008; Thomas et al. 2008).

There are also several limitations of these studies that may have impacted the reported results. For example, the sample sizes were relatively small which may have

resulted in some type 2 errors, with insufficient power to detect between-group changes. Many of the studies were pilot studies and thus did not have a large enough sample size for statistical power. The relatively short duration of many of the study periods could also impact the results. And in many instances, it was not possible to control for mediating effects of medication or eating habits.

Conceptual Model Overview

In relation to bariatric surgery patients, components of MM may have effects on post-surgical weight outcomes, both directly and indirectly. Theoretical MM-related increases in mindfulness are proposed to increase weight loss through improvements in physical activity patterns, eating behaviors and psychosocial factors.

Physical activity. While TC is typically assessed as low to moderate intensity (Lan, Chou, Chen, Lai, & Wong, 2010; Taylor-Pillae & Froelicher, 2004), it may be responsible for weight loss simply given the energy expenditure of the movements. Additionally, past research has shown that MM can lead to more activity levels overall and more vigorous activity (DeChamps et al., 2007; Larkey et al., 2009).

Dietary Behaviors. MM has been associated with decreases in disordered eating (Kristellar & Hallett, 1999; Livhits et al., 2010; McIver, McGartland, & O'Halloran, 2009; & Neimeier, Phelan, Fava, & Wing, 2007). Additionally, Engstrom (2007) reported that mindful eating in bariatric patients led to more long-term weight loss. And, finally, MM has been associated with increases in dietary quality (Kristal, Littman, Benitez, & White, 2005; Miller, Kristeller, Headings, Nagaraja, & Miser, 2012; Taetzsch et al., 2014). It is clear from the literature that improving dietary behaviors can lead to weight loss and longer-term weight loss maintenance.

Psychosocial Factors. While the data are mixed, there is a large body of research that indicates a strong positive association between levels of depression and anxiety and obesity. MM has been shown to significantly decrease levels of both of these psychological variables (Cheung et al., 2007; Lee, Soo Lee, Kim, & Moon, 2003). Other aspects of MM, such as the relaxation response and reduced stress associated with deep breathing and meditative states, may influence weight through changes in inflammatory processes (Irwin & Olmstead, 2012; Oh et al., 2012; Yeh et al., 2007).

By promoting a heightened bodily awareness of physiological signals, MM may increase the ability to recognize and respond to hunger and satiety cues, leading to more healthy eating patterns and associated weight loss (Heatherton & Baumeister, 1991). Therefore, this study will collect data on eating and physical activity patterns as well as psychosocial variables as described in Chapter 3.

CHAPTER 3

METHODS AND MATERIALS

Research Design

Study design. This study was a one-group, pre-post 8-week Tai Chi Easy (TCE) intervention to examine potential trend of intervention effects and to gain effect size information for future studies. This study also evaluated the acceptability, demand, and barriers to adherence or retention of a TCE practice among bariatric patients and was the first step in a program of research testing the feasibility and acceptability of an easy-to-learn form of MM, TCE, with bariatric patients and to determine if MM shows a trend for initiating and/or increasing weight loss.

Sample. The subjects in this study were a convenience sample of 11 women who had gastric bypass (GB) surgery only once, i.e., they have not had multiple bariatric surgeries, at the Scottsdale Bariatric Center (SBC) or the Mayo Clinic Scottsdale at least 12 months prior to study initiation. There were two distinct cohorts in this study. Cohort one (n=7) participated in the study from approximately October 2013 through January 2014 and the second cohort (n=4) participated from approximately January through March 2014. An initial sample size of 30 participants was set based on power calculations for detecting a medium effect size using paired t-tests.

An attrition rate of 20% was estimated based on previous studies involving physical activity interventions in both GB and adjustable gastric band (AGB) bariatric patients between 12-52 weeks in length (Moroshko, Brennan, & O'Brien, 2011).

Setting. The TCE sessions were held at both the Scottsdale Bariatric Center (SBC) and the Healthy Lifestyles Research Center at Arizona State University (ASU) at a variety of days of the week and times.

Protection of Participants' Rights

This research was approved by the Arizona State University Institutional Review Board (IRB), and the Scottsdale Healthcare IRB (Appendix A & B). The researcher carried out the recruitment, introduction of the study, informed consent, intervention, and data collection. Written informed consent was obtained from all participants after a thorough discussion about the study between the researcher and potential participant occurred (Appendix C). All questions were answered and the participant verbalized understanding of the study and consent prior to signing. A copy of the informed consent document was offered to the participant after signing.

Eligibility Criteria

Inclusion criteria. Inclusion criteria included women between the ages of 18-70, having undergone a single gastric bypass bariatric surgery in the 12-36 months preceding study enrollment and have begun to re-gain weight, specifically those who have re-gained at least 5 pounds. This information was obtained from patient self-report. The 12-36 month timeframe is the point at which most patients will start to re-gain weight after surgery (Bond et al., 1998; Hsu et al., 2007, 2008; Meguid et al., 2008). Additionally, all participants must have the ability and the medical clearance to safely participate in low impact PA, which was assessed through the Physical Activity Readiness Questionnaire (PAR-Q). Study subjects were required to read and write in English. A copy of the PAR-Q questionnaire can be found in Appendix D.

Exclusion criteria. Exclusion criteria for the study were patients who have not gained at least 5 pounds at the time of study, those who did not have gastric bypass surgery specifically or had multiple surgeries, and those who answered "yes" on the PAR-Q and subsequently could not provide physician approval and clearance for participation.

Recruitment

The target for recruitment was 36 female gastric bypass patients able to speak and write in English. Subjects in this study self-identified as 82% white and 18% Hispanic, which is representative of the national bariatric surgery patient demographics (Pratt et al., 2009).

Table 1

Targeted and Actual Enrollment Numbers

	Female	White	Hispanic	African American	Native American	Other
Goal (n=30)	30	25	3	1	1	0
Actual (n=11)	11	9	2	0	0	0

Rolling recruitment was ongoing during the duration of the study, from October 2013 to March 2014. A total of 23,995 total recruitment emails were sent to current and former bariatric patients at Scottsdale Healthcare Shea (SHC) campus (Appendix E). The email did not target by inclusion criteria, and the exact number of female gastric bypass patients within the study timeframe (1-3 years) that were contacted was not available.

Study information was also relayed via the SHC online bariatric surgery support group web portal and flyers were distributed in the SBC surgery center (Appendix F). In addition, research staff attended ongoing patient support groups at the Mayo Clinic Scottsdale to recruit in person. A total of 47 women responded to recruitment efforts, of which 40 were eligible, consented and enrolled into the study. Further details of recruitment and retention are presented in Table 2.

Table 2

Details of Recruitment

Recruitment Type	Total Responses	Eligible/Enrolled Participants	Attrition	Completed
SHC Emails	42	35	24	8
Mayo Clinic Scottsdale	5	5	2	3

The SBC performs bariatric surgery on approximately 350 men and women annually and the Mayo Clinic performs more than 500 such surgeries each year nationally. The population served at the SBC is approximately 85% Caucasian, 9% Hispanic and predominantly female (70%). The population demographics for Mayo Clinic patients were not ascertained. A letter of support is attached from SBC (Appendix G).

Informed Consent and Enrollment

After receiving an email from SBC describing the study, interested individuals contacted the researcher and expressed interest in study participation either by telephone or email. Once interest was expressed, the researcher made contact, explained the study, answered any questions, and completed a brief screening questionnaire, if appropriate (Appendix H). Forty-seven participants were screened, and 40 eligible participants were

enrolled into the study and later consented. Appointments were made for the first study visit, i.e., the baseline visit (week 0) and to obtain informed consent. A brief outline of study visits was discussed with the subjects.

At the baseline visit, informed consent was obtained in writing. Each participant received a folder containing a written summary of the study's purpose, requirements, and visit schedule during the first participant meeting. All time expectations were clearly stated at the beginning of the study. Questionnaires were completed and data collected as described in Table 3. A copy of all questionnaires can be found in Appendix I-U. The first visit lasted approximately 60 minutes, although some subjects took up to 90 minutes, based on the time it took them to complete the questionnaires.

Study Retention

Weekly attendance at class was emphasized during every step of recruitment and at the weekly classes. Telephone calls, emails and texts, were utilized to remind all participants of scheduled data collection times. Additionally, attendance rosters were collected weekly and if a participant missed a class, she received a phone call, email or text to ascertain the reasons for the absence. Participants were compensated with a $20 gift card at the completion of the study, after the final data were collected.

Data Collection

Data collection was conducted by research staff at each individual recruitment site, either at SHC or ASU. Data collection occurred at week 0 (pre-intervention) and at the end of week 8 (post-intervention). See Table 3 for specific details on data collection time points and measures. Well-lit rooms were used for data collection and participants were allowed access to water and bathrooms during the completion of the surveys.

Tai Chi Easy Intervention Structure

TCE is a simple TC/QG form that was developed by Dr. Roger Jahnke and developed into a standardized research intervention protocol by a team of researchers (Jahnke, Larkey, & Rogers, 2010). It has been used in several prior projects (Larkey, Szalacha, Rogers, Jahnke, & Ainsworth, in press, 2012; Larkey, Jahnke, Etnier, & Gonzalez, 2009) and one recently completed NIH/NCCAM-funded randomized controlled trial (RCT) with breast cancer survivors (Larkey et al., 2014) showing reduction in fatigue and depression, and improved sleep and physical function. The 8-week length of this intervention was based on prior studies examining effects of MM on health outcomes (Chen et al., 2010; Dechamps et al., 2009).

TCE is led by a practice leader who has completed at least 25 hours of training that consists of studying the TC Easy Practice Leader Training Manual, in-person group classes, and practicing the methods guided by a training DVD (as was the researcher). The TCE intervention combines simplified TC movements with QG methods that include gentle flowing movements and slow shifts of body weight while incorporating deep, soothing breathing.

The TCE sessions began with low and natural light when possible rather than bright lights to promote a comfortable atmosphere. Music appropriate for MM was used at a low volume using a consistent playlist. The movements began with a warm up of slow, deep breathing and aligning posture (sitting or standing) for approximately 5 minutes. The TCE movements (as described below) were repeated in differing sequences and timeframes during the course of the study. The variety and combination of the exercises began easy and progressed to more advanced movements and/or intensities as

the study progressed and participants became more experienced and comfortable with the routine. Throughout the exercises, the participants were reminded of correct alignment, continuing slow, deep, breathing, and to relax the mind. The exercises began with the opening sequence that include shifting weight to one foot and taking a step to the side so that feet are shoulder width apart for the majority of participants who chose the standing form of TCE. One or two participants chose to complete the exercises in a seated position, and this was based upon the participant's fitness, comfort level and injury status. The exercise session concluded with the closing sequence (opposite of the opening sequence with weight shift and the leg brought in toward the other). The descriptions of the exercises below have been adapted from Jahnke (2010).

Twisting at the Waist. With feet shoulder width apart, gently twist at the waist from right to left, left to right, and repeat allowing the arms to swing freely. A gentle patting of the back and abdomen are encouraged, as the arms are gently rotate from side to side. Slowing down the movement until the body is no longer twisting and is back to the center position concluded this exercise.

Right and Left Bending of the Spine. Right and left bending of the spine entails gently bending the upper body to the right side while exhaling and allowing the right arm to dangle in front of the body while slow deep breathing continues. This is then repeated to the left side. For participants who feel they need more challenge, the opposite arm can be stretched over the head. This can be performed in the standing opening position or in a seated position.

Flowing motion. Flowing motion encourages slow inhalation and deep breathing while turning the palms into a forward position. A gentle forward rocking motion while

lifting the body weight onto toes and swinging arms forward and upward, to the maximum height of the shoulders or lower, dependent upon participant comfort with elbows slightly bent is the main motion. Participants are reminded to do this gently and to feel as though they are sinking their body weight down toward the ground.

Front and Back Bending Spine (Crushing Rocks). This movement may be done from the standing opening position or a seated position. Inhalation while raising the hands up with palms up and arms bent at about 90-degree angle. At chest height, palms are at face level and then upward as arms reach up. When arms are above shoulder height the head is tilted upward. During exhalation, the arms move forward and down, palms toward the face. Hands are placed near each other into fists and the whole body is contracted. The head is bent forward as the shoulders are rounded and full exhalation occurs. During this exercise the participant is encouraged to clear and calm their mind, body and spirit and during exhalation everything is contracted.

Gathering Heaven and Earth. With arms in front of the chest open arms to a 45-degree angle, palms facing each other. Bend the knees and lower the arms so that the palms are facing up. Sink down by gradually bending at the knees while making a scooping motion with both hands "gathering Earth" below. Slowly stand up while moving arms up to the sky (Heaven) while looking up. "Gather Heaven" and move the arms downward until palms are facing each other and repeat.

Reaching Upward and Stretching Outward. During inhalation, the fingers are laced together, palms toward body as they are passed in front of the body and face. Palms are rotated downward, then upward and toward the sky as arms are extended up and the participant is encouraged to rise on their toes if able.

Meditation. The participant is encouraged to close their eyes and clear their mind by concentrating on the present moment, including sounds within the room. A reminder that there is "no other place you need to be but right here, right now" will be used. Deep breathing and alignment are also part of the focus.

Passing Clouds. Arms are crossed in front of the chest and weight is equally distributed to each foot. Arms are opened out from the center of the body to shoulder height as weight is shifted to the left foot. The right arm is moved down in a scooping arc motion and left hand opens away for the body at about chin level. The movement continues until the right hand reaches the rib cage and the left hand moves with the palm slightly angled down to just above the right hand and weight is shifted to the opposite foot. This movement is continued until the right hand is chin level on right side of the body, palms facing the face. The left hand is waist height with palm angled toward torso, weight on right foot. Continue this motion and finish by raising arms and crossing in front of the chest.

Cutting the Path to Clarity. With arms crossed after the above "Passing Clouds" is concluded, palms are then placed outward. The hand closest to the heart is then pulled toward the back and the hand farthest from the heart pushes forward. The torso is turned and one hand is pushed forward, leading with the pinky finger as if "cutting air". The opposite hand turns forward and the other hand pulls back. The motion is repeated side to side.

Harmonizing Yin and Yang. In the standing opening position or seated position, hands are raised to the chest level with palms facing the chest, The left hand with palm up is brought across the front of the torso below the right hand, palm down, as to simulate

holding a beach ball. Body weight is shifted slightly to the right. The left hand moves to the left, as if serving a tray, palm open and facing up. The right hand drifts toward the right with the palm down. The waist is slightly turned to the left as weight is shifted to the left foot. The right palm floats down toward the hip while left palm faced the chest as if to turn the serving tray over. This motion continues back and forth, making a "ball" on each side of the body while shifting the weight of the body, slowly. Slow, deep, methodical breathing is encouraged as well as reminders of alignment and relaxation.

Brush Knee, Send Qi. This exercise can conclude Harmonizing Yin and Yang by turning the "ball" over and moving hands clockwise so that the left hand is on top and right hand is on the bottom of the "ball". Both hands slowly drop down. The left hand floats across the front of the torso and brushes past the knees. The right hand drops down to the side and rises forward, simulating a swimming motion. The waist is turned to move the right hand past the ear (sending Qi) and the weight shifts to the side. The motion is repeated. To conclude the exercise the lower hand is brought upward with palm up as weight is shifted equally to both feet. Hands cross as they are raised upward until they are both at the level of the chest.

Meditating Imagery. Participant is encouraged to close the eyes and imagine a scene that invokes comfort, peace, relaxation, and positive thoughts. Examples such as a field of flowers, a beautiful sunset, ocean waves, a mountain view, or a colorful garden are used to help the participant find an image conducive to their personality. Slow deep breathing is encouraged and proper alignment is reinforced.

Tracing of the Channels. Hands are rubbed together to generate heat then directed over the participant's face, head, neck, shoulders, around to the back and down

the spine, over the kidneys, down the outside of the legs and bending over to a comfortable level (either standing or sitting) around the legs or feet and up the inside of the legs, over the abdomen, chest, neck. The tracing sequence is then repeated two more times.

Self-Massage. After tracing of the channels, one hand is placed over the shoulder while the opposite hand supports the elbow. Pressure is applied in a self-massaging manner. The participants will be encouraged to massage arms, hands, ears, face, legs, abdomen and any part of the body desired.

Spontaneous Qigong. In a seated position or standing at the opening posture, the participant is encouraged to bounce, lifting and dropping heals, shifting weight from one side of the body to the other. Flopping of the hands or snapping fingers vigorously is next. The neck and head move around and the shoulders are raised and lowered. This is done for a few moments with deep, relaxed breathing and then stopped. The participant is encouraged to notice how they feel and the exercise is repeated.

TCE Implementation

The first TCE session was held within 10 days after baseline data was collected in its entirety at the participant's preferred location. Participants received general verbal information on how to perform TCE safely and the benefits of its practice. A DVD featuring a set of introductory principles of practice and 10 core exercises (easy to learn within the first 2 weeks) and an additional 7 exercises (for participants who like more variety) was professionally produced and given to each participant to help guide their practice at home. The group sessions were held weekly and home practice of "most days of the week" was highly encouraged. Participants were provided with both a paper copy

and an electronic copy of the Participant Log, to track their TCE participation, both in class and at home and any other PA performed. The researcher attempted to collect the log weekly, either in person or electronically. Movements were demonstrated and performed by the researcher with the group. A chair was provided for each participant if they needed to sit during the practice or as a sturdy object during movements that required balance concentration. Participants were observed to ensure correct technique and safety.

Class size for the intervention was limited to a maximum of 15 participants, which was not an issue given the small sample size. A small class size helps ensure close observation and supervision from the TCE leader so that individual attention to each participant could be provided. Class sizes ranged from 1-6 participants per session; there was only subject that attended the TCE morning session at the ASU location.

Consistent performance of the movements, observations and reminders of practicing within a safe and comfortable range, and noting any emergent emotional challenges are all better managed with small groups. It was also stressed that whatever was conveyed during the sessions should remain confidential within the group.

Attendance was documented in the Intervention Log, as the participants signed in at each MM session (Appendix I). If a participant missed a session, they were contacted to learn of their concerns or reasons for missing. Because there were several days and times of TCE classes during the week, those participants that wanted to make up a missed session that same week were able to do so. The TCE sessions were concluded with an opportunity for participants to ask any questions (either before or after the session) and a reminder to practice at home, documenting any practice minutes in the Participant Log.

Measurement Instruments

Table 3 provides a list of the instruments used in the study, when they were administered, and for what purpose. Assessments were administered on paper with the researcher available to answer any questions.

Table 3

Measurement Instruments

Table of Study Measures	**Pre-Eligibility**	**Baseline**	**Weeks 2-8**	**Post Study**
Eligibility				
Age	x			
Number of surgeries	x			
Type of surgery	x			
Date of bypass surgery	x			
Weight re-gain status and amount	x			
Miscellaneous Measures				
Informed Consent		x		
Demographics		x		
Physical Activity Measures				
Physical Activity Readiness Questionnaire (PAR-Q)		x		
MN Leisure-Time Physical Activity Questionnaire				x
Borg rating of perceived exertion (RPE)			x	
Body Composition Measures				
Bioelectrical Impedance Analysis (BIA)		x		x
Eating Behavior Measures				
Three Factor Eating Questionnaire (TFEQ-R18V2)		x		x
Dietary Screener Questionnaire (DSQ)		x		x
Mindfulness Measures				
Mindful Attention and Awareness Scale (MAAS)		x		x
Meditative Movement Inventory (MMI)				x
Psychosocial Measures				
Body Awareness Questionnaire (BAQ)		x		x
Profile of Mood States subscales (POMS)		x		x
Ongoing Process Control and Intervention Fidelity				
Feasibility Questionnaire				x
MM Participant Log		x	x	
Intervention Log		x	x	
Follow-up Questionnaire				x

Demographics. Demographic variables included (a) age in calendar years; (b) ethnicity and race; (c) date of initial surgery; and (d) pre-surgery and current weight.

Height, weight and body composition. Height was obtained via self-report. Weight and body composition were measured by a digital bioelectrical impedance scale (Tanita TBF 300A-Arlington Heights, IL). Bioelectrical impedance analysis (BIA) is a based on the conduction of a small, applied electrical current throughout the body. BIA has been shown to be a reliable and valid method to estimate body composition (Lukaski, Johnson, Bolonchuk, & Lykken, 1985) and correlates highly with DEXA measures, the gold standard of body composition measurement (Duz, Kocak, & Korkusuz, 2009). Additionally, BIA appears to be accurate in measuring decreases in body fat with decremental weight loss (Johnson, Rinke, & Burman, 1987), which is important given this population.

Physical activity readiness questionnaire (PAR-Q). The Physical Activity Readiness Questionnaire (PAR-Q) is a screening tool and consists of 7 closed-ended questions that assess an individual's level of physical fitness and ability to engage in physical activity. The PAR-Q is designed to determine if physical activity is appropriate for adults who are between the ages of 15-69 and for whom physical activity may cause harm. The PAR-Q advises the adult who is over than the age of 69, and for whom physical activity is not apart of his or her normal routine to contact his or her health professional regarding beginning engaging in physical activity regardless of his or her score on the PAR-Q. If the subject answers "yes" to any of the seven questions, it is recommended that the individual consult with their doctor prior to becoming physically active and a medical release will be required for study participation.

Minnesota leisure-time physical activity questionnaire (MNLTPAQ). Physical activity was measured over the course of the study using a revised version of the Minnesota Leisure-time Physical Activity Questionnaire (MNLPAQ). The MNLPAQ was originally designed as a 52 week PA record and was modified to collect data over a 3-month timeframe for the current study. The data were retrospectively collected at a single time point, at week 12. The MNLTPA condenses PA into seven distinct activity categories: 1) Walking and Miscellaneous; 2) Conditioning; 3) Water, 4) Other, 5) Sports; 6) Lawn and Gardening and 7) Household. The MNLPAQ has an overall reliability of 0.92.

Borg rating of perceived exertion scale (RPE). The Borg Rating of Perceived Exertion (RPE) is a way of measuring physical activity intensity level (Borg, 1998) and ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Perceived exertion is how hard an individual perceives their body is working and it is based on the physical sensations a person experiences during physical activity, including increased heart rate, increased respiration or breathing rate, increased sweating, and muscle fatigue. Although this is a subjective measure, a person's exertion rating may provide a fairly good estimate of the actual heart rate during physical activity (Borg, 1998). Practitioners generally agree that perceived exertion ratings between 12 to 14 on the Borg Scale suggest that physical activity is being performed at a moderate level of intensity. RPE was measured weekly via the Participant Log.

Three-factor eating questionnaire (TFEQ-R18V2). Eating behavior was evaluated using the revised Three-Factor Eating Questionnaire (TFEQ-R18V2) (Capellari et al., 2009; Stunkard and Messick, 1985). The TFEQ-R18V2 is an 18-item

questionnaire, which measures levels of cognitive restraint, disinhibition of eating and hunger cues/emotional eating patterns. Reliability of the TFEQ-R18V2 was 0.96 with α of 0.94. Higher scores in the respective scales are indicative of lesser cognitive restraint, and greater uncontrolled, and/or emotional eating behaviors.

Body awareness questionnaire (BAQ). The BAQ is an 18-item scale that measures attentiveness to normal, internal bodily processes and sensations and has been shown to be internally consistent (α = .82) (Shields, Mallory, & Simon, 1989). Responses are measured on a 7-point Likert scale ranging from 1 (*not at all true about me*) to 7 (*very true about me*). Higher scores indicate greater body awareness.

Profile of mood states (POMS). The POMS measures the total mood disturbance dimensions of tension-anxiety; depression-dejection; anger-hostility; and confusion-bewilderment (McNair, Lorr, & Droppleman, 1971) and has excellent validity and reliability in a multitude of populations (α = .93). For this study, only the subscales of depression and anxiety were utilized and lower scores reflect lesser severity of a depressed and/or anxious mood.

Mindful attention and awareness scale (MAAS). The Mindful Attention and Awareness Scale (MAAS) (Brown and Ryan, 2003) measured the construct of mindfulness. The MAAS is a 15-item scale that focuses on the presence or absence of attention to and awareness of what is occurring in the present moment. The MAAS has been validated in multiple samples with α ranging from 0.80 to 0.87 and higher scores indicate a higher level of mindfulness.

Meditative movement inventory (MMI). The MMI is a tool to validate that participants are implementing the key components of the TCE experience (Larkey,

Szalacha, Rogers, Jahnke, & Ainsworth, 2012). The MMI has 17 items that assess the three distinct MMI factors of breath focus (α =0.86), meditative connection (α = 0.90) and flowing motion (α = 0.61).

Feasibility questionnaire. The Feasibility Questionnaire was administered at week 8 of the intervention. The majority of questions are on a Likert-scale with the opportunity for the participant to add open-ended answers for more detail on their experiences. The questions were specifically designed to assess feasibility (timing, format, length) (e.g., "It was easy for me to find time to practice", "The home TCE materials were easy for me to use"), demand (e.g., "I think TCE is helpful after bariatric surgery" and "I intend to continue to practice TCE at home"). Two implementation (proposed changes in the coordination of a future program) questions were open ended ("What would have made the TCE home sessions better?" and "What would have made the TCE group sessions better?") and one implementation question is on a Likert-scale with the opportunity for the participant to add information ("I benefited more from home practice than group TCE sessions"). Acceptability (perceptions of participants, adherence to classes and intervention) of the TCE program are addressed with questions such as "It was easy for me to find time to practice TCE at home", and "The movements in the TCE sessions were easy for me to do." All of these questions are designed to assess feasibility as described in specific aim 1.

Dietary screener questionnaire (DSQ). The 26-item Dietary Screener Questionnaire (DSQ) captures categorical intakes of fruits and vegetables, dairy/calcium, added sugars, whole grains/fiber, red meat, and processed meat. For the purposes of this project, only the food categories of fruits and vegetables, added sugars, red meat and

processed meat were examined. The DSQ was added to the 2009-2010 NHANES and includes selected foods and drinks over the past 30 days. The DSQ has been tested extensively against the NHANES 24-hour recall data and other screeners with high correlations (0.44-0.74).

Participant log. The Participant Log is used to record details of TCE practice such as date, time, length of practice and any comments on participant mood, suggestions for program improvement, and ease or difficulty of practice. The Log also captures any non-MM, intentional physical activity and the rating of perceived exertion of the at-home TCE practice.

Intervention log. At each separate weekly TCE session, participants were requested to sign in on an Intervention Log. The Intervention Log was designed to enable the research staff to track each TCE session's date, time, participants in attendance, and any participant comments.

Follow-up questionnaire. The follow-up questionnaire was developed to obtain information on participant experiences and reasons for 1) not joining, 2) joining and not completing and 3) completing the study. This assessment was created during the course of the study when the higher-than-anticipated attrition rates became apparent.

Data Management

As questionnaire data were collected, they were reviewed for missing data, and participants were given an opportunity to (a) complete questions or pages that they overlooked or (b) indicate that they would prefer not to answer. All data is identified via a participant number; names are not on any of the data collection forms as using only aggregate data protects participant anonymity. The data were collected in paper form and

are stored in locked file cabinets in a locked room in a secure building. As data was entered, the researcher independently verified accuracy of data entry. Computer files were backed up following each use. The database is maintained on a dedicated computer that is not linked to public access servers and stored in a locked office in a secure building. Access is password protected and maintained behind enterprise-level firewalls and antivirus barriers.

Data Analysis

Data was entered into an Excel spreadsheet, which then was imported for analysis into PASW Statistics 22 (SPSS/IBM, Quarry Bay, Hong Kong). Data was checked for normality and then differences between pre and post intervention were analyzed using a paired samples t-test. Changes in PA and minutes of MM practice over the duration of the study were assessed using a repeated measures analysis of variance (ANOVA) test. Alpha was set at 0.05 for determining significance. Proper checks and corrections were conducted for all outcome variables (normality, sphericity, homogeneity), and no transformations were necessary for any of the data.

Effect sizes were calculated using Cohen's d which measures the magnitude of the intervention effects from pre to post-intervention. Cohen (1988) defined the effect size *d* as: $$d = \frac{\bar{x}_1 - \bar{x}_2}{s}$$ where X_1 and X_2 denote the means, and *s* denotes the standard deviation, between two variables. According to Cohen interpretation of effect sizes are as follows: Small effects range from .20-.49; medium effects range from .50-.79; and large effects are greater than or equal to .80.

CHAPTER 4

RESULTS

Forty women were deemed eligible and enrolled into the study after providing written informed consent. The final study sample consisted of 11 female post bariatric surgery patients with a mean age of 54.7 years. The average time since bariatric surgery was 23.8 months and only 2 of the study participants had prior meditative movement experience. Average attendance for all of the TCE sessions across all participants was 55.7%, with a range of 12.5% to 87.5%. Details of the demographics for the study are summarized in Table 4.

Table 4

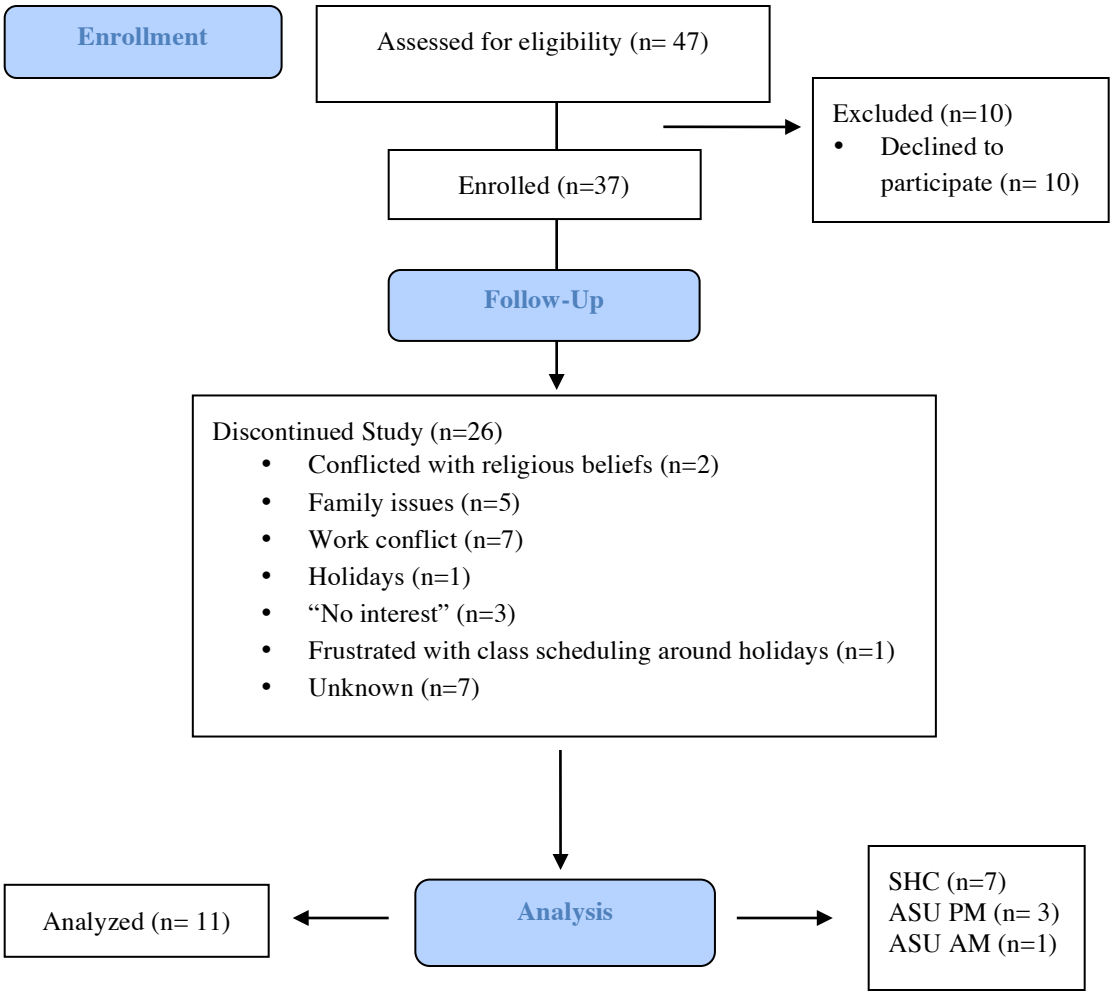
Demographic Data (n=11)

Demographic variable	N	Mean ± SD	Minimum	Maximum
Age (years)		54.27 ± 7.74	40.00	63.00
Current Weight (Pounds)		203.34 ± 25.88	165.00	251.00
Time Post Surgery (Months)		23.82 ± 7.40	14.00	35.00
Ethnicity				
Hispanic/Latino	2			
Non-Hispanic/Latino	9			
Race				
Caucasian	11			
Education				
High School Diploma/GED	2			
Associates/Some College	3			
≥ Four-Year College	6			
Any MM Practice				
Yes	2			
No	9			
Practice Length (Months)		5.00 ± 14.35	0.00	48.00
Any Meditation Practice				
Yes	3			
No	8			
Practice Length (Months)		25.10 ± 48.14	0.00	120.00

Of the 47 women that were initially screened for study eligibility, 40 were enrolled into the intervention and consented; the others were not interested after hearing the details of the study. During the course of the study, 26 women ceased participation at varying points of the intervention. Common reasons for attrition included conflicting work and/or family commitments. Many participants (7 out of 26) did not communicate the reason(s) for dropping. Figure 2 provides the screening, recruitment, and dropout sequence for this study.

Figure 2

Flow Diagram of Participant Recruitment and Retention



Correlational and independent sample t-test statistical analyses of demographics and pre-intervention data did not reveal any significant correlations or differences between those who completed and those who did not complete the study.

Descriptive Data

Baseline physical activity is reported in mean minutes per month and categorized according to MNLTPA instructions, in Table 5. Data in Table 5 is reported for all participants, whether or not they reported zero activity or any activity in a particular category. Household activities had the highest number of minutes performed per month, followed by "other activities," which includes in this study, pushing a wheelchair and canine obedience training. Also with high minutes per month were the categories of "walking and miscellaneous activities" and "water activities."

Table 5

Baseline Physical Activity Patterns from the MN Leisure-Time Physical Activity Questionnaire (n=10)

Physical Activity Categories	Mean ± SD (Minutes/Month)
Walking and Misc Activities	271.80 ± 291.65
Conditioning Activities	116.00 ± 188.28
Water Activities	200.00 ± 169.71
Sports	180.00 ± 0.00
Lawn and Garden Activities	153.50 ± 237.74
Other Activities	730.00 ± 0.00
Household Activities	928.60 ± 577.64
Total Activities	356.27 ± 182.39

Baseline dietary data from the Dietary Screening Questionnaire (DSQ) indicate that most of the subjects consumed very low frequencies of the foods listed in this particular instrument. Fruits and vegetables had the highest mean daily frequency at 2.78 ± 0.71, followed by foods with added sugars with a mean daily frequency of 2.18 ± 2.20. Baseline daily dietary data are reported in Table 6.

Table 6

Baseline Dietary Patterns from the Dietary Screener Questionnaire (DSQ) (n=11)

Food Categories	Baseline M ± SD (Servings/Day)
Fruits and Vegetables	2.78 ± 0.71
Foods with Added Sugars	2.18 ± 2.20
Red Meats	0.15 ± 0.15
Processed Meats	0.41 ± 0.37

Weekly 60-minute TCE sessions were conducted for a total of 8 weeks at both Arizona State University and the Scottsdale Healthcare Shea Campus. The mean attendance rate for all participants over all locations and/or times of day was 55.7%. The average MM practice time outside of class was approximately 4.50 hours per week per participant, based on self-report from the Participant Logs. There is a slight unimodal distribution of at-home MM practice time with the majority of the minutes occurring at the mid-point of the study. The mean average non-MM PA was substantially more than that of MM (Table 7 and Table 8, respectively).

Table 7

Weekly MM Practice Minutes as Assessed by the Participant Log

Intervention Week	N	Mean ± SD	Minimum	Maximum
Week 1	8	48.75 ± 46.66	0	120.00
Week 2	7	58.57 ± 42.70	0	120.00
Week 3	8	75.63. ± 79.03	0	235.00
Week 4	8	85.63 ± 119.42	0	355.00
Week 5	6	98.33 ± 134.49	0	360.00
Week 6	3	45.00 ± 18.03	25	60.00
Week 7	3	8.33 ± 14.43	0	25.00
Week 8	0	0	0	0

Table 8

Weekly Non-MM PA Minutes as Assessed by the Participant Log

Intervention Week	N	Mean ± SD	Minimum	Maximum
Week 1	8	191.88 ± 96.58	90	360.00
Week 2	7	188.57 ± 74.93	45	255.00
Week 3	8	158.13 ± 109.35	50	360.00
Week 4	8	211.11 ± 149.70	0	425.00
Week 5	6	280.83 ± 242.89	45	705.00
Week 6	3	238.33 ± 87.37	165	355.00
Week 7	3	236.67 ± 85.05	140	300.00
Week 8	0	0	0	0

Specific Aim 1

(a) Evaluate intervention feasibility, acceptability, demand, and barriers to adherence or retention of TCE among first time bariatric patients who have started to gain weight post surgery (b) Evaluate recruitment strategies and/or estimate recruitment and retention rates in the intervention.

Specific aim 1(a).

Participant Responses to the Feasibility Questionnaire. The Feasibility Questionnaire was distributed after the week-8 intervention. Table 9 illustrates the statistical analysis of the questions on the Feasibility Questionnaire. Feasibility Questionnaire response frequencies are detailed in Table 10, again with the most common responses bolded. The most common answer for the majority of the questions was "agree." Question 6 "It was easy for me to find time to practice TCE." and question 14 "I enjoyed the social aspects of TCE more than the TCE exercises" received "somewhat agree" from 91% (10) of the participants. These questions referred to the social support aspect of the intervention. Questions 16-21 were open-ended questions used to assess various areas of feasibility (Appendix W). The following areas of focus (acceptability, demand, implementation, facilitators, barriers, and practicality) used to examine feasibility of the TCE intervention were adapted from Bowen et al., 2009.

Table 9

Feasibility Questionnaire Subscale Statistics (n=11)

Subscale	Mean ± SD
Acceptability	1.45 ± 3.58
Demand	2.32 ± 2.01
Implementation	1.55 ± 1.21
Barriers	1.55 ± 1.21
Social Support	2.32 ± 2.97

Based on 5-point Likert scale from 1 (agree) to 5 (disagree)

Table 10

Feasibility Questionnaire Frequencies (n=11)

Question	Agree % (n)	Somewhat agree % (n)	Neutral % (n)	Somewhat disagree % (n)	Disagree % (n)
1. The people important to me support my learning of TCE (Tai Chi Easy)	**90.9 (10)**	0	9.1 (1)	0	0
2. I think that people who are like me are interested in trying out practices like TCE.	**72.7 (8)**	18.2 (2)	0	9.1 (1)	0
3. I enjoyed practicing TCE.	**81.8 (9)**	18.2 (2)	0	0	0
4. The movements in the TCE sessions were easy for me to do.	**81.8 (9)**	18.2 (2)	0	0	0
5. The TCE home materials were easy to use.	**81.8 (9)**	9.1 (1)	9.1 (1)	0	0
6. It was easy for me to find time to practice TCE.	27.3 (3)	18.2 (2)	9.1 (1)	**45.5 (5)**	0
7. I feel TCE was appropriate during this time of my life.	**90.9 (10)**	9.1 (1)	0	0	0
8. I feel less sad when I practice TCE.	**54.5 (6)**	27.3 (3)	9.1 (1)	9.1 (1)	0
9. I am in better physical shape because of TCE.	**36.4 (4)**	**36.4 (4)**	27.3 (3)	0	0
10. I think TCE is helpful after bariatric surgery.	**100 (11)**	0	0	0	0
11. TCE has made my weight loss process easier.	9.1 (1)	**63.6 (7)**	27.3 (3)	0	0
12. I discussed my challenges with weight with other group members.	**27.3 (3)**	**27.3 (3)**	9.1 (1)	18.2 (2)	18.2 (2)
13. I felt connected with group members who were participating in TCE.	**36.4 (4)**	27.3 (3)	18.2 (2)	18.2 (2)	0
14. I enjoyed the social aspects of TCE more than the TCE exercises	18.2 (2)	0	18.2 (2)	**45.5 (5)**	18.2 (2)
15. I intend to continue to practice TCE	**90.9 (10)**	9.1 (1)	0	0	0

Acceptability (satisfaction, intent to continue, perceived appropriateness) was evaluated by questions 1-10, 15, and the Participant Log. All 11 subjects (100%) reported that TCE was helpful after bariatric surgery and 90.9% of women reported feeling supported in learning TCE by the people important to them.

Demand (expressed interest or intention to use, perceived demand, actual use) was assessed by questions 2 and 9 and the Participant Log. Seven participants (63.6%) agreed "TCE has made my weight loss process easier."

Implementation (success or failure of execution, amount, type of resources needed to implement, factors affecting implementation ease or difficulty, efficiency, speed, or quality of implementation) was assessed by questions 4, 5, and 11 and the Participant Log. A difficulty noted by the researcher regarding implementation was the fact that the first cohort of the study began during the Thanksgiving and Christmas holidays. Regarding the actual intervention, 9 participants (81.8%) agreed, "the movements in the TCE sessions were easy for me to do" however, only three participants (27.3%) agreed that "it was easy for me to find time to practice TCE."

The issues of facilitators, barriers and practicality (positive or negative effects on target participants, ability of participants to carry out intervention) were addressed by questions 4, 5 and 11 and the Participant Log. Social support was addressed by questions 1, and 12-14 and the Participant Log.

There were no known negative effects noted among the participants. A lack of time (3 responses) was cited as the most common reason for participants not to practice away from the group sessions. Other reasons for missing TCE sessions or not practicing were the holiday season and other responsibilities. One participant had foot surgery that

required an absence from two group TCE sessions and another indicated that her eagerness to lose weight/get more fit made her impatient with TCE and she wanted to do more intense exercise.

During this study, the cost was kept at a minimum since the space for TCE was offered to the researcher free of charge and the materials (TCE DVD) was also free to the participants. For all participants, the cost of gas for transportation and time were the only expenses incurred. Each subject was given $20 in cash at the end of final data collection.

The Participant Log was specifically designed with an area for open-ended comments to be recorded, however, no comments were shared with the researcher on this form.

Analyses of RPE data revealed that less than 50% of the participants reported RPE estimates each week (Table 11) and this percentage declined each week, with no subjects reporting RPE in Week 8. The average RPE was 9.45 (very light) on a scale of 6-20.

Table 11

Borg Rating of Perceived Exertion Scale (RPE) Frequencies

Intervention Week	N	Mean ± SD	Minimum	Maximum
RPE Week 1	5	9.20 ± 2.36	6.00	12.50
RPE Week 2	5	10.75 ± 3.28	7.00	15.00
RPE Week 3	5	11.78 ± 3.65	6.40	15.00
RPE Week 4	5	8.45 ± 5.35	0.00	12.50
RPE Week 5	4	9.13 ± 2.66	6.00	12.00
RPE Week 6	2	9.75 ± 2.47	8.00	11.50
RPE Week 7	2	10.50 ± 3.54	8.00	13.00
RPE Week 8	0	NR	NR	NR

Borg RPE Scale 6-20; NR= Not recorded

Means, standard deviations, maximum and minimum statistics were analyzed for the subscales of the MMI. Questions 2, 3, 4, 6, and 12 are questions for the breath focus subscale and questions 8, 10, 13, and 17 are part of the meditative connection subscale. The flowing motion subscale is measured by questions 1, 5, 7, 9, 11 and 14-16. The choices for the MMI questions are as follows: 1= all of the time, 2 = very frequently, 3 = occasionally, 4 = rarely, 5 = very rarely, 6 = never. The key component subscales of the MMI breath focus (M = 1.84) and meditative connection (M = 2.28) show that participants were strongly experiencing the core elements of breathing and of meditative connection (Table 12). Participants also reported a frequent sense of flowing motion (M= 1.95).

Table 12

Meditative Movement Inventory (MMI) Subscale Statistics (n=11)

Subscale	Mean ± SD	Minimum	Maximum
Breath Focus	1.84 ± 0.42	1.20	2.60
Meditative Connection	2.28 ± 0.42	1.63	3.00
Flowing Motion	1.95 ± 0.47	1.00	2.50

Based on 5-point Likert scale from 1 (all of the time) to 5 (never)

Frequencies and descriptive statistics were used to examine the MMI data (Table 13). The most frequent answer of "All of the time" was selected only for the question, "I was getting addicted to the feeling of inner peace." "Very frequently" was the most common answer chosen for MMI questions 1- 7, 9-14, and 16-17. Two questions, "I was connected to something greater than myself", and "I was going into a state of reverie" were each chosen once (9.1%) for the "never" category. The most common responses are in bold.

Table 13

Meditative Movement Inventory (MMI) Frequencies (n=11)

Question	All of the time % (n)	Very frequently % (n)	Occasionally % (n)	Rarely % (n)	Never % (n)
1. My mind really became quiet	0	**81.8 (9)**	18.2 (2)	0	0
2. I was going into a state of relaxation	27.3 (3)	**63.6 (7)**	9.1 (1)	0	0
3. I was breathing fully and deeply	36.4 (4)	**54.5 (6)**	9.1 (1)	0	0
4. I took in deep breaths with the movement	27.3 (3)	**72.7 (8)**	0	0	0
5. I was getting addicted to the feeling of inner peace	**36.4 (4)**	**36.4 (4)**	18.2 (2)	9.1 (1)	0
6. I was using my breathing to go into a relaxed state	36.4 (4)	**54.5 (6)**	9.1 (1)	0	0
7. I moved in relaxed, fluid motions	9.1 (1)	**45.5 (5)**	**45.5 (5)**	0	0
8. I was connected to something greater than myself	0	36.4 (4)	**45.5 (5)**	9.1 (1)	9.1 (1)
9. I was happy or smiling a little	18.2 (2)	**63.6 (7)**	18.2 (2)	0	0
10. I was going into a state of reverie	0	**54.5 (6)**	18.2 (2)	18.2 (2)	9.1 (1)
11. I was loosening up with the movements	44.5 (5)	**54.5 (6)**	0	0	0
12. I was breathing nice and slow	36.4 (4)	**54.5 (6)**	9.1 (1)	0	0
13. I was meditating	9.1 (1)	**72.7 (8)**	18.2 (2)	0	0
14. My mind was clear of all thought	18.2 (2)	**36.4 (4)**	**36.4 (4)**	9.1 (1)	0
15. I was deeply in tune with myself	9.1 (1)	36.4 (4)	**45.5 (5)**	9.1 (1)	0
16. My attention was turned inward	18.2 (2)	**81.8 (9)**	0	0	0
17. I was in touch with the field of energies around me	0	**81.8 (9)**	18.2 (2)	0	0

Intervention fidelity refers to the degree to which the delivery of an intervention adheres to the original planned program (Mowbray, Holter, Teague, & Bybee, 2003). Time on task, MMI, observation of verbal and non-verbal communication, and instructor feedback from participants are used to examine the fidelity of the TCE program.

Time on task. Conversations were kept to a minimum and focused on the TCE sessions and answering questions regarding home practice. There were occasional short discussions after TCE sessions outside of class among participants. Interruptions during the TCE sessions were also kept to a minimum. The practice room had few windows and allowed little to no distraction. Otherwise, interruptions were limited to participants occasionally arriving late for the TCE sessions.

Specific aim 1(b).

Recruitment, retention, and attrition. Rolling recruitment was ongoing during the duration of the study, from October 2013 to March 2014. A total of 23,995 total recruitment emails were sent to current and former bariatric patients at Scottsdale Healthcare Shea (SHC) campus (See Appendix G for letter of support). The email did not target by inclusion criteria, and the exact number of female gastric bypass patients within the study timeframe (1-3 years) that were contacted was not available. Study information was also relayed to the SHC online bariatric surgery support group web portal. In addition, research staff attended ongoing patient support groups at the Mayo Clinic Scottsdale to recruit in person.

A target recruitment number of 30 participants had been established for this study. This goal was not achieved due to various factors including family issues, work conflicts, disinterest in the intervention, the holidays, and religious beliefs.

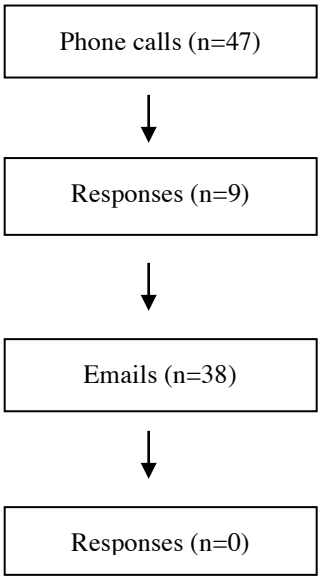
The attrition rate for this study was 65%. Twenty-six participants dropped from the study once consented. The most frequent reason for dropping out was work conflict (n=7), followed by family issues (n=5), and "no interest" (n=3). Seven subjects did not respond to attempts at determining their reason for ceasing their participation. Other reasons for dropping out included feeling that TCE conflicted with religious beliefs (n=2), and the holiday season (n=2). In terms of completers, 3 of the 11 (27%) were recruited from the Mayo clinic and the remaining 8 (73%) were SBC patients.

Extensive follow-up was attempted to determine the reasons for the very low enrollment numbers and the extremely high attrition rate experienced in this study. A phone call was made to all of the individuals that expressed interest in the study but did not join and to those that joined, both the completers and non-completers (n=47) (See Appendix V for script).

A total of 9 individuals returned researcher phone calls (approximately 9%). A follow-up email was subsequently sent to the remaining 38 women that had not responded to the initial phone contact. There were no responses to the secondary email.

Figure 3

Flow Diagram of Follow-Up Contacts



For those that were screened but decided not join the study, reasons for non-participation included the study site being too far to travel to (n=1), becoming ill (n=1), forgetting about the study (n=1), and time constraints (n=1). Reasons for dropping once enrolled included TCE conflicting with religious beliefs (n=1) and lack of individual's organization to attend regularly (n=1). See Table 14 for more details.

Table 14

Follow-up Questionnaire Responses

Screened but not enrolled (n=4)

Why did you decide to not participate in the study? What, if anything may have changed your mind about participating?

Too far to travel for study
Became ill
Forgot
Time constraints

Enrolled but dropped (n=2)

What were the reasons that you dropped from the study? What, if anything may have changed your mind about participating?

Religious belief conflicts
Not organized enough to attend regularly

Completed (n=3)

What were the most challenging aspects of the study for you?

The most challenging aspect of the study was the discipline required to complete the weekly activity forms. For me it was the trip up to Phoenix from Tucson.

Were you at all uncomfortable physically or emotionally doing the TCE movements? If so, how?

The physical aspects of the TCE movements were not uncomfortable; however there was significant pain after the first session in my left knee which resulted in swelling and discomfort for about a week.
The emotional aspects of the TCE movements which I found challenging surrounded working in a small space. A few times the instructor requested that we do our movements while moving in a circle. This increased the difficulty of the task for me. I found it challenging to concentrate on the movements, maintain the circular movement of a group, and maneuver in a small space. Another emotional aspect that was a concern was being in a very small group (less than 3).
A little apprehensive of what others would think. But that went away with all the support from the instructor and my own engagement and home practice.
Fitting it in among competing priorities. Primarily the in person class, but also the home TCE felt daunting after going through it completely once.

What would have made the study better than it was originally designed?

From what I understand and was able to observe, the study was well designed. Ways to improve on this may include creating record forms using Adobe Acrobat which might speed their completion.
More meeting times and a closer proximity to the location of the study.
I know it's good to slow down and I think the concept is great but since regain was the focus, an aerobic-type focus might have had a better following.

Specific Aim 2

To evaluate whether the TCE intervention is associated with weight loss, improved behavioral eating factors, mood, body awareness, measures of mindfulness or PA levels in post-surgical bariatric patients as compared to baseline measures.

Change in baseline data. There were no significant changes in body composition measurements, including body weight, body fat percentage or body mass index (BMI) between week 1 and week 8 of the study (Table 15). However, both anxiety and body awareness changed significantly ($p<.05$) pre and post study completion (Tables 16 and 17, respectively). Additionally, the subscale of Cognitive Restraint in the Three Factor Eating Questionnaire increased significantly ($p<.05$) (Table 18). Mindfulness was measured by the MAAS and while there was a slight increase in mindfulness, it was non-significant with a small effect size of 0.35 (Table 19).

Table 15

Paired Sample t-Test Results as Assessed by Bioelectrical Impedance Analysis (n=10)

Measure	Pre-intervention mean ± SD	Post-intervention mean ± SD	t-test	*p*	Effect size (Cohen's d)
Body Weight (lb)	203.36 ± 25.88	203.40 ± 26.11	-.187	.856	0.06
Body Fat (%)	42.60 ± 4.06	42.85 ± 4.62	.520	.616	0.16
BMI (kg/m^2)	34.56 ± 5.21	34.40 ± 5.43	-1.44	.596	0.17

*p-value < 0.05

Table 16

Paired Sample t-Test Results – Profile of Mood States (POMS) Subscales (n=11)

Measure	Pre-intervention mean ± SD	Post-intervention mean ± SD	t-test	*p*
Anxiety	2.49 ± 0.78	1.80 ± 1.01	3.35	.007*
Depression	0.93 ± 0.71	0.73 ± 0.91	-.899	.390

Based on 5-point Likert scale from 0 (not at all) to 4 (extremely)
*p-value < 0.05

Table 17

Paired Sample t-Test Results – Body Awareness Questionnaire (BAQ) Scores (n=11)

Measure	Pre-intervention mean ± SD	Post-intervention mean ± SD	t-test	*p*	Effect Size (Cohen's d)
Total BAQ	71.45 ± 15.45	85.45 ± 16.26	3.76	.004*	1.13

Based on 7-point Likert scale from 1 (not true of me at all) to 7 (very true of me)
*p-value < 0.05

Table 18

Paired Sample t-Test Results – Three Factor Eating Questionnaire (TFEQ) Subscales

Measure	Pre-intervention mean ± SD	Post-intervention mean ± SD	t-test	*p*
Cognitive Restraint	3.64 ± 0.81	4.00 ± 0.65	-2.85	.017*
Disinhibited Eating	4.91 ± 1.26	4.71 ± 1.05	-.706	.496
Emotional Eating	2.36 ± 0.53	2.23 ± 0.57	.734	.480

Based on a 4-point Likert scale from 1 (definitely false) to 4 (definitely true)
*p-value < 0.05

Examining trends in physical activity reported on the Minnesota Leisure-Time Physical Activity Questionnaire (MNLTPAQ), the duration of household activities increased significantly ($p<0.05$) pre and post measurement. Additionally, conditioning

activities, approached significance (p=0.67) with a medium effect size of 0.66. There was no consistent distribution of activity over months 1-3 as there was for the MM practice minutes (Table 20).

A comparison of minutes of PA reported on the Participant Log and the MNLTPAQ, shows that in weeks 1-4 (Month 2 on the MNLTPAQ) a total of 6,310 minutes of non-MM activity was reported on the Logs while only 2,679 minutes were reported on the MNLTPAQ. Similar discrepancies were observed for weeks 4-8 (Month 3 on the MNLTPAQ); MNLPTAQ activity totals were 2,124 minutes in comparison to the Logs, which totaled 3,110 minutes in the same timeframe.

A repeated measures ANOVA was performed to determine any changes in activity levels (in minutes) over the course of the study (Table 21). Data from the Participant Logs revealed that there were no significant changes in MM practice (F=0.579; p=0.738) or other reported non-MM PA (F=0.574; p=0.742) over the first 7 weeks; the RM ANOVA analyses would not run with the last week (week #8) included, given the small sample size. An ANOVA test revealed that there were not any significant differences in PA levels between cohorts 1 and 2.

Table 19

Paired Sample t-Test Results – Mindful Attention and Awareness Scale (MAAS) Scores (n=11)

Measure	Pre-intervention mean ± SD	Post-intervention mean ± SD	t-test	*p*	Effect Size (Cohen's d)
Total MAAS	3.28 ± 0.70	3.62 ± 0.72	-1.16	.273	0.35

Based on 6-point Likert scale from 1 (almost always) to 6 (almost never)

Table 20

Physical Activity Data as Assessed by the MN Leisure Time Physical Activity Questionnaire (MNLTPAQ)

Physical Activity Categories	Month 1 M ± SD (mins/month)	Month 2 M ± SD (mins/month)	Month 3 M ± SD (mins/month)	t-test	*p*	Effect Size (Cohen's d)
Walking & Misc	271.80 ± 291.65	285.70 ± 321.94	309.00 ± 350.78	-3.92	.704	0.12
Conditioning Activities	116..00 ± 0.00	181.00 ± 23.09	219.00 ± 20.82	-2.08	.067	0.66
Water Activities	200.00 ± 169.71	0.00 ± 0.00	0.00 ± 0.00			
Sports Activities	180.00 ± 0.00	250.00 ± 98.99	290.00 ± 155.56			
Lawn & Garden Activities	153.50 ± 237.74	114.50 ± 162.74	98.50 ± 123.11	.823	.432	0.26
Other Activities	730.00 ± 0.00	610.00 ± 0.00	39.00 ± 0.00			
Household Activities	928.60 ± 577.64	1405.00 ± 950.856	1642.00 ± 1125.62	-2.79	.021*	0.88
Monthly PA Mean Minute Totals	2579.90 ± 336.01	2846.20 ± 496.42	2597.50 ± 598.42	.350	.738	0.13

Table 21

RM ANOVA for Activity Patterns as Assessed by the MN Leisure-Time Physical Activity Questionnaire

	F	df	p
Walking and Misc Activities			
Time	.112	2	0.89
Conditioning Activities			
Time	3.56	2	0.05
Lawn and Garden Activities			
Time	.673	2	0.52
Household Activities			
Time	4.28	2	0.054

In terms of psychosocial variables, body awareness and cognitive restraint increased and anxiety decreased, all significantly ($p<.05$) post intervention. Interestingly, while obesity and depression have been linked in the past (Alvarado et al., 2005; Mahony, 2008; Song & Fernstrom, 2008), this sample of women scored very low on the depression subscales of the POMS, both before and after the study.

In comparing pre and post-study dietary habits from the Dietary Screener Questionnaire, daily frequencies of fruit and vegetable consumption, based on the DSQ categories, increased non-significantly but with a slight trend towards significance ($p=0.10$, $d=0.38$). Additionally, processed meat consumption decreased significantly ($p=0.01$, $d=1.63$). No other foods were near significance in terms of any changes in daily frequencies. Please see Table 22 for details. When examining only whole fruit and green salad frequencies, indicators of high dietary quality, daily whole fruit consumption increased non-significantly ($p=0.052$), but trended towards significance with a medium effect size. Green salad frequency consumption unfortunately decreased, although non-significantly ($p=.074$) (Table 23).

Table 22

Paired Sample t-Test Results – Daily Frequencies of Dietary Screener Questionnaire (DSQ) Food Categories

DSQ Food Category	Baseline mean ± SD	Post-intervention mean ± SD	t-test	*p*	Cohen's d
Fruits and Vegetables	2.78 ± 0.71	3.95 ± 3.33	-1.27	0.10	0.38
Foods with Added Sugars	2.18 ± 2.20	1.82 ± 1.53	-0.45	0.66	0.15
Red Meats	0.15 ± 0.15	0.29 ± 0.29	-1.81	0.23	0.55
Processed Meats	0.41 ± 0.37	0.18 ± 0.29	5.40	.001**	1.63

**p<.001

Table 23

Paired Sample t-Test Results – Daily Frequencies of Select Items from the Dietary Screener Questionnaire (DSQ)

DSQ Food Category	Baseline mean ± SD	Post-intervention mean ± SD	t-test	*p*	Cohen's d
Whole Fruits	4.73 ± 3.23	7.27 ± 1.35	-2.20	.052	0.66
Green Salad	5.36 ± 2.73	3.18 ± 2.12	1.99	.074	0.60

CHAPTER 5

DISCUSSION

Recruitment, retention, attrition, participant feedback, and intervention fidelity were examined to determine the feasibility of a TCE program in bariatric patients. Preliminary effects of the TCE intervention on psychosocial variables, physical activity habits and eating patterns were also assessed. Thirty-seven participants were initially enrolled into the study after providing written informed consent and twenty-six women subsequently dropped from the study at different time points. Therefore, pre and post data analyses were performed on the remaining 11 subjects. This chapter discusses the interpretation of the findings in this specific population and how the results may inform future research endeavors as well as the strengths and limitations of the intervention.

Specific Aim 1(a)

Feasibility. The results of the Feasibility Questionnaire and Participant Logs would suggest that TCE is a feasible and acceptable activity overall for post surgical bariatric patients. In fact, all of the participants that completed the study indicated that they believed that TCE was helpful after their surgery and there was a high level of perceived social support for TCE practice. However, given the higher-than-expected attrition rate (65%), there was a clear gap between attitude and action in this specific group of women.

Extensive follow-up was attempted to determine the reasons for the very low enrollment numbers and the extremely high attrition rate experienced in this study. A phone call was made to all of the individuals that expressed interest in the study but did

not join and to those that joined, both the completers and non-completers (n=47). Nine subjects responded positively to the follow-up phone call and provided feedback. A subsequent email was sent out to the remaining women (n=38), to which no one responded. The follow-up data provided no clear consensus as to why women chose to either not join (n=4) or drop (n=2) from the TCE study. Out of the six women that responded in this category, there was not a single reason in common.

Attrition rates for this study are substantially higher than others reported in the literature for intervention studies attempting to change health behavior. A one-year intensive lifestyle intervention consisting of diet and physical activity was conducted in severely obese adults. Retention rates were reported as 90% at 6 months and 73% at 12 months (Goodpaster et al., 2012). The baseline mean BMI of subjects was 43.6 kg/m^2 with a mean age of 46.8 years. In a multidisciplinary weight management clinic, higher attrition rates were reported for medically (54%) than surgically (11%) treated patients (Habib, Samame, & Galvani, 2013). Some predictors of attrition included younger bariatric patient age and lower pre-surgical BMI (Habib, et al., 2013). The mean BMI and age of patients that dropped from the weight management clinic were 48.4 kg/m^2 and 42.2 years, respectively. Those that remained compliant had a higher mean BMI of 52.3 kg/m^2 with a mean age of 43.0 years.

The literature provides mixed data regarding lifestyle interventions in overweight and obese persons, including post-surgical patients, and possible correlates with attrition rates. Goodpaster et al. (2012) observed that those with lower ages and baseline BMI were more adherent, while Habib and colleagues (2013) noted higher attrition rates in younger patients with lower initial BMI values. The age of the women in the current

study was higher than those in the literature already cited and the feasibility participants and their mean BMI was lower. Given the small sample size in this intervention, these same predictors, or any predictors described in the literature, could not truly be ascertained in the current project.

The study subjects provided many suggestions to improve the TCE program that may have made a difference in whether or not they would have adhered more to the protocol. These suggestions were: Including a specific time in the weekly sessions to share feelings and experiences; providing participants with music for at-home practice; longer and more varied class times; and the inclusion of non-bariatric patients in the TCE classes. Additionally, the first cohort of the study attended TCE classes during the Thanksgiving and Christmas holiday season and this was mentioned as a negative factor in terms of conflicting priorities. Adoption of participant suggestions and recommendations should be considered for implementation of a larger-scale future project of similar nature. More data is needed to isolate true predictors of adherence and attrition in bariatric patients to better formulate successful interventions.

RPE and MMI results. The RPE showed a mean 9.45 (9= very light) on a scale of 6-20. The scores indicate that although the TCE is not an extremely rigorous aerobic exercise, it requires effort and is not categorized as an extremely light activity or one requiring no exertion at all, for the majority of the participants.

The MMI subscale scores indicated breath focus (e.g. "I was using my breath to go into a relaxed state") was used "very frequently" with a mean score of 1.84 (SD = .42). The meditative connection subscale (e.g., "I was meditating") indicated a mean of 2.28 (SD = .42) with an answer of "occasionally." The MMI scores provided evidence

that the participants were performing TCE as instructed, although the ultimate aim is to achieve high levels (i.e. an answer of "all of the time") of both breath focus and meditative connection.

Possible reasons for the mid-range scores of the meditative connection may have been related to the stressors of the holiday season or the fact that MM was a new concept for more than 80% of the study participants. Beginning any new exercise can be challenging for individuals, especially one that requires the coordination of the whole body and breathing, such as MM (Li et al., 2003). Older adults reported significant cognitive distractions while learning individual movements in an overall TC program to reduce falls (Li et al., 2003). In an overview of TC and its potential role in health promotion, its authors assert that a minimum of 6 months of training may be needed to evaluate the full impact of the MM (Lan, Lai, & Chen, 2003).

Similar to the reports in the literature, the focus on physical movements possibly affected the meditation aspects of the TCE practice, decreasing the meditative connection (and subsequently MMI scores). In the initial weeks of the study, several participants commented that it was difficult to clear the mind because of the emphasis on getting the movements correct and watching the instructor (researcher), despite instructions to consider the movements to be acceptable within a wide range of performance and to "let go" of the need or expectations to do the movements exactly like the teacher. Nevertheless, as the weeks progressed, by the end of the study, there was a substantial level of experience of the meditative aspects of the practice (as evidenced by the moderately low mean score on this factor (2.28 on a scale of 1-5).

In light of these accounts, the MMI results from this study are encouraging, especially for such a short intervention length, which suggests that those with little MM experience can quickly experience its benefits.

Qualitative analysis. Written and occasional verbal comments collected throughout the 8-week study were evaluated (i.e., Participant Log, Intervention Log, and Feasibility Questionnaire questions 16-21). Common words describing TCE were gentle movement, mood, relaxation of the mind, and thoughtfulness. These comments may suggest that study participants were deriving the essential core elements of TCE. Another observation made during qualitative examination found that some participants reported an inability to achieve and maintain focus during the initial weeks of the intervention but as the intervention progressed this seemed to decrease.

Exploration of the data also indicated a change from more negative mood states prior to the TCE practice to more positive moods after, specifically regarding stress. One participant wrote on the Feasibility Questionnaire, "Before: A little depressed, stressed about weight and personal life issues; very high strung and edgy. After: More positive, at ease, more clear-minded, focused on the good, not the bad." Another stated on the same questionnaire, "My stress level is more manageable. I've been able to adopt and modify my stress reactions with specific techniques." This qualitative data supports the findings of the quantitative results of the POMS anxiety subscale, which decreased significantly after the TCE intervention.

Additional qualitative comments also support the significant improvements observed in the cognitive restraint scale of the TFEQ. "I am ready to get "back on track" to make healthier food choices and if I'm under stress, take a few minutes to use the TCE

movements I learned" reported one participant. Another stated, "Before – I knew my eating patterns weren't beneficial and I lacked motivation to exercise. After – TCE has helped motivate me to be more active again."

Although not recorded on any Logs, during class several participants discussed the fact that despite its gentle nature, TCE was still "movement," which they did not like to do in general. Many participants indicated that even though their physicians indicated that bariatric surgery was not a "magic pill" and they would have to exercise/stay active to maintain weight loss, they did not believe that would apply to them and hence TCE was challenging to them. Several participants suggested that this non-interest in moving might have negatively impacted class adherence. As one woman stated, "Being sedentary is what got us to the place of needing surgery in the first place; it's no surprise that we still don't want to move."

Specific Aim 1(b)

Recruitment. The main form of recruitment was a series of emails sent to the Scottsdale Bariatric Center patient database. A total of 23,995 total recruitment emails were sent to current and former bariatric patients at Scottsdale Healthcare Shea (SHC) campus. There are 4,799 patients in their database and the email was sent 5 total times. The emails did not target by inclusion criteria as originally intended, and so the exact number of female gastric bypass patients within the study timeframe (1-3 years) that were contacted was not available. Study information was also relayed to the SHC online bariatric surgery support group web portal and flyers were distributed in the SBC surgery center during their support groups. In addition, research staff attended 2 ongoing patient support groups at the Mayo Clinic Scottsdale to recruit in person. Each Mayo group had

approximately 20 people, both male and female. Estimating that approximately 24,000 contacts were made for study recruitment, and a resulting total of 47 responses, the overall recruitment response rate was .002.

Retention and attrition. Average attendance for all of the TCE sessions combined and including all participants was 55.7% and the attrition rate for this study was 65%. It is unknown whether or not this attrition rate is typical since there have been only two randomized interventions to date examining PA patterns in the bariatric population. Twenty-six participants dropped from the study once enrolled, despite attempts to minimize attrition, such as holding classes at different locations, on differing days of the week and at various times of day. For those that traveled to Arizona State University, any incurred parking costs were reimbursed.

The most frequent reason for dropping out was work conflict (n=7), followed by family issues (n=5), and "no interest" (n=3). Seven subjects did not respond to attempts at determining their reason for withdrawing their participation. Other reasons for dropping out included feeling that TCE conflicted with religious beliefs (n=2), and the holiday season (n=2).

Overall, the practice of TCE with bariatric patients to initiate weight loss was not demonstrated to be feasible, at least in this specific intervention and population of women. The results of this intervention are somewhat surprising given the feedback from the feasibility study that was conducted prior to this intervention, which was that 71% of participants indicated a positive attitude about learning more about MM, 65% reported a positive attitude about trying MM in the future and 69% indicated a positive intention towards the behavior.

However, relatively little demographic information was collected from subjects during the feasibility study and so comparisons between these individuals and the current participants are not possible. Out of 3 focus groups held during the feasibility study, the one with the most participants (n=16) included individuals with only a maximum of 1 month post-surgery. The mean age of all feasibility study subjects was 49.4 years and approximately one-third of the participants were male; BMI data was not collected. The current study observed a mean age of 52.4 years, with a mean BMI of 34.6 kg/m^2 and they were all female. It is unknown whether the age or gender differences of the subjects in the feasibility and MM groups impacted the results. Perhaps it was the short timeframe that had elapsed after bariatric surgery for the feasibility subjects that made them more favorable to the idea of MM? For patients with longer post-operative times, they may have quickly realized as mentioned above, that MM was "still movement" and unpleasant, as opposed to those who were still perhaps in the "honeymoon" phase after their procedures and more open to the idea.

The timing of the study was unfortunate as it was conducted mainly over both the Thanksgiving and Christmas holidays, which can be a stressful, busy time for people. However, while mentioned as a challenge, the holiday season was not the most common reason cited for lack of participation.

Specific Aim 2

There were no significant improvements observed in body composition measures, and effect sizes for body weight, body fat percentage and body mass index (all < .20) do not indicate positive directional trends for these variables. The lack of weight loss in this study can be potentially explained by many factors. The average attendance rate for the

study overall by all participants was only 55.7% and one could theoretically argue that missing half of the TCE classes would preclude gaining the benefits of a more frequent MM practice, both in terms of the indirect effects of mindfulness and the direct effects of physical activity.

Additionally, many of the women (n=7) joined the study during the holiday season, which is a time of year where individuals gain an average of 0.50 kilograms (1.0 pounds) (Yanovski et al., 2000). Perhaps any increases in caloric intake attenuated the MM benefits and at a different time of year, the results in weight loss would have been more positive.

Mindfulness was measured by the MAAS and while there was a slight increase in mindfulness, it was non-significant with an effect size of 0.35. The MAAS measures mindfulness somewhat narrowly, i.e., focusing solely on attention. Mindfulness scores may have been muted given the learning curve of TCE, potential self-consciousness of subjects due to moving in a new way in a group environment or due to attention on the instructor during the TCE sessions.

The revised Three-Factor Eating Questionnaire is comprised of three subscales, and assesses the eating behaviors of cognitive restraint, emotional eating and disinhibited eating. There were no significant changes in the emotional or disinhibited eating scales but there was a significant improvement in cognitive restraint. Given that for most individuals, the holiday season brings with it overindulgence, it is especially noteworthy that restraint increased during this time.

Much of the mindfulness-based research on disordered eating has focused on binge eating disorder (Engstrom, 2007; Lillis et al., 2009; McIlver et al., 2009), which

was not an outcome measure in this study. However, emotional eating and external eating have also been demonstrated to decrease after mindfulness interventions (Alberts et al., 2012; Dalen et al., 2010; Daubenmier et al., 2012; Kearnet et al., 2012). This study observed no such decreases, or trends in improvement in, emotional eating or disinhibited eating patterns. This could be associated with poor overall attendance rates or the timing of the holiday season.

There were two psychosocial variables that significantly improved by the end of the intervention; anxiety decreased and body awareness increased. Anxiety has been shown to decrease emotional regulation skills and allow and individual to indulge in more immediate impulses, such as binge eating (Hearon, Quatromoni, Mascoop, & Otto, 2012). Research also indicates a link between anxiety and experiential avoidance behaviors, such as maladaptive eating patterns (Fulton et al., 2011). Specifically, individuals high in anxiety may be unwilling or unable to tolerate anxiety-related bodily sensations and thus, may be driven to engage in behaviors to escape or lessen these sensations and their associated distress, e.g., disordered eating (Fulton et al., 2011). Perhaps the decrease in anxiety impacted any potential disordered eating that may have otherwise occurred during the study.

For activities reported on the MNLTPAQ, household activities increased significantly post intervention. Also for PA reported on the MNLTPAQ, a RM ANOVA analysis found that there were significant increases in conditioning activities and household activities closely approached significance.

The overall lack of change in activity levels could be explained by a variety of factors. Again, the study was conducted was over the Thanksgiving and Christmas

holidays, a time where not only do people have less free time in general, but also traditionally, rates of exercise are lower than the spring and summer months (Gallup, 2013; Levin, Jacobs, Ainsworth, Richardson & Leon, 1999). It was hypothesized that the increase in minutes spent performing household activities would be explained by the holiday season. However, there were no significant differences between cohorts 1 and 2 in terms of household PA. This increase in household activity may simply be an error in reporting. The MNLTPAQ asked participants to go back 3 months and recall PA patterns which may have led to inaccurate reporting of baseline activity, i.e., lower than actually performed. The participants potentially could have given biased information based on their relationship with the researcher in an effort to be helpful and wanting the study to be "successful" for the researcher's benefit. Additionally, self-reported data of PA in general has been found to be overestimated, especially in women (Prince et al., 2008).

The average baseline daily activity level reported per participant on the MNLTPA was 35.60 minutes, which is already above the recommended PA guidelines amount (ACSM, 2014). If most of the subjects were theoretically already meeting PA recommendations, it may not have been realistic to expect additional increases. However, these reported rates are likely an error as bariatric candidates generally report more sedentary time than the general population (Matthews et al., 2008).

There were considerable differences in non-MM PA minutes reported on the MNLTPAQ versus the Participant Logs. Minutes of PA were consistently higher on the Participant Logs and it is unknown why the Logs reflected higher totals than the PAQ. Future research in this population should include an objective measure of PA for a more accurate assessment of activity levels.

In examining food categories from the DSQ, there were no significant changes in dietary quality between the start and the end of the study, except for a significant decrease in processed meat consumption. Within the category of fruits and vegetables, consumption did increase and while non-significant, trended slightly towards significance with small effect sizes. When looking at just whole fruit and green salad consumption, fruit intake increases approached significance with a medium to large effect size and green salad intake decreased.

The reported decreases in processed meats over the course of the study could reflect the typical seasonal reductions in red meat consumption during the months of October through December (Mutondo & Henneberry, 2007). Most Americans eat more poultry products over the holidays and unfortunately, the DSQ did not capture data on white meats.

In summary, few of the theoretical mediating factors thought to potentially impact weight outcomes in this population were positively changed as a result of MM. Physical activity did not increase overall, nor did mindfulness. In terms of dietary quality, only processed meat consumption decreased significantly although changes in red meat and fruit consumption trended towards significance. The psychosocial variables of body awareness and cognitive restraint of eating did improve significantly but the long-term impacts of these on bariatric patient weight loss are unknown.

Strengths

Strengths of this study include the originality of the concept. Interventions examining MM with bariatric patients have not been conducted and this study provides evidence and improvement strategies for a larger randomized study of similar nature.

Limitations

This was a feasibility study led by a single researcher. A team focused on recruitment, retention and data collection may have increased the participant rate, thus increasing the power of the sample. A team may have been able to stay in closer contact with the participants to encourage adherence and retention during the duration of the study. More team members may also have been able to increase recruitment efforts at support groups, i.e., attend more groups than a single researcher and would have allowed more TCE classes to be taught, which may have captured more participants.

The initial program length was 12 weeks but due to concerns about adherence, the study was decreased to 8 weeks. However, paradoxically, an 8-week program may not have been a long enough time to evaluate the effects of TCE. Even with an 8-week program it was difficult for participants to attend every session, as overall attendance was slightly above 50%.

There was a higher-than-anticipated attrition rate of 65%, resulting in a very small sample size (n=11). Given the sample size, any significant changes may be the result of random chance alone and not the TCE intervention. The oftentimes weekly decrease in study participants may have impacted attendance, and/or the morale of the remaining group members.

Despite constant reminders and multiple attempts, a large majority of the subjects did not submit their weekly Participant Logs to the researcher and it is unknown whether or not this means they forgot to complete it or didn't practice MM that week. A "buddy system" may have been useful to hold one another accountable to practice and/or Log

submission. However, while this may have increased TCE practice, it may have confounded any results given the social support aspect of a buddy system.

The researcher could have provided more tools to make at-home MM practice easier. For example, making a CD or playlist of the music that was used during the weekly group TCE sessions. Additionally, a written manual could have been given to participants for those with a differing learning style than the DVD offered.

The sample was comprised of all female gastric bypass patients and as such any results may not be generalizable to males and/or other types of bariatric surgeries. There were also no African Americans, Asians or Pacific Islanders that participated in this study and so the results are generalizable to a small segment of the population as a whole.

Conclusions

This is the first study known to the researcher that examined MM and body composition outcomes in bariatric patients. The current feasibility study showed some encouraging results in the improvement of body awareness, cognitive restraint in eating and anxiety that, according to the literature, could theoretically improve weight outcomes.

Implications for Future Research and Practice

The overall feasibility of and acceptability, recruitment, and retention strategies in this study were evaluated to refine the research protocol in preparation for a future larger scale study. There are several recommendations for future projects. Prior studies of exercise studies in bariatric patients have observed high adherence rates with the inclusion of frequent and structured participant contact (Goodpaster et al., 2010). During months 1 through 6, participants received 3 group meetings and 1 individual contact per

month. Additionally, the researchers provided low-cost supplies related to the intervention (e.g., a pedometer and exercise videos) and participants were eligible to periodically receive small financial incentives for adherence to the goals of the intervention These strategies could potentially work well with future MM interventions. Specifically, more frequent weekly contact with study participants and providing subjects with accelerometers and perhaps more intermittent incentives might improve adherence.

Financial incentives have also served to improve adherence in obese individuals attempting to lose weight (Kullgren et al., 2013). In an employer-sponsored weight loss program, group-incentive participants lost more weight and maintained more weight loss than the non-incentive subjects. This strategy should be considered in a MM-focused intervention to determine if study outcomes would be positively impacted. The inclusion of a non-incentivized control group would help determine if the inclusion of an incentive would be a true predictor of weight loss. While this study did provide a small financial incentive, it was a small amount ($20) and this may not have been a large enough sum (and it was not tied to weight loss, but rather to completing the study) to facilitate change in this group of women.

Technological innovations could also be utilized in future studies. Results on short-term messaging systems (SMS) have been mixed in the obese population (de Niet et al., 2012). An SMS intervention could prompt subjects to send regular data to researchers on their physical activity levels, MM practice or other outcomes of interest. Additionally, utilizing videoconferencing technology to do virtual MM groups may increase MM practice and study adherence for those that are absent from the group practice sessions.

Lastly, widening the inclusion criteria to include males, other types of bariatric surgeries and more diverse locations in the south and/or west areas in the Phoenix Metro area may provide a more rich cache of results to help guide the path of future MM research.

While bariatric surgery remains the most effective long-term weight loss solution for the obese, weight re-gain after surgery is common. Finding effective ways to combat these increases in weight is of utmost importance, both to society, but more importantly to the individuals themselves. This feasibility study had poor recruitment and retention rates, and did not prove effective in initiating weight loss in this specific bariatric surgery population studied as hypothesized. However, there were several important variables that did improve suggesting that TCE could be found efficacious in future studies, if the research design, recruitment and adherence strategies are modified to account for the low interest in moving that seems prevalent in this population.

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APPENDIX A

ARIZONA STATE UNIVERSITY IRB APPROVAL

ASU Knowledge Enterprise Development

Office of Research Integrity and Assurance

To:	Linda Larkey Campus: NH
From:	Carol Johnston, Chair Biosci IRB
Date:	08/01/2013
Committee Action:	**Amendment to Approved Protocol**
Approval Date:	08/01/2013
Review Type:	Expedited F12
IRB Protocol #:	1305009240
Study Title:	A FEASIBILITY STUDY ON THE EFFECTIVENESS OF A 12-WEEK MEDITATIVE MOVEMENT INTERVENTION TO INITIATE WEIGHT LOSS IN FEMALE GASTRIC BYPASS BARIATRIC PATIENTS EXPERIENCING POST-SURGICAL WEIGHT GAIN
Expiration Date:	06/13/2014

The amendment to the above-referenced protocol has been APPROVED following Expedited Review by the Institutional Review Board. This approval does not replace any departmental or other approvals that may be required. It is the Principal Investigator's responsibility to obtain review and continued approval of ongoing research before the expiration noted above. Please allow sufficient time for reapproval. Research activity of any sort may not continue beyond the expiration date without committee approval. Failure to receive approval for continuation before the expiration date will result in the automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and cannot be reported or published as research data. If you do not wish continued approval, please notify the Committee of the study termination.

This approval by the Biosci IRB does not replace or supersede any departmental or oversight committee review that may be required by institutional policy.

Adverse Reactions: If any untoward incidents or severe reactions should develop as a result of this study, you are required to notify the Biosci IRB immediately. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Biosci IRB. The new procedure is not to be initiated until the IRB approval has been given.

Please retain a copy of this letter with your approved protocol.

APPENDIX B

SCOTTSDALE HEALTHCARE IRB APPROVAL

SCOTTSDALE HEALTHCARE.
Research Institute

October 7, 2013

Linda Larkey, Ph.D.
10510 N. 92nd Street
Suite 100
Scottsdale, AZ 85258

RE: **SHC IRB #2013-050**: Your new submission received on 9/10/2013 regarding A Feasibility Study on the Effectiveness of a 12-week Meditative Movement Intervention to Initiate Weight Loss in Female Gastric Bypass Bariatric Patients Experiencing Post-Surgical Weight Gain

Dear Dr. Larkey:

I have reviewed your request for expedited approval of the new study listed above. Your study is eligible for expedited review under FDA and DHHS (OHRP) Category 7. Research on individual or group characteristics or behavior designation.

This is to confirm that as of 9/27/2013 I have approved your application. The protocol is approved through version dated as submitted with the application . The consent form as previously approved remains in effect. You must obtain signed written consent from all subjects. Consent form version 9/27/2013 has been approved at this time.

The following documents were taken into consideration during the review of this study:
Application Received 9/10/2013
IRB Fee Waiver- Approved
Consent form version 9/27/2013
HIPAA Authorization Form
Data Collection Form
Telephone PreScreen
Feasibility Questionnaire
Feasibility Questionnaire Scoring
Study Data Collection Checklist
POMS Short Form
PAR-Q & You
Information Sheet
Former Patient Contact Letter
Study Announcement
Three-Factor Eating Questionnaire
MM and Weight Regain - Attendance Sheet
Data Collection Checklist
ASU Approval Letter
Dietary Screener Module

You are granted permission to conduct your study as described in your application effective immediately. The study is subject to continuing review before the expiration date of 9/27/2014, unless closed before that date.

10510 N 92nd Street, Suite 300, Scottsdale, AZ 85258
Ph: 480-323-3071 Fax: 480-323-3208

Institutional Review Board 1-FWA00001751

APPENDIX C

INFORMED CONSENT

SCOTTSDALE HEALTHCARE
INSTITUTIONAL REVIEW BOARD

Consent to Participate in Research

Protocol Name: A FEASIBILITY STUDY ON THE EFFECTIVENESS OF A 12-WEEK MEDITATIVE MOVEMENT INTERVENTION TO INITIATE WEIGHT LOSS IN FEMALE GASTRIC BYPASS BARIATRIC PATIENTS EXPERIENCING POST-SURGICAL WEIGHT GAIN.

Sponsor: Arizona State University

Principal Investigator: Linda K. Larkey, PhD

Contact Name and Telephone: Lisa L. Smith, 480-255-7682 or llsmith6@asu.edu

Introduction

You are invited to consider taking part in this research study because you have had gastric bypass surgery in the past 12-36 months and have re-gained at least 5 pounds. We will be evaluating a form of meditative movement, specifically Tai Chi Easy, to assess if it can help you lose weight. This form will describe the purpose and nature of the study, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take whatever time you need to discuss the study with your physicians, hospital personnel and your family and friends. The decision to take part or not is yours. If you decide to take part, please initial each page, and sign and date the last line of this form.

Background and Purpose of the Study

The purpose of the research is to (1) evaluate the use of meditative movement (MM), specifically Tai Chi Easy in the bariatric patient population and (2) to assess if Tai Chi Easy can help initiate weight loss in gastric bypass bariatric patients that have gained at least 5 pounds after bypass surgery. Additionally, potential changes in mindfulness and physical activity levels will be measured.

Total Number of Participants

About 30 people will take part in this study nationally. People in the study are referred to as "participants." 30 participants will be enrolled in this study.

General Plan of This Study

If you decide to participate, then you will join a study involving research using Tai Chi Easy to help bariatric patients lose weight who have begun to re-gain weight after their initial surgery. Once you have agreed to join the study, and if you are eligible, you will be enrolled into the study group. The group will both receive instruction of Tai Chi Easy during weekly classes, and a DVD of the Tai Chi Easy movements for practice at home.

Your group sessions will last 12 weeks. Two to three in-person one-hour Tai Chi Easy classes will be offered weekly for participants at the Scottsdale Healthcare Shea campus in Scottsdale, AZ or at the ASU Healthy Lifestyles Research Center in downtown Phoenix. Participants are required to attend the in-person Tai Chi Easy class to learn how to complete the program safely. During the first session, you will be given a DVD of the Tai Chi Easy movements to be used in practice at home. You will be asked to attend one instructor led Tai Chi Easy class each week (you will chose between two to three available class days each week at the study sites) and then practice with the DVD program an additional three to five days per week.

You will also be asked to wear an accelerometer during the study. An accelerometer is a small, lightweight device that is worn on the hip and collects data electronically on your physical activity levels. The accelerometer will be worn during all waking hours and only removed for sleeping, showering or swimming activities. You will wear the accelerometer for a total of 2 weeks; one week before the study begins and again during the last week of the study. At the end of each of those specific weeks, you will be asked to bring in the accelerometer so that the activity data may be downloaded.

Each week you will be asked to complete a log including the days and amount of Tai Chi Easy practice you have completed and any other physical activity that you may have engaged in. Logs will be collected each week at the instructor-led Tai Chi Easy class. Physical activity data from your accelerometer will be collected a total of two times.

Length of the Study for Each Participant

At least 10 days prior to your first class, at the end of the 12-week period of classes, and again at 24 weeks, (that is, 12 weeks after you complete the classes), you will meet with the researchers for approximately 90 minutes to collect information from you to track your progress.

Your total participation will be as follows:

Week 0: 1 baseline visit to collect informed consent and data (approximately 90 minutes)
Weeks 1-12: 12 weekly study MM sessions (60 minutes each)
Weeks 12-13: 1 final study visit to collect data (approximately 90 minutes)
Week 24: 1 follow-up visit at week 24 (approximately 90 minutes)

The total time that you spend participating in the study will be approximately 17 hours over the 24-week period.

Week 0, 12-13 and 24 measures may include the following:

1. Questionnaires that ask about your current level of depression, anxiety, eating patterns, body image and mindfulness.
2. Body composition using bioelectrical impendence (BIA), and weight.
3. Physical activity levels.

Your total time of participating in the study will be between 5 and 6 months total, that is, for all of the data collection points before and after the classes. You will only be coming into Scottsdale Healthcare or to ASU weekly for a total of 13 weeks. There will be an additional final follow-up visit at week 24.

Possible Benefits of Participating in the Study

There are no guaranteed direct benefits as a result of your participation in this study. However, you may possibly experience weight loss. Others may benefit in the future from the information we obtain while you are in this study.

Possible Risks or discomforts

It is not expected that problems will occur with the restful movements and breathing exercises used in this study, but as with any movements, muscles may become strained or injury may occur. Also, deep breathing may cause dizziness and you might fall during standing exercises. The instructor will coach you carefully to avoid such problems and you are encouraged to sit or use a chair for support if you think you may lose your balance. If you are not feeling well in any way, you may stop and rest during the Tai Chi Easy sessions.

Who Can Participate?

This study is designed for women who have had gastric bypass surgery in the past 12-36 months who have regained at least 5 pounds. Additionally, all participants must have the ability and the medical clearance to safely participate in low impact and/or seated physical activity.

Who Cannot Participate

Males, women who have had other forms of bariatric surgery than gastric bypass, those who cannot do any type of physical activity (including seated activity) and those who have not gained at least 5 pounds in the 12-36 months after surgery cannot participate in this study.

Confidentiality of the Data Collected During the Study

Every effort will be made to keep your medical records confidential, as well as other personal information that we gather during this study. Please see the attached "Authorization to Share Protected (personal) Health Information (PHI) in Research."

Whenever data from this study are published, your name will not be used.

Individuals from the Scottsdale Healthcare IRB, Scottsdale Healthcare, and Arizona State University may look at research records related to this study, both to assure quality control and to analyze data. We will disclose personal information about you to others as required by law.

Who can see or use my information? How will my personal information be protected?

Only individuals from the Scottsdale Healthcare IRB, Scottsdale Healthcare, and Arizona State University will have access to your study information.

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

In order to maintain confidentiality of your records, the researchers will use a number to identify your files and data, and will keep these separate from your name. In order to maintain confidentiality of your records, Dr. Larkey will keep all files in a secure and locked file cabinet in her office. No one will have access to this information except Dr. Larkey, her research staff and Scottsdale Healthcare and Scottsdale Healthcare IRB.

Payments to You for Participating

Study participants will be paid for participating in this study. Payments will be made as follows: **$20 gift card will be provided at the completion of the final data collection visit.**

Compensation in Case of Injury

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds are available from Scottsdale Healthcare or the federal government to compensate you for a study-related injury or illness. This does not mean that you are giving up any of your legal rights.

Your Rights as a Participant in the Study

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Should you decide to leave the study, the procedure is the following: Notify study staff verbally or in writing; either is acceptable. Should you decide not to participate or to withdraw, your medical care will not be affected nor will your relations with your physicians, other personnel, and the hospital.

Problems and Questions

Call Dr. Linda Larkey at (602) 821-2366 day or night if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

Regulatory or Ethical Issues

The Scottsdale Healthcare Institutional Review Board (IRB) has reviewed this document for compliance with federal guidelines, and ethics. *Please note the IRB staff will NOT have information regarding appointment times. You will need to contact the investigator at the number above.* If you have questions about your rights as a research participant, you may call or write: IRB Coordinator or Robert Marlow, MD, Chair, IRB, 9003 E. Shea Blvd., Scottsdale, AZ 85260, 480-323-3071.

Withdrawal by Investigator, Physician, or Sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you

from the study for various other administrative and medical reasons. They can do this without your consent.

Participant's Consent

You have read the information provided in this Informed Consent Form (or it was read to you by _____). All of your questions were answered to your satisfaction. You voluntarily agree to participate in this study.

[Upon signing, you will receive a copy of this form, and the original will become part of your medical record.]

Your signature _____
Date _____

Investigator's Statement

I have fully explained this study to the participant. I have discussed the procedures and treatments, the possible risks and benefits, the standard and research aspects of the study, and have answered all of the questions that the participant and the participant's family members have asked.

Signature of Investigator
or Investigator's Designee _____
Date_____

SHC IRB #: 2013-050

Study Title: A feasibility study on the effectiveness of a 12-week meditative movement intervention to initiate weight loss in female gastric bypass bariatric patients experiencing post-surgical weight gain.
Principal Investigator: Linda K. Larkey, PhD

AUTHORIZATION TO SHARE PROTECTED (PERSONAL) HEALTH INFORMATION IN RESEARCH

The word "you" means **both** the person who takes part in the research, and the person who gives permission to be in the research. This form and the attached research consent form need to be kept together.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect the following:

- health information that identifies you,
- the results of tests, questionnaires and interviews,
- any research information from your medical record.

This information is described in the attached consent form. For you to be in this research, we need your permission to collect and share this information

We will share your health information in the following manner:

- with people at the hospital who help with the research,
- with people outside of the hospital who are in charge of, pay for, or work with us on the research.

The "confidentiality" section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your health information.

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. All the information will be kept protected and confidential until the end of the research study.

- *If you sign* this form, you are giving us permission to collect, use and share your health information as part of this research study.
- You do not need to sign this form. *If you decide <u>not</u> to sign* this form, you cannot be in the research study. If you do not sign this form, it will not result in any penalty or loss of benefits to which you are entitled.

If you change your mind later and do not want us to collect or share your health information, you will need to send a letter to your study doctor listed on the attached consent form. The letter will need to say that you have changed your mind and do not want your study doctor to collect and share your health information. You will also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected because we need to know what happens to everyone who starts a research study, not just those people who stay in it. It is possible that you may not have access to your health information in the study record until the study is complete.

Any questions? Please ask your study doctor. You can also call 480-323-3071 with questions about the research use of your health information. Your study doctor will give you a signed copy of this form.

The health information about _____ may be collected and used by your
(enter name of participant)
study doctor and staff for the research study described in this form and the attached consent form.

Signature: _____ Date: _____

Print name: _____

Relation to study participant: _____
SHC IRB approved: 4/11/03, revised 04/23/03, revised 08/27/03

SHC IRB #2013-050
Effective: 9/27/2013
Robert A. Marlow, MD - Chair, IRB

APPENDIX D

PHYSICAL ACTIVITY QUESTIONNAIRE

2013 PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physically active is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	**YES**	**NO**
1) Has your doctor ever said that you have a heart condition ☐ OR high blood pressure ☐ ?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____	☐	☐
6) Do you have a bone or joint problem that could be made worse by becoming more physically active? Please answer **NO** if you had a joint problem in the past, but it *does not limit your current ability* to be physically active. For example, knee, ankle, shoulder or other. **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

If you answered NO to all of the questions above, you are cleared for physical activity.
Go to Page 4 to sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at **www.eparmedx.com** before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

20-05-2013

APPENDIX E

RECRUITMENT EMAIL

Dear Former Patient:

We are recruiting for a new study that is examining the potential impact of meditative movement, specifically a simple form of Tai Chi called Tai Chi Easy on weight loss in female bariatric patients that have started to re-gain weight.

Please contact us if you:

- Are female.
- Have had bypass surgery between 12-36 months ago.
- **Have gained at least 5 pounds since surgery.**
- Are looking to jump start your physical activity participation and can safely exercise.

The study is 8 weeks long and the Tai Chi Easy classes will meet weekly for 60 minutes on the Scottsdale Healthcare Shea Campus or at the Healthy Lifestyles Research Center on the downtown ASU campus. There will be several days and times to choose from to ensure your ease of participation. In addition to the Tai Chi Easy classes, you will be asked to come to one of the study sites for another two visits; one before the classes begin and one 8 weeks after. Each of these separate visits will take approximately 90 minutes to complete.

All study participants will be given a $20 gift card upon the final data collection.

For more information or to see if you qualify, please contact Lisa Smith, Study Coordinator at 480-255-7682 or at llsmith6@asu.edu.

Thank you!

Sincerely,

SBC Staff

APPENDIX F

RECRUITMENT FLYER

Scottsdale Healthcare– Shea Campus
Study Team: Lisa L. Smith, M.S., Dr. Linda K. Larkey, Dr. Robin Blackstone, Melisa Celaya, M.A.

Scottsdale Bariatric Center

Background/Premise:
Meditative movement practices (e.g., Tai Chi, Yoga) are associated with many positive health outcomes including potential weight loss. This study examines the ability of meditative movement to help increase weight loss in female bariatric surgery patients that have started to re-gain weight 12-36 months after surgery.

Study Objective:
The purpose of the research is to (1) evaluate the use of meditative movement, specifically Tai Chi Easy in the bariatric patient population and (2) to assess if Tai Chi Easy can help initiate weight loss in women who have started to re-gain weight after bariatric surgery. Additionally, potential changes in mindfulness and physical activity levels will be measured.

Study Details:
The 8-week study will offer a free weekly 60-minute Tai Chi Easy class. There will also be an additional initial and final study visit (two separate visits in addition to the Tai Chi Easy classes), each lasting approximately 60 minutes where data collection will occur (scheduled at the convenience of the participant).

Study Schedule:
Participants will take a part in a weekly 60-minuteTCE class at the Scottsdale Healthcare Shea Campus or at the Healthy Lifestyles Research Center on the downtown ASU campus for a total of 8 weeks. Participants will be given a TCE video to allow at-home practice. Varying class days and times will be offered.

Compensation:
Participants will receive a $20 gift card upon the final collection of data.

To Join the Study:
Ideal volunteers will be women between 18-70 years of ago who have had bariatric surgery in the last 12-36 months who have started to re-gain weight (at least 5 pounds) since their surgery. Additional criteria apply, and research staff will interview those who respond to determine eligibility.

For further information or to join the Meditative Movement and Weight Re-Gain study, please call
Lisa Smith at 480-255-7682, or email llsmith6@asu.

APPENDIX G

SHC LETTER OF SUPPORT

SCOTTSDALE HEALTHCARE℠

August 1, 2011

Dear Review Panel,

I am writing to express my full support of Lisa L. Smith's NRSA Fellowship application entitled, "Effectiveness of Meditative Movement in Bariatric Patients to Attenuate Post Surgical Weight Gain" and to confirm my role as a collaborator on this project.

As the Medical Director for the Scottsdale Healthcare Bariatric Program and the current president elect of the American Society for Metabolic and Bariatric Surgery, I feel that I am well-qualified to collaborate with Lisa Smith on the development of her project. Our program has been in place for over 10 years and we have a very active research program in collaboration with the Scottsdale Healthcare Research Institute. With regard to Ms. Smith's project, my research staff and I will be assisting her in the recruitment of her study participants, providing a quiet and private space to conduct her research activities and allowing her access to our body composition equipment as needed.

Ms. Smith recently completed her Feasibility Study of Meditative Movement in Bariatric Patients study at our facility with much success. It was a pleasure collaborating with her on the Feasibility study and makes my support of her on this current project even more enthusiastic. I will available to meet with Ms. Smith on an as-needed basis for the duration of her project.

Please do not hesitate to contact me if there is something that I can do to further support this application.

Sincerely,

Robin Blackstone

Robin Blackstone, MD, FACS, FASMBS
Medical Director, Scottsdale Healthcare Bariatric Center
Associate Clinical Professor of Surgery
University of Arizona School of Medicine-Phoenix

SCOTTSDALE HEALTHCARE SHEA
9003 E. Shea Boulevard • Scottsdale, AZ 85260-6709
Tel 480-323-3000

APPENDIX H

SCREENING QUESTIONNAIRE

Telephone Prescreen:

MM and Weight Re-Gain in Female Bariatric Patients Study

Interviewer:		
Date:	/ /20	Time: : am pm
Participant Name		
Participant ID number		

1. How did you hear about the study?
____SBC letter (1)
____Flyer (2)
____Dr. office (provide Dr. name/contact):_____ (3)
____Other (describe):_____ (4)

2. What kind of bariatric surgery did you have? _____

3. What was the date of your surgery? _____

4. Have you stopped losing weight since your surgery? _____

5. Have you gained any weight since you surgery? _____

6. If yes, how much weight have you gained? _____

7. Are you able to do gentle movements/physical activity either standing or sitting?_____

8. Are you able to attend a 60-minute class one day per week for 8 weeks?_____

9. Are you able to attend daytime classes? _____

10. Are you able to attend nighttime classes? _____

11. Would you be more likely to attend daytime or nighttime classes? _____

12. Would you prefer to come to downtown Phoenix to ASU or SHC? _____

13. Are there any days or nights of the week that absolutely would not work for you?

_____

APPENDIX I

INTERVENTION LOG

MM and Weight Re-Gain in Female Bariatric Patients Study

Attendance Sheet

Date:

Day/Time:

Instructions:

1. Provide your study ID number and signature below for attendance to today's class.
2. Please turn in your weekly log to Lisa if you brought it.

ID #	SIGNATURE	WEEK # OF STUDY

APPENDIX J

DEMOGRAPHIC QUESTIONNAIRE

Participant ID_____1
Staff Initials _____2
Date of Baseline Data Collection_____3
Date of Study Completion Data Collection_____4
For staff use only

Meditative Movement and Weight Re-Gain in Female Bariatric Patients Study

PART I – PARTICIPANT COMPLETION

1. What was the date of your bariatric surgery? _____
2. What was your highest weight before surgery? _____
3. What was your weight at the time of surgery? _____
4. What is your current weight?
5. Date of your last menstrual cycle? _____
6. Have you ever practiced any form of "meditative movement" regularly, such as yoga, tai chi, qigong?

   ☐YES (1) ☐NO (0)

   If Yes, How long have you practiced? Years _____ Months _____

7. Have you ever practiced any form of meditation regularly, such as mantra meditation, mindfulness-based meditation, transcendental meditation, or other?

   ☐YES (1) ☐NO (0)

   If Yes, How long have you practiced? Years _____ Months _____

8a. What is the highest level of education you have completed?

- ☐$_1$ Less than High School Diploma
- ☐$_2$ High School Diploma/GED
- ☐$_3$ Associates Degree, Technical Training, or Some College
- ☐$_4$ Four-Year College Degree or Beyond

8b. Date of Birth	___ ___/ ___ ___/___ ___ ___ ___(confirm ≥18- 70)
8c. Gender	☐1 Female
8d. Ethnicity	Hispanic or Latino? ☐1 No ☐2 Yes
8e. Race (Please check all that apply)	☐1 American Indian or Alaska Native ☐2 Asian ☐3 Native Hawaiian or Other Pacific Islander ☐4 Black or African American ☐5 White

9.What medications and/or supplements are you currently taking? Please include hormone replacement therapy (HRT) if applicable. If none, please write NONE.

_____

_____

_____

_____

_____

_____

PART 2 – STAFF COMPLETION

Body Composition Measures - Baseline

Height (cm) _____

Weight (kg) _____

Body Fat % _____

Body Composition Measures - Study Completion Date: _____

Height (cm) _____

Weight (kg) _____

Body Fat % _____

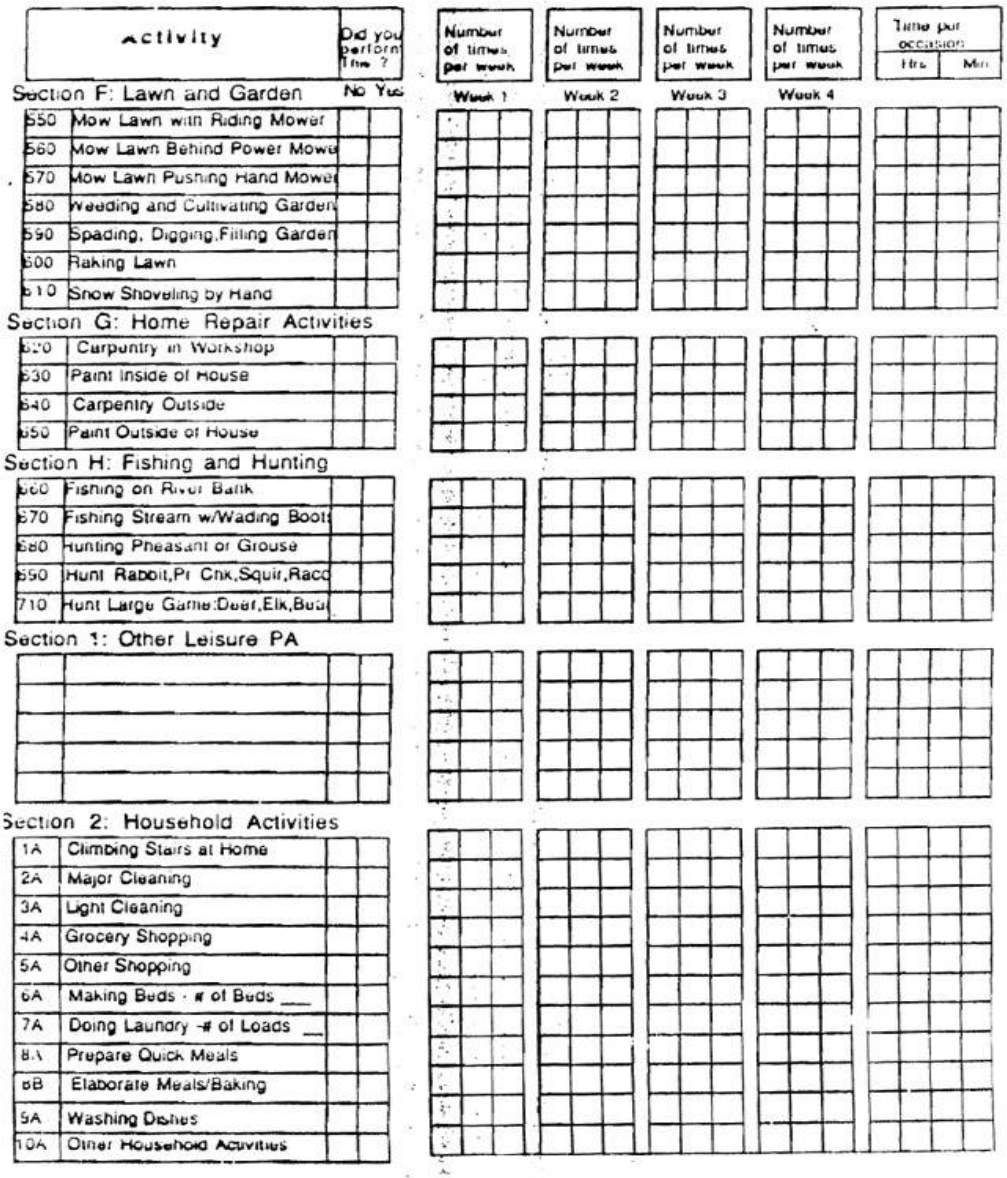
APPENDIX K

MINNESOTA LEISURE TIME PHYSICAL ACTIVITY QUESTIONNAIRE

Interviewer I.D. [ ][ ][ ]

FOUR WEEK HISTORY
LEISURE TIME PHYSICAL ACTIVITIES

	Activity	Did you perform this ?	Number of times per week	Number of times per week	Number of times per week	Number of times per week	Time per occasion Hrs.	Time per occasion Min.
SECTION A: Walking and Miscellaneous		No Yes	Week 1	Week 2	Week 3	Week 4		
010	Walking for Pleasure							
020	Walking to Work							
030	Using Stairs When Elevator							
040	Cross Country Hiking							
050	Back Packing							
060	Mountain Climbing							
115	Biking to Work/Pleasure							
125	Dancing-Ballroom,Square,Disc							
135	Dancing-Aerobic, Ballet							
140	Horseback Riding							
SECTION B: Conditioning Exercise								
150	Home Exercise							
160	Health Club Exercise							
180	Jog/Walk Combination							
200	Running							
210	Weight Lifting							
SECTION C: Water Activities								
220	Water Skiing							
235	Sailing in Competition							
250	Canoeing/Rowing for Pleasure							
260	Canoeing/Row in Competition							
270	Canoeing on a Camping Trip							
280	Swimming (50 ft.) at a Pool							
295	Swimming at the Beach							
310	Scuba Diving							
320	Snorkeling							
SECTION D: Winter Activities								
340	Snow Skiing, Downhill							
350	Snow Skiing, Cross Country							
360	Ice (or *Roller*) Skating							
370	Sledding or Tobogganing							
SECTION E: Sports								
390	Bowling							
400	Volly Ball							
410	Table Tennis							
420	Tennis, Singles							
430	Tennis, Doubles							
440	Softball							
450	Baminton							
460	Paddle Ball							
470	Raquet Ball							
480	Basketball:Non-Game							
490	Basketball:Game Play							
500	Basketball:Officiating							
510	Touch Football							
520	Handball							
530	Squash							
540	Soccer							
	GOLF:							
070	Riding a Power Cart							
080	Walking, Pulling Cart							
090	Walking, Carrying Clubs							



ection 3: Other Comments; Illness, Vacation, Interruption

APPENDIX L

BORG RATING OF PERCEIVED EXERTION SCALE

Borg Rating of Perceived Exertion

6 No exertion at all
7
8 Extremely light
9 Very light
10
11 Light
12
13 Somewhat hard
14
15 Hard (heavy)
16
17 Very hard
18
19 Extremely hard
20 Maximal exertion

APPENDIX M

THREE FACTOR EATING QUESTIONNAIRE

The Three-Factor Eating Questionnaire—Revised 18-Item

1. When I smell a sizzling steak or juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

2. I deliberately take small helpings as a means of controlling my weight.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

3. When I feel anxious, I find myself eating.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

4. Sometimes when I start eating, I just can't seem to stop.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

5. Being with someone who is eating often makes me hungry enough to eat also.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

6. When I feel blue, I often overeat.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

7. When I see a real delicacy, I often get so hungry that I have to eat right away.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

8. I get so hungry that my stomach often seems like a bottomless pit.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

9. I am always hungry so it is hard for me to stop eating before I finish the food on my plate.

   Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

10. When I feel lonely, I console myself by eating.

    Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

11. I consciously hold back at meals in order not to weight gain.

    Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

12. I do not eat some foods because they make me fat.

Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

13. I am always hungry enough to eat at any time.

    Definitely true (4)/ mostly true (3)/ mostly false (2)/ definitely false (1)

14. How often do you feel hungry?

    Only at meal times (1)/ sometimes between meals (2)/ often between meals (3)/ almost always (4)

15. How frequently do you avoid "stocking up" on tempting foods?

    Almost never (1)/ seldom (2)/ usually (3)/ almost always (4)

16. How likely are you to consciously eat less than you want?

    Unlikely (1)/ slightly likely (2)/ moderately likely (3)/ very likely (4)

17. Do you go on eating binges though you are not hungry?

    Never (1)/ rarely (2)/ sometimes (3)/ at least once a week (4)

18. On a scale of 1 to 8, where 1 means no restraint in eating (eating whatever you want, whenever you want it) and 8 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?

    The 1–2 scores were coded 1; 3–4 scores were coded 2; 5–6 scores were coded 3; 7–8 scores were coded 4.

The cognitive restraint scale was composed of items 2, 11, 12, 15, 16, and 18. The uncontrolled eating scale was composed of items 1, 4, 5, 7, 8, 9, 13, 14, and 17. The emotional eating scale was composed of items 3, 6, and 10.

APPENDIX N

BODY AWARENESS QUESTIONNAIRE

Body Awareness Questionnaire (Shields, Mallory & Simon, 1989)
Instructions:
Listed below are a number of statements regarding your sensitivity to normal, nonemotive body processes. For each statement, select a number from 1 to 7 that best describes how the statement describes you and place the number in the box to the right of the statement.

Not al all true of me Very true of me
1 2 3 4 5 6 7

1. I notice differences in the way my body reacts to various foods.
2 I can always tell when I bump myself whether or not it will become a bruise.
3. I always know when I've exerted myself to the point where I'll be sore the next day.
4. I am always aware of changes in my energy level when I eat certain foods.
5. I know in advance when I'm getting the flu.
6. I know I'm running a fever without taking my temperature.
7. I can distinguish between tiredness because of hunger and tiredness because of lack of sleep.
8. I can accurately predict what time of day lack of sleep will catch up with me.
9. I am aware of a cycle in my activity level throughout the day.
*10. I don't_ _notice seasonal rhythms and cycles in the way my body functions.
11. As soon as I wake up in the morning, I know how much energy I'll have during the day.
12. I can tell when I go to bed how well I will sleep that night.
13. I notice distinct body reactions when I am fatigued.
14. I notice specific body responses to changes in the weather.
15. I can predict how much sleep I will need at night in order to wake up refreshed.
16. When my exercise habits change, I can predict very accurately how that will affect my energy level.
17. There seems to be a "best" time for me to go to sleep at night.
18. I notice specific bodily reactions to being over hungry.

APPENDIX O

PROFILE OF MOOD STATES

POMS-Short Form

Ppt ID:

Below is a list of words that describe feelings people have. Please read each one carefully. Then circle ONE answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

Please circle the number that describes how much you feel like the word listed on the left.

0 = Not at all	**1 = A little**	**2 = Moderately**	**3 = Quite a bit**	**4 = Extremely**
Tense	0	1	2	3	4
On edge	0	1	2	3	4
Uneasy	0	1	2	3	4
Restless	0	1	2	3	4
Nervous	0	1	2	3	4
Anxious	0	1	2	3	4
Unhappy	0	1	2	3	4
Sad	0	1	2	3	4
Blue	0	1	2	3	4
Hopeless	0	1	2	3	4
Discouraged	0	1	2	3	4
Worthless	0	1	2	3	4

APPENDIX P

MINDFUL ATTENTION AND AWARENESS SCALE

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6
It seems I am "running on automatic," without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6

1 Almost Always	2 Very Frequently	3 Somewhat Frequently	4 Somewhat Infrequently	5 Very Infrequently	6 Almost Never

I drive places on 'automatic pilot' and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention.	1	2	3	4	5	6
I snack without being aware that I'm eating.	1	2	3	4	5	6

APPENDIX Q

FEASIBILITY QUESTIONNAIRE

FEASIBILITY QUESTIONNAIRE

Please read each statement carefully, and choose the number that best describes your experience from this study and circle the number/choice after the statement that best describes you.

1. Agree
2. Somewhat agree
3. Neutral
4. Somewhat disagree
5. Disagree

Please add any comments you may have for any question at the end.

Please do not skip any items.

1. The people important to me support my learning of TCE (Tai Chi Easy). 1 2 3 4 5

2. I think that people who are like me are interested in trying out practices like TCE.

1 2 3 4 5

3. I enjoyed practicing TCE. 1 2 3 4 5

4. The movements in the TCE sessions were easy for me to do. 1 2 3 4 5

5. The TCE home materials were easy to use. 1 2 3 4 5

6. It was easy for me to find time to practice TCE. 1 2 3 4 5

7. I feel TCE was appropriate during this time of my life. 1 2 3 4 5

8. I feel less sad when I practice TCE. 1 2 3 4 5

9. I am in better physical shape because of TCE. 1 2 3 4 5

10. I think TCE is helpful after bariatric surgery. 1 2 3 4 5

11. TCE has made my weight loss process easier. 1 2 3 4 5

12. I discussed my challenges with weight with other group members. 1 2 3 4 5

13. I felt connected with group members who were participating in TCE. 1 2 3 4 5

14. I enjoyed the social aspects of TCE more than the TCE exercises. 1 2 3 4 5

15. I intend to continue to practice TCE 1 2 3 4 5

16. What would have made the TCE home sessions better?

_____

17. What would have made the TCE group sessions better?

_____

18. What did you like about TCE?

_____

19. What made it difficult to practice?

_____

20. Please tell me about your emotional state **before** and **after** the Tai Chi Easy program.

_____

_____

_____

_____

21. Please use this section to write any other comments or suggestions that you may have.

APPENDIX R

MEDITATIVE MOVEMENT INVENTORY

PPT ID#:_____

Meditative Movement Inventory (MMI)

We are interested in finding out more about your experience with doing Tai Chi Easy. Please circle your responses below. Please do not skip any questions.

When I was doing the Tai Chi Easy exercises, I felt like….

Question	All of the time	Very Frequently	Occasionally	Rarely	Very Rarely	Never
1. My mind really became quiet	1	2	3	4	5	6
2. I was going into a state of relaxation	1	2	3	4	5	6
3. I was breathing fully and deeply	1	2	3	4	5	6
4. I took in deep breaths with the movements	1	2	3	4	5	6
5. I was getting addicted to the feeling of inner peace	1	2	3	4	5	6

6. I was using my breathing to go into a relaxed state	1	2	3	4	5	6
7. I moved in relaxed, fluid motions	1	2	3	4	5	6

8. I was connected to something greater than myself	1	2	3	4	5	6
9. I was happy or smiling a little	1	2	3	4	5	6
10. I was going into a state of reverie	1	2	3	4	5	6
11. I was loosening up with the movements	1	2	3	4	5	6
12. I was breathing nice and slow	1	2	3	4	5	6

13. I was meditating	1	2	3	4	5	6
14. My mind was clear of all thought	1	2	3	4	5	6
15. I was deeply in tune with myself	1	2	3	4	5	6
16. My attention was turned inward	1	2	3	4	5	6
17. I was in touch with the field of energies around me	1	2	3	4	5	6

Please feel free to add any comments you may have regarding your Tai Chi Easy experience

APPENDIX S

DIETARY SCREENER QUESTIONNAIRE

DIETARY SCREENER MODULE (DTQ)
2-11 – Household
12+ – MEC

DTQ.010 G/Q/U These questions are about the different kinds of foods {you/SP} ate or drank during the past month, that is, the past 30 days. When answering, please include meals and snacks eaten at home, at work or school, in restaurants, and anyplace else.

During the past month, how often did {you/SP} eat **hot or cold cereals**? You can tell me per day, per week or per month.

|___|___|___|
ENTER QUANTITY IN DAYS, WEEKS, OR MONTHS

NEVER	0	(DTQ.030)
REFUSED	777	(DTQ.030)
DON'T KNOW	999	(DTQ.030)

ENTER UNIT

DAY	1
WEEK	2
MONTH	3
REFUSED	7
DON'T KNOW	9

CAPI INSTRUCTION:
IF RESPONSE > 1 AND UNIT = 1 (DAY), OR
IF RESPONSE > 14 AND UNIT = 2 (WEEK), OR
IF RESPONSE > 60 AND UNIT = 3 (MONTH),
THEN DISPLAY QUESTION DTQ.015.

DTQ.015 You said (DISPLAY NUMBER FROM DTQ.010) times per (DISPLAY UNIT FROM DTQ.010). Is that correct?

YES	1	(CONTINUE)
NO	2	(RETURN TO DTQ.010)
REFUSED	777	(CONTINUE)
DON'T KNOW	999	(CONTINUE)

DTQ.020 During the past month, what kinds of cereal did {you/SP} **usually** eat?

ENTER FIRST FEW LETTERS OF CEREAL NAME TO START THE LOOKUP.
SELECT CEREAL FROM LIST. IF CEREAL NOT ON LIST, PRESS BS TO DELETE THE ENTRY AND TYPE ** TO ENTER CEREAL NAME.

CAPI INSTRUCTION:
DISPLAY CEREAL LIST. INTERVIEWER SHOULD BE ABLE TO SELECT CEREAL FROM LIST OR PRESS BS TO DELETE ENTRY AND TYPE ** TO ENTER NAME OF CEREAL.

NEW BOX 0

CHECK ITEM DTQ.300:
IF THIS IS THE FIRSTENTRY, CONTINUE.
OTHERWISE, GO TO DTQ.030.

DTQ.025 IS THERE ANOTHER CEREAL SP USUALLY EATS?

OR ASK IF NECESSARY (Is there another cereal {you/SP} usually eat(s)?)

YES	1	(RETURN TO DTQ.020)
NO	2	(DTQ.030)

DTQ.030 G/Q/U (During the past month), how often did {you/SP} have **milk** {either to drink or on cereal}? Do **not** include soy milk or small amounts of milk in coffee or tea. (You can tell me per day, per week or per month.)

INTERVIEWER INSTRUCTION:
INCLUDE: SKIM, NO-FAT, LOW-FAT, WHOLE MILK, BUTTERMILK, AND LACTOSE-FREE MILK. ALSO INCLUDE CHOCOLATE OR OTHER FLAVORED MILKS.
DO NOT INCLUDE: CREAM.

|___|___|___|
ENTER QUANTITY IN DAYS, WEEKS, OR MONTHS

NEVER	0	(DTQ.040)
REFUSED	777	(DTQ.040)
DON'T KNOW	999	(DTQ.040)

ENTER UNIT

DAY	1
WEEK	2
MONTH	3
REFUSED	7
DON'T KNOW	9

CAPI INSTRUCTION:
IF DTQ.010 >= 1, DISPLAY PHRASE {"either to drink or on cereal"}.

CAPI INSTRUCTION:
IF RESPONSE > 2 AND UNIT = 1 (DAY), ELIMINATE >2 AND UNIT = 1 FOR HOUSEHOLD QUESTIONNAIRE SECTION (SPs 2-11 YEARS OLD)
IF RESPONSE > 14 AND UNIT = 2 (WEEK), OR
IF RESPONSE > 60 AND UNIT = 3 (MONTH),
THEN DISPLAY QUESTION DTQ.035.

DTQ.035 You said (DISPLAY NUMBER FROM DTQ.030) times per (DISPLAY UNIT FROM DTQ.030). Is that correct?

YES	1	(CONTINUE)
NO	2	(RETURN TO DTQ.030)
REFUSED	777	(CONTINUE)
DON'T KNOW	999	(CONTINUE)

DTQ.040 G/Q/U

During the past month, how often did {you/SP} drink **regular soda** or pop that contains sugar? Do **not** include diet soda. You can tell me per day, per week or per month.

INTERVIEWER INSTRUCTION:
INCLUDE: MANZANITA AND PEÑAFIEL SODAS.
DO NOT INCLUDE: DIET OR SUGAR-FREE FRUIT DRINKS. DO NOT INCLUDE JUICES OR TEA IN CANS.

|___|___|___|
ENTER QUANTITY IN DAYS, WEEKS, OR MONTHS

NEVER	0	(DTQ.050)
REFUSED	777	(DTQ.050)
DON'T KNOW	999	(DTQ.050)

ENTER UNIT

DAY	1
WEEK	2
MONTH	3
REFUSED	7
DON'T KNOW	9

CAPI INSTRUCTION:
IF RESPONSE > 2 AND UNIT = 1 (DAY), OR
IF RESPONSE > 14 AND UNIT = 2 (WEEK), OR
IF RESPONSE > 60 AND UNIT = 3 (MONTH),
THEN DISPLAY QUESTION DTQ.045.

DTQ.045

You said (DISPLAY NUMBER FROM DTQ.040) times per (DISPLAY UNIT FROM DTQ.040). Is that correct?

YES	1	(CONTINUE)
NO	2	(RETURN TO DTQ.040)
REFUSED	777	(CONTINUE)
DON'T KNOW	999	(CONTINUE)

APPENDIX T

PARTICIPANT LOG

MM Practice Log
(Bring back each week to your MM group or email to Lisa weekly @ llsmith6@asu.edu)

Instructions: Please use this log to keep track of the number of minutes you practice MM at home, in between the weekly scheduled MM classes. Please be sure to record all practice sessions no matter how long or short. Please also record any other total minutes of intentional physical activity, e.g., walking, yard work, structured exercise, etc… You may also add notes as to how you were feeling before and after the practice session. Everything in the log will remain confidential as to your identity. You will be identified only by your participant ID number.

Participant ID: _____

Date log started: _ _ / _ _ / _ _ _ _

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Total minutes of MM practiced at home.							
RPE of practice							
Total minutes of other non-MM intentional activity (e.g., walking, hiking)							
Type of non-MM activity							

Date log stopped: _ _ / _ _ / _ _ _ _

Please indicate or describe any difficulties with your weekly practice below, including mood or challenges with practicing. Alternatively, please report any positive experiences and/or moods as well.

_____

_____

_____

_____

APPENDIX U

FOLLOW-UP QUESTIONNAIRE

Participant ID_____

Name: _____

Date of Follow-up Data Collection_____

MM & Weight
FOLLOW-UP QUESTIONNAIRE

CONTACTED BUT NOT SCREENED

Why did you decide to not participate in the study?

_____

_____

_____

What, if anything, would have changed your mind about participating?

_____

_____

SCREENED BUT NOT ENROLLED

Why did you decide to not participate in the study?

_____

_____

_____

What, if anything, would have changed your mind about participating?

_____

_____

ENROLLED BUT DROPPED

What was the primary reason that you dropped from the study?

Were there any other reasons that caused you to stop participating?

Were you at all uncomfortable physically doing the TCE movements? If so, how?

Were you at all uncomfortable emotionally doing the TCE movements? If so, how?

ENROLLED & COMPLETED

What were the most challenging aspect(s) of the study for you?

Were you at all uncomfortable physically doing the TCE movements? If so, how?

Were you at all uncomfortable emotionally doing the TCE movements? If so, how?

What would have made the study better than it was originally designed?

APPENDIX V

FOLLOW-UP SCRIPT

MM & Weight Follow-Up Script

Hello, I am calling to follow-up on the Bariatric Surgery and Tai Chi study that you (expressed interest in/joined initially/completed). Given the challenges to recruit and maintain study participants, we are hoping to get your input on the intervention. Do you have approximately 5 minutes or less to answer a few questions on your decision to (not join/drop from/experience while in) the study?

If yes: Great, thank you. I will read the questions to you and record your responses. Please be aware that you may skip any questions that you do not want to answer for any reason.

If no: Would it be acceptable to send you the questions via email for you to answer and send back to the research staff?

APPENDIX W

FEASIBILITY QUESTIONNAIRE RESPONSES (#16-21)

Question16. What would have made the TCE home sessions better?

Adding in a few movements each week with a focus on practicing those
Making time to do
N/A (more time = my fault!)
A better flow in the exercises
Not having school – having a group to practice with
Taking a set time to practice
Nothing comes to mind
Setting aside a specific time
Music like in class (recordings)
Nothing
Shorter segments

17. What would have made the TCE group sessions better?

Timing to show results was pretty unfortunate
Nothing, they were excellent
Time of year
Having a short talk session before or after. Maybe sometimes before and sometimes after to see how it affected our conversation.
More time
More people
It was not a group, but that worked perfect for me. (Participant was only one in the group the entire 8 weeks).
Location. The actual session was great.
Having the TCE part integrate others without bariatric surgeries.

18. What did you like about TCE?

The gentle, meditative motion
Making me think "thoughtfulness"
Great instructor
Movement – non judgmental group attitude – the learning process
New experience
The true sense of letting go of everything else going on in my life and just relaxing my mind.
Stress reduction, focusing on being in the moment/mindful
Judgment-free environment
Smoothness and ease
The rhythmic flow to it

19. What made it difficult to practice?

Finding time to practice consistently; remembering the movements
Time (3)
Busy time of year
Other home responsibilities
Because it requires no set up, it's easy to put off and not do it
At home, time.
My eagerness to lose weight/get more fit made me impatient with TCE and I switched to more active exercising.

20. Please tell me about your emotional state before and after the TCE program?

I truly am calmer, less prone to being stressed and slower to anger.
I am ready to get "back on track" to make healthier food choices and if I'm under stress, take a few minutes to use the TCE movements I learned.
I think learning TCE has helped me be more self-aware of my feelings and emotions.
I believe that Tai Chi calms me and makes me more aware of my body and its messages.
I found my emotional state quite positive. I felt more willing to accept good changes and the negative changes were easier to handle.
I was sort of in a rut and I learned how deep breathing improves everything.
Before: A little depressed, stressed about weight and personal life issues; very high strung and edgy. After: More positive, at ease, more clear-minded, focused on the good, not the bad. Coping better with issues in life, taking deep breaths, staying calm.
Generally, I feel better about my stress management, feel I have more tools for dealing with it.
My stress level is more manageable. I've been able to adopt and modify my stress reactions with specific techniques.
Before I felt weak and unmotivated. After, I feel I can continue and keep moving.
Before – I knew my eating patterns weren't beneficial and I lacked motivation to exercise. Now/After – TCE has helped motivate me to be more active again.
I breath and feel much better and more in control.

21. Other comments/suggestions?

Perhaps more restrictive in "requiring" attendance and weekly practice.
Requesting a commitment to the full 8 weeks if possible.
I wish that it was possible to have these programs closer to home. (Participant travelled 115 miles one way to attend).
As being older I really enjoyed this class, not too strenuous but taught a lot about breathing and focus.
Having a back-up option for class would have been helpful (it was offered and I couldn't make it) and 1:1 would have been uncomfortable for me.