THE EFFECT OF A SUPPLEMENTAL TELEPHONIC PHYSICAL ACTIVITY COACHING PROGRAM FOR TREATING OBESITY: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Purpose: To evaluate the impact of a supplemental telephonic physical activity coaching program based on Active Living Every Day (ALED) when combined with the services of a specialty medical practice on weight loss, body and truncal fat reduction, and blood pressure improvement when treating obese persons over six months.

Setting: Participants were recruited from the Minnesota Center for Obesity, Metabolism and Endocrinology (MNCOME) specialty medical practice.

Methods: Forty obese adults participated in the study. The design was a single-blinded, randomized controlled trial, with participants randomized to receive either: (1) treatment group which included telephonic physical activity coaching with pedometer-based tracking and active participation with MNCOME or (2) control group which included only active participation with MNCOME. Measures for all variables were assessed at baseline and six months

Results: Weight, body and truncal fat, and blood pressure variables did not differ significantly between groups after six months. However, the results indicate that both telephonic coaching and control groups achieved a statistically significant within-group difference from baseline to a period of six-months for mean weight losses of 14.7 ± 3.4 ($p \leq 0.002$) and 15.4 ± 3.2 lbs ($p \leq 0.001$) respectively, but not for any other variables under consideration. A greater percentage of initial weight loss was achieved on average by the telephonic coaching group of 6.5% than the control group of 5.9% after six months. However, a greater percentage of the control group (61%) achieved the 5-10% weight loss goal than the telephonic coaching group (44%) over six months.

Conclusion: At the present time, this is the only study to evaluate the impact of a supplemental telephonic physical activity coaching program based on ALED to the services of a medical specialty care clinic for the purpose of treating obesity. However, the findings suggest that there is no significant impact when such a program is added to MNCOME for improvements in weight, body composition, and blood pressure over six months based on the number of obese participants of this trial.

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Abbreviations

ACSM	American College of Sports Medicine
AFL	Active for Life
AHA	American Heart Association
ALED	Active Living Every Day
BMI	Body Mass Index
CDC	Centers for Disease Control
CHD	Coronary heart disease
CI	confidence interval
CT	computed tomography
DXA	Dual-energy x-ray absorptiometry
ES	effect size
FDA	Food and Drug Administration
HDL	high-density lipoprotein
HIPAA	Health Insurance Portability Accountability Act
in	Inches
kg	Kilograms
lbs	Pounds
LCD	low-calorie diet
LDL	low-density lipoprotein
m	Meters
mmHg	millimeter of mercury
MNCOME	Minnesota Center for Obesity, Metabolism and Endocrinology
MRI	magnetic resonance imaging
NHANES	National Health and Nutrition Examination Survey
NIDDM	Non-insulin dependent diabetes mellitus
NWCR	National Weight Control Registry
PACE	Patient-Centered Assessment and Counseling for Exercise
RR	risk ratio
SOC	stages of change
TTM	Transtheoretical Model
US	United States
USDHHS	United States Department of Health and Human Service
VAT	visceral adipose tissue
WC	waist circumference
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

Obesity refers to the condition of having an excessive amount of weight than what is generally considered healthy for a given height. Men and women classified with a body mass index (BMI) greater than 30 kilograms per meter squared (kg/m^2) are considered to be obese. Among those who are considered to be obese, an excessive level of abdominal fat tissue may accumulate as a result of excessive weight gain. Abdominal adiposity is considered a physical condition of having excessive fat cell and tissue growth and development with adverse health consequences inhibited by a lifestyle of prolonged positive caloric intake. Obesity is widely considered a complex, multi-factorial disease that develops from the interaction between genetics and the environment.

In the past several decades, the prevalence of obesity has doubled to more than 30 % of the United States adult population (National Heart, Lung, and Blood Institute [NHLBI] Obesity Education Initiative, 1998, p. 77). The rise in prevalence of obesity is a concern because of the association with decreased life expectancy and increased risk of morbidity from cardiovascular disease, type 2 diabetes, hypertension, asthma, sleep apnea, and various forms of cancer such as prostate, breast, and colon (Flegal et al., 2012). Based on data from the U.S. National Health Expenditure Accounts dataset, obesity was responsible for as much as $147 billion of health care spending per year in 2006 (Finkelstein, Trogdon, Cohen, & Dietz, 2009).

A variety of treatment protocols exist for the management of obese patients, including dietary therapy, altering physical activity patterns, behavior therapy, pharmacotherapy, surgery and any combinations of these treatments. The management option most relevant to the purpose of this study is the incorporating physical activity accountability in the form of telephonic coaching and pedometer use in assisting with weight loss, abdominal fat reduction, and improved blood pressure. Improved physical activity levels as a strategy has been evaluated and evidence has grown in recent years for treating obesity. The evidence suggests that physical activity should be recommended as part of a comprehensive weight loss therapy program because it

modestly contributes to weight loss in obese adults, may decrease abdominal fat, increase cardio-respiratory fitness, and help with maintenance of long-term weight loss (NHLBI, 1998, p. 42).

Recent studies have investigated the effectiveness of facilitating physical activity behavior change through telephonic coaching and pedometer-based monitoring for reducing weight (Goode, Reeves, Eakin, 2012; Richardson, Newton, Abraham, Sen, Jimbo, & Swartz, 2008). Few studies however, have evaluated the manner in which a telephonic physical activity and pedometer-based monitoring program should be implemented for the purpose of contributing to weight loss, abdominal fat reduction, and blood pressure improvement among the obese. Even fewer studies have evaluated telephonic coaching when added as a supplemental resource to a specialty metabolic medical practice that provides clinical care. Of the 15 highlighted studies evaluating a telephonic physical activity intervention in recent years, only four studies involved the goal of weight loss for obesity (Tucker, Nokes, & Adams, 2008; Hellerstedt & Jeffery, 1997; Sherwood, Welsh, VanWormer, & Hotop, 2010; Lombard, Lombard, & Winnett, 1995). There was a study in which a personal weight loss telephonic coaching program was implemented with successful results (Tucker et al., 2008). However, the study did not use a pedometer-based step tracking tool, or acknowledge any programming or important mediators of behavior change.

Research has supported pedometer-based step monitoring to be effective for achieving physical activity. It is accepted that adherence to physical activity levels equivalent to achieving at least 10,000 steps daily is recommended for sufficient energy expenditure for successful metabolic and cardiovascular responses for enhanced health and well-being (Richardson et al., 2008).

Few of the current telephonic-based physical activity interventions for weight loss have incorporated a theory based approach to behavior change. Over the past decade, the trans-theoretical model (TTM) of behavior change has emerged as providing a useful framework to help participants recognize and meet physical activity recommendations. Furthermore, a 12 lesson program called Active Living Every Day

(ALED) encompasses the advanced aspects of a successful behavioral therapy program based on TTM (Blair, Dunn, Marcus, Carpenter, & Jaret, 2011).

At the present time, there are no studies that have managed to combine pedometer-based self monitoring with the added accountability of a telephonic physical activity coach based on the TTM and the ALED programming principles as a supplement to a specialty medical practice for the purpose of weight loss, body fat reduction, as well as blood pressure improvement among obese patients. In collaboration with the Minnesota Center for Obesity Metabolism and Endocrinology (MNCOME), the purpose of this intervention is to determine whether the supplementation of a physical activity telephonic coaching program based on ALED with the goal of promoting adherence to at least 10,000 daily steps will achieve greater differences for targeted weight loss, reduction in abdominal body fat, and blood pressure improvement for obese participants over a six-month time frame.

CHAPTER 2

LITERATURE REVIEW

Introduction

In order to understand the implications of obesity, a review of the current associated demographic prevalence, pathophysiology, and health and economic burden is necessary.

Obesity and Abdominal Adiposity: Background

BMI, a formula that combines weight and height, is commonly used in epidemiological studies assessing the relationship between weight and disease. Public health recommendations are based on BMI, which is computed as weight measured in kilograms divided by height in meters squared. To estimate BMI from pounds and inches the formula changes to weigh in pounds divided by height in inches squared multiplied by a factor of 703. Obesity refers to having a BMI greater than or equal to 30

kg/m² according to the World Health Organization (WHO) and National Heart, Lung, and Blood Institute (NHLBI).

Abdominal adiposity is reached when human abdominal body fat tissue has accumulated in excess of visceral capacity in a state of obesity. It is typically expressed as either a percentage of total body tissue or by a circumference of waist size measured in inches. It is then promoted by prolonged patterns of a positive caloric energy intake difference as well as sedentary pattern of living in genetically and environmentally susceptible patients. The caloric imbalance over time may signal the recruitment, proliferation and differentiation of additional fat cells in order to store energy while maintaining normal adipose tissue functionality over time. The presence of excess fat tissue in the abdomen beyond normal proportion to total body fat is an independent predictor of risk factors and morbidity (Kissebah, Vydelingum, & Murray, 1982). Fat located in the abdominal region is associated with greater health risks than that in peripheral regions, e.g., the gluteal femoral area (Kissebah et al., 1982). Waist circumference is commonly used as a surrogate measure for abdominal visceral fat. Men with greater than 40 inches and women with greater than 35 inches have increased relative risk for the development of obesity-associated risk factors in most adults (NHLBI, 1998, p. 61).

Given the fact that waist circumference cut-points lose their incremental predictive power in patients with BMI > 35 kg/m², the DXA scan has also been proven to more accurately depict the indication of abdominal adiposity for all BMI values above 30 kg/m² in more recent clinical trials involving weight management for obesity.

Demographic Variation and Prevalence

The prevalence of obesity has increased dramatically among adults within the last three decades, but has leveled off within the last decade. According to the 2009-2010 Nutritional Health and Nutrition Examination Survey (NHANES), the prevalence of obesity was 35.5% among adult men and 35.8% among adult women (Flegal et al., 2012).

Historically the prevalence of obesity has been much higher among African American and Hispanics. Approximately 49.5% of non-Hispanic black adults and 39.1% of Hispanic adults are obese, compared with 34.3% of non-Hispanic white adults in 2010. Obesity levels have also varied by geographic region within the United States. According to the Centers for Disease Control (CDC), Mississippi had the highest adult obesity rate in 2011 with 34.9% and Colorado had the lowest at 20.7% (Flegal et al., 2012).

Obesity rates in United States adults are projected to increase nationwide by 2030, exceeding 44% of the population in all 50 states, 50% in 39 states, and 60% in 13 states. The highest rate would be in Mississippi with 66.7% and the lowest in Colorado with 44.8% (Wang et al., 2008). There are projected to be 66 million more obese adults in the United States by 2030 (Wang et al., 2011).

Pathophysiology and Determinants

Body weight and body composition are a function of genetics, health status, basal metabolic factors, dietary intake, physical activity, race, and hormonal factors. Obesity may result from a lifestyle pattern of consuming more energy than what is expended, especially among more genetically susceptible people. Much of the excess energy is stored as fat cells of adipose tissue, with the amount of fat in a person's body reflecting both the number and size of fat cells. When energy intake exceeds expenditure, fat cells accumulate triglycerides and expand in size, which in turn may stimulate cell proliferation so that their numbers increase again (Rosen, E.D., 2002). Obesity may then result and develop when a person's fat cells increase in number, in size, or both.

When energy output exceeds energy in a weight loss effort, the size of fat cells may diminish, but not their number. When fat cells have enlarged and energy intake continues to exceed output, fat cells may increase in number again throughout adulthood (Rosen, 2002). People with the increase in fat cells over time tend to regain their lost weight more rapidly than those with an average number (Rosen, 2002).

Patterns of eating that generally contribute to weight gain start from a food supply that contains readily available, energy-dense foods, served in large portions. Over the last few decades human energy expenditure has been lowered by a lifestyle of decreased physical activity required at work and leisure than ever before in our history. Low-calorie diets and regular patterns of moderate and/or vigorous physical activity offer a way to lessen the severity of obesity in the population, along with proper eating habits (Grundy, Blackburn, Higgins, Lauer, Perri, & Ryan, 1999).

Health Risks

Morbidity

Excessive weight increases the risk of death, particularly due to cardiovascular disease. There is strong evidence that weight loss in obese individuals reduces risk factors for type II diabetes, cardiovascular disease, reduces blood pressure in hypertensive individuals, and reduces serum triglycerides, increases high-density lipoprotein, and some reduction in total serum cholesterol. Results over the course of time have consistently shown that adults with a BMI greater than 30 kg/m^2 are at increased risk of death (Wadden, & Sunkard, 2002). The increase in obesity among adults would increase new cases of coronary heart disease and stroke, type II diabetes, hypertension, cancer, and mental health and quality of life.

Excessive fat tissue resulting from a positive caloric balance over a period of time is typically stored in adipose tissue which may be well tolerated in comparison to fat stored in visceral adipose tissue. Fat accumulation in such tissues and organs such as the heart and liver can lead to the development of diseases such as heart failure or fatty liver (Schaffer, 2003).

Coronary Heart Disease

Young and middle-aged men and women who are obese are more likely than their leaner peers to develop heart disease. A survey study conducted on 29,122 US men who were between 40 to 75 years of age observed that those with a BMI of at least 33 kg/m^2 were three times more likely to develop coronary heart disease (CHD) (RR = 3.4,

95% CI = 1.7 – 7.1) than those with a BMI below 23 kilograms per meter squared during the three years of follow up (Wadden et al., 2002). Associations between excessive weight and CHD have been observed in adult women although less common than among men. Another study observed that among 1,259 white women in NHANES I, those who were overweight with a BMI greater than 29 kg/m² had a threefold increase risk (RR = 2.7, 95% CI = 1.7 -4.4) of developing CHD than those who had fairly stable weights (Harris et al, 1993).

One primary mechanism by which obesity and weight gain might increase the risk of CHD is through hyperlipidemia. BMI is positively correlated with triglyceride levels, and inversely correlated with high-density lipoprotein (HDL) levels. Low HDL levels are more predictive than high total cholesterol of developing heart disease. Thus obesity increases risk of heart disease in part by increasing total triglycerides, which may make the ratio of HDL to total cholesterol less favorable (Bray, 1996).

Type 2 Diabetes

Type 2 diabetes is characterized by peripheral insulin resistance, impaired regulation of hepatic glucose production, and low Beta cell function. Excessive weight increases the risk of Type 2 diabetes through insulin resistance (Mahler & Adler, 1999). After adjusting for weight, weight gain has been observed to be strongly associated with the risk of developing type 2 diabetes (Colditz, Willett, Rotnisky & Manson, 1995).

Hypertension

High blood pressure is defined a mean systolic blood pressure ≥140 mm Hg, or mean diastolic blood pressure ≥ 90 m Hg or currently taking anti-hypertensive medication. The prevalence of high blood pressure in adults with BMI ≥ 30 is 38.4 percent for men and 32.2 percent for women. The pathophysiology underlying the development of hypertension associated with obesity includes sodium retention and associated increases in vascular resistance, blood volume, and cardiac output. The precise mechanism whereby weight loss results in a decrease in blood pressure is unknown. However, it is known that weight loss is associated with a reduction in

vascular resistance, total blood volume, cardiac output, and a reduction in sympathetic nervous system activity (NHLBI, 1998, 12).

Both weight and weight gain are positively associated with the development of hypertension (Field, Byers, Hunter, Laird, Manson, Williamson & Willett, 1999; Yong, Kuller, Rutan, & Bunker, 1993). Blood pressure is very sensitive to weight change as a maintained weight loss of 10 – 15% can result in sustained lowering of blood pressure, as well as improving other CHD risk factors (Wing & Jeffrey, 1995). Weight loss is recommended to patients with mildly elevated blood pressure or risk factors for developing CHD. One study observed that among 82,473 women in the Nurse's Health Study, those who lost at least 10 kilograms (kg) and were able to maintain the loss for at least two years were 45% less likely to develop hypertension (RR = 0.6, 95% CI = 0.4 ± 0.7) than their peers who were weight-stable (Huang et al., 1998)

Cancers

Excessive weight is associated with the development of numerous cancers, including breast, endometrial, gastric, and colon. Obesity is thought to increase risk of developing cancer primarily through its effect on hormones (Wadden et al., 2002).

Mental Health and Quality of Life

There are social consequences of being overweight in a Westernized society that values thinness and a fit appearance. In a survey conducted on approximately 1,000 adults in a weight gain prevention program, 22% of the women and 17% of the men reported that they had been mistreated because of their weight (Falkner, French, Jeffery, Neumark-Sztainer, Sherwood & Morton, 1999). The prevalence of mistreatment increased across quartiles of BMI, from 5.7% among the leanest quartile to 42.5% among the heaviest participants.

Obesity may also have an impact on other aspects in terms of quality of life. Two studies that used a 36-Item Short-Form Health Survey for Medical Outcomes observed that there was a linear association between increasing BMI and decreases in physical functioning and vitality (Coakley et al., 1998; Fine et al., 1999). Women who

gained more than 20 pounds over 4 years of the study follow-up had significant decreases in physical functioning, whereas weight losses were associated with increases in functioning and vitality.

Economic Costs

Current Estimates

Treating obesity and obesity-related conditions costs billions of dollars a year. By one estimate, the U.S. spent $190 billion on obesity-related health care expenses in 2005 (Cawley & Meyerhoefer, 2012).

Two types of costs are associated with the treatment of obesity and obesity-related conditions:

1. Direct costs are those that result from outpatient and inpatient health services (including surgery), laboratory and radiological tests, and drug therapy.
2. Indirect costs are those that "resources forgone as a result of a health condition", which may include value of lost work, insurance, and wages (USDA Economic Research Service, 2012).

Given that indirect costs are harder to identify and measure than direct costs, more estimates of direct costs have been retrieved. One from the U.S. MEPS found that obesity was responsible for 10 percent of medical costs or nearly $86 billion a year (Finkelstein, Trogdon, Cohen, & Dietz, 2009). Furthermore, Finkelstein and colleagues estimate from the U.S. National Health Expenditure Accounts dataset that in 2006, per capita medical spending for obese individuals was an additional $1,429 or 42% higher than for individuals who were not obese (Finkelstein et al., 2012). Overall, the direct costs of inactivity and obesity are estimated to consume 9.4% of national health care expenditures in the United States (Voelker, 2012).

Future Projections

By 2030, treatment costs for preventable obesity-related diseases are expected to add between $48 billion and $66 billion to current costs that are estimated between

$147 billion and $210 billion. By 2030, total health-care costs attributable to obesity would double every decade to 860 to 956 billion US dollars, accounting for 16 to 18 % of total US health-care costs (Wang et al., 2008). Economic productivity losses would be estimated to be between $390 billion to $580 billion as well (Voelker, 2012). However, it a noteworthy estimate by Voelker (2012) suggested that a 5% population-wide decrease in BMI could help prevent thousands of obesity-related disease cases in many states as well as billions of dollars in health care expenditures (Voelker, 2012). This estimate is encouraging given the anticipation of population-wide public health dissemination efforts of interventions for preventing and treating obesity.

Goals of Weight Loss and Management in Treating Obesity

Goals of Weight Loss Therapy

1) To prevent further weight gain
2) To reduce body weight by 5-10% of initial weight
3) To maintain a lower body weight over the long term.

Reasonable Time Line

For obese patients, deficits up to 500 – 1,000 kilocalories per day will lead to a weight loss of about half a pound to two pounds per week and a 10 % weight loss in 6 months. After six months, the rate of weight loss usually is known to decline and weight plateaus because of a lesser energy expenditure at the lower weight.

For overweight patients with BMI in the range of 27 to 35 kg/m², a decrease of 300 – 500 kilocalories per day will result in weight losses of about ½ lb to 1 lbs and a 10 percent weight loss in 6 months. For more severely obese patients with BMIs greater than 35 kg/m², deficits of up to 500 to 1,000 kilocalories per day will lead to weight losses of about 1 - 2 lbs per week and a 10% weight loss in six months.

Evidence suggests that lost weight usually will be regained unless a weight maintenance program consists of dietary therapy, physical activity, and behavior therapy is continued indefinitely.

Impact on Other Health Indicators

Blood Pressure

A 1987 meta-analysis covering five acceptable studies by the National Heart, Lung, and Blood Institute's (NHLBI) Obesity Education Initiative found in hypertensive patients concluded that weight loss accomplished by dietary interventions significantly lowered blood pressure (Haynes et al., 1984; Heyden et al., 1985; MacMahon et al., 1985; Ramsay et al., 1978; Reisin. et al. 1978). Among hypertensive patients, a 10 kg (22 lbs) weight loss was associated with an average reduction of 7 mm Hg systolic and 3 mm Hg diastolic blood pressure compared with controls (MacMahon, et al., 1987). Weight loss produced by lifestyle modification reduces blood pressure in overweight hypertensive and non-hypertensive individuals.

Abdominal Fat

Abdominal fat is described as having three compartments: visceral, retroperitoneal, and subcutaneous. Several studies suggest that the visceral fat component of abdominal fat is the most strongly correlated with cardiovascular risk factors (Bjorntorp, 1988; Fujioka,, Matsuzawa, Tokunaga & Tarui, 1987; Despres, Moorjani, & Ferland, 1989; Pouliot, Depres, & Nadeau, 1989). The presence of increased abdominal fat overall appears to be an independent risk factor predictor when BMI is not increased.

Six randomized controlled trials deemed acceptable by the NHLBI Obesity Education Initiative on weight loss that measured waist circumference all show that weight loss is associated with reductions in waist circumference. One of those observational studies examines changes in visceral fat showed significant decreases in visceral fat with an average weight loss of 12.9 kg (28 lbs). (Leenen, Seidell, Droop, Bakker, & van der Kooy, 1993).

Dual-Energy X-ray Absorptiometry (DXA) has been used extensively to study bone demineralization and osteoporosis. It also represents an advance in body fat assessment because of use in clinical settings and accuracy and precision for differentiation of lean and fat tissues (Cornier et al, 2011). DXA defines a technology

by which the attenuation of radiation at two energies is used to determine two components of both bone and soft tissue or fat and lean soft tissue. Assessment of body fat of DXA requires very little radiation which makes it easy and appropriate for repeated measures in a clinical setting.

A high waist circumference is also associated with excessive levels of abdominal fat tissue and high risk for type II diabetes, high blood pressure, and heart disease, a concerted effort was made to use this indicator to evaluate progress in treating obesity.

Current Weight Loss Therapies for Treating Obesity

Dietary Therapy

Success with weight loss requires a sustained negative energy balance: energy output must exceed energy intake. In particular, the National Weight Control Registry (NWCR) and the Mayo Clinic College of Medicine recommend achieving long-term weight loss by a combination of reducing total fat intake to no more than 30% of dietary composition, reducing portion size, reducing energy density, along with increasing physical activity (Thompson, 2007).

Besides decreasing total fats to less than 30%, saturated and trans fats should also be reduced to less than 10% of the diet to enhance lowering of LDL cholesterol levels. However, reducing the percentage of dietary fat alone will not produce weight loss unless total calories are also reduced. It is suggested by the NHLBI Obesity Education Initiative that reducing dietary fat, along with reducing dietary carbohydrates, usually will be needed for an acceptable weight loss for obesity.

Low-calorie diets (LCD) can reduce total body weight by an average of 8% over 3 -12 months (NHLBI, 1998, p. 42). Four randomized controlled trials testing the effects of LCDs alone on weight loss also had measures of abdominal fat, as measured by waist circumference and showed that with a weight loss as little as 0.3 BMI unit to as much as 11 kg (24 lbs) body weight can result in a concomitant reduction in waist circumference of 1.5 - 9.5 centimeters compared to controls (NHLBI, 1998, p. 42).

Pharmacotherapy

In carefully selected patients, appropriate drugs can augment low-calorie diets, physical activity, and behavior therapy in weight loss for obesity. Weight loss drugs that have been approved by the FDA for long-term use can be useful adjuncts to dietary therapy and physical activity for patients with a BMI greater than 30 kg/m² with no concomitant risk factors or diseases.

Combined Therapy

Although the evidence in the field of weight loss interventions is favorable of reduced caloric intake via diet compared to increase caloric expenditure for precipitating initial weight loss, there is evidence to suggest physical activity can be effective when combined with dietary adjustments. A combined intervention of behavior therapy of low-calorie diet and increased physical activity provides the most successful therapy for weight loss and weight maintenance.

A study conducted on obese non-insulin dependent diabetes mellitus (NIDDM) patients at a research center in Nagoya University in Nagoya, Japan evaluated the effects of a walking program with the goal of completing 10,000 steps per day combined with a diet therapy on insulin sensitivity and weight loss. A comparison of a diet along group and a diet plus exercise group found that while body weight in both groups decreased significantly after eight weeks, the amount of body weight reduction in the diet and exercise combined group was greater than that in the diet alone group (7.8 ± 0.8 kg vs 4.2 ± 0.5 kg, $p < 0.01$, Yamanouchi et al., 1995).

Physical Activity in Treating Obesity

Evidence

An increase in physical activity is an important component of weight loss therapy. However, research suggests that it will not lead to substantially greater weight loss over six-months. Most weight loss occurs because of decreased caloric intake. Sustained physical activity is most helpful in the prevention of weight regain and has

the added benefit of reducing cardiovascular and diabetes risks beyond that produced by weight loss alone (Thompson, 2007).

The current body of literature on weight loss interventions has concluded that physical activity alone produces only modest weight loss. A meta-analysis of weight loss studies found that 21-week aerobic exercise programs produce weight loss of 2.9 kg, compared with a loss of 11 kg from 15-week programs of caloric restriction (Miller, Koceja, & Hamilton, 1997). According to the NHLBI Obesity Education Initiative, efforts to achieve weight loss through physical activity alone generally produce an average of a 2 to 3 percent decrease in body weight or BMI (NHLBI, 1998, p.77).

It is very difficult for people to lose a substantial amount of weight or even lose weight quickly by exercise alone. A general metabolic guideline is that a pound of body fat yields about 3,500 kilocalories when oxidized. Given that a 75 kg person burns approximately 100 kilocalories by walking 1 mile, the average human subject would have to walk about 35 miles to expend the energy contained in 1 lbs of fat (Wadden & Stunkard, 2002). This may seem like a formidable challenge for individuals who are primarily looking to lose 10% initial body weight by six months.

One randomized controlled trial compared the effect of a 700 kilocalorie per day energy deficit on three-month weight loss when produced through a reduction in energy intake versus an increase in energy expenditure through physical activity (Ross, Dagnone, Jones, Smith, Paddags, Hudson & Janssen, 2000). The investigators of the study reported comparable weight losses of 7.6 kg in both groups, providing some evidence that exercise can be as effective as changes in diet for producing weight loss. An individual would need to engage in 116 minutes or close to two hours per day of brisk walking to expend 700 kilocalories per day in physical activity to produce this magnitude of weight loss (Ross, R. Dagnone, D., Jones, P., Smith, H., Paddags, A., Hudson, R., & Janssen, I., 2000). However, it can be said that most of the studies produced observed obese individuals who were unlikely to engage in sufficient levels of physical activity to produce the magnitude of weight loss typically observed with reductions in energy intake.

With particular attention to the recommended levels of activity of 10,000 daily steps for the intervention of this study, it has been widely promoted that such a prescription can result in adequate weight loss. One particular study showed that adherers to averaging more than 9500 steps per day for up to 36 weeks demonstrated modest and significant improvements in body weight (2.6 kg), waist circumference (-1.8 cm), and hip circumference (-1.9 cm) (Schneider, Bassett, Thompson, Nicolaas and Bielak, 2006). One drawback however, was that the study failed to produce an adherence rate of only one third of the original participants.

Several of these studies, as highlighted by the Roundtable Consensus Statement by the American College of Sports Medicine (ACSM), were relatively small and observed modest weight changes. Evaluated in 1999, the Expert Panel on Clinical Guidelines for the Treatment of Obesity identified 13 randomized trials that consistently showed benefits of exercise for weight loss as modest, which may have resulted from small sample sizes, short study durations, and poor adherence to the exercise prescription (Wing, 1999).

Recommendations

There is a growing body of scientific literature suggesting that at least 60 - 90 minutes a day of moderate-intensity physical activity may be necessary to maximize weight loss and also prevent significant weight regain. Physical activity may also have an independent effect on health-related outcomes when compared with body weight (Jakicic, 2005).

A sedentary and unfit way of life increases risk of several chronic diseases, premature mortality, loss of physical function, and depressed mood (U.S. Department of Health and Human Services, 1996). Therefore various recommendations made by the Centers for Disease Control (CDC), American Heart Association (AHA), and National Institutes of Health (NIH) Consensus Development Panel on Physical Activity and Cardiovascular Health in 1996, suggest that all sedentary adults accumulate at least 30 minutes of at least moderate-intensity physical activity over the course of most, preferably all, days of the week or 75 minutes per week of vigorous intensity activity.

Moderate intensity is defined as moderate to brisk walking as in walking two miles in 30 – 40 minutes or walking at a pace of 15 – 20 minutes per mile. Vigorous activity is defined as running at a pace of 10 minutes per mile or 6 mph in which there is rapid breathing and a substantial increase in heart rate. As with success in weight loss, activity does not have to be done at a high intensity or done in one occasion to meet physical activity guidelines for preventing major risk factors of chronic diseases.

There is evidence that physical activity does not completely alleviate the negative health outcomes associated with obesity. It has been shown that both physical activity and a smaller waist circumference are both associated with classification of enhanced metabolic health in obese individuals. This suggests that it is important to intervene on both physical inactivity and excess body weight to have the greatest improvements in health outcomes.

Behavior Therapy in Treating Obesity

Evidence

Behavior therapies provide methods for overcoming barriers to compliance with dietary therapy and/or increased physical activity making it an important component of weight loss therapy. Behavioral strategies to reinforce changes in diet and physical activity can produce a weight loss in obese adults in the range of 10% of baseline weight over 4 months to 1 year. The acquisition of new habits is more important for long-term weight maintenance at a lower weight.

Recommendations

The primary assumptions of behavior therapy are that:

1) By changing eating and physical activity habits, it is possible to change body weight
2) Patterns of eating and physical activity are learned behaviors and can be modified
3) To change these patterns over the long term, the environment must be changed.

Strategies for Physical Activity Behavior Facilitation

Physical Activity Counseling through Physician Care

Physicians and medical professionals have been identified as important sources of information support for people who hope to become more physical active. A survey conducted on 2,300 Australians suggested that those who were inactive were asked to choose their preferred source of advice on how to become more physically active. Advice from a doctor or license health professional was preferred over all other listed sources including books, videotapes, and exercise groups (Lox, 2010). Another population study of Canadians indicated that nearly a quarter of those surveyed looked to health professionals for advice on how to become physically active (Canadian Fitness, 2007, p.12).

Project PACE (Patient-Centered Assessment and Counseling for Exercise) looked and examined the impact of physician recommendations and brief physical activity counseling delivered to sedentary adults. At follow-up of six weeks, patients who received PACE counseling increased their minutes of weekly walking by 38.1 compared with 7.5 minutes among controls. Additionally, 52 percent of the patients who received PAC counseling adopted "some" physical activity compared with just 12 percent of the control group.

In the United States, a survey found that nearly two-thirds of patients would be interested in exercising to stay healthy if they were advised by their doctor to do so (American College of Sports Medicine [ACSM], 2007, p.12). Organizations such as the ACSM have started to create resources such as information flyers, exercise prescription and referral forms, and websites to make it easier for physicians to counsel their patients to become more physically active (ACSM, 2007, p.12). However, activity counseling still occurs during less than half of all patient visits and physical activity prescriptions and exercise program referrals are issued by only a small minority of primary care physicians.

Even among physicians who do prescribe exercise few spend more than five minutes on physical activity counseling (Rogers, Bailey, Gutin, et al., 2002). Given the complexity of prescribing exercise and the many questions that patients may have regarding the prescriptions, five minutes is certainly not enough time to provide adequate information.

To circumvent these barriers to exercise prescription, some physicians have been known to form partnerships with local health clubs so that they can prescribe exercise to their patients and then refer those patients to a fitness consultant at the health club for further exercise information. Given that these consultants may have the training and dedicated time to talk with patients about exercise, they could probably provide more information and effective physical activity counseling than physicians (Tulloch, Fortier, & Hogg, 2006).

Pedometer-based Monitoring

There are various studies that have promoted pedometer-based walking programming as an effective way to help people to increase physical activity for weight loss. According to meta-analysis regression results from one study, an average participant adhering to a pedometer-based walking program can expect physical activity levels to increase and to lose about 0.05 kg of weight per week (Richardson et al, 2008). Over one year, participants can expect to lose about 2.5 kg or 5 lbs which may represent a rate of weight loss of 2% to 3% of initial body weight. Since these are modest amounts of weight loss, it is also important for participants initiating such programs to set realistic and obtainable goals for success with sticking to the walking programs.

There are widespread pedometer-based interventions that promote the achievement of 10,000 steps per day to meet physical activity guidelines for weight loss and weight maintenance success. Walking 10,000 steps per day works out to roughly five miles. Assuming that the average walker is to complete a moderate level of activity at a rate of 15 - 20 minutes per mile, then the associated duration of activity with 10,000 steps equates to 75 - 100 minutes per day. It can be said that achieving 10,000 steps per day meets the physical activity standard for weight loss and weight loss maintenance (Miyatake, Nishidawa, Morishita, 2002; Chan, Ryan & Tudor-Locke, 2004).

A study designed to examine the effects of a 10,000 steps per day exercise prescription on sedentary, overweight/obese adults and of adherence to body composition found that the adherers saw significant improvements in walking volume (3994 steps per day), body weight (-2.4 kg) and percentage body fat (-1.9%) over 36

weeks (Schneider, Bassett, Dixie, Pronk, & Kenneth, 2006). This study, along with several others (Chan et al., 2004; Moreau et al., 2001; Miyatake et al., 2002), showed that pedometers were used to motivate participants, while measuring daily accumulated walking before and during the interventions. They also showed that walking improvements as a result of adherence to pedometer tracking impacts and is a function of the magnitude of weight loss observed among obese/overweight participants.

Telephonic Physical Activity Interventions

Several interventions have included regular telephone calls from an exercise counselor or interventionist as the primary strategy for increasing and maintaining physical activity levels. The general idea behind these types of lifestyle interventions is that regular phone calls may provide the participant looking to increase and physical activity recommendations with a source of informational and emotional support. Recently, there has been strong evidence in favor of telephone-delivered physical activity and dietary change interventions as suggested from findings from an updated review (Goode, Reeves, & Eakin, 2012). Overall, 20 out of 27 study comparisons from the review reported improvements at end-of-intervention for at least 50% of physical activity and/or dietary behavior outcomes. In fact, the evidence seemed so strong for Goode and colleagues that they supported the contention that randomized controlled trial designs are no longer needed and a concerted focus should be on research that may assist integration of telephone-delivered health behavior change interventions within healthcare and also population health delivery systems.

Lombard and colleagues summarized that the content of the phone calls is not as important as the frequency of the calls (Lombard et al, 1995). Their study showed that people who receive weekly phone calls were far more likely to walk regularly than people who received a call every three weeks, even if the purpose of the call was simple to "touch base" and provided no information, advice, or tips.

Despite the strong evidence for telephonic based physical activity interventions, it is imperative to seek whether it translates to weight loss trials as well, particularly among obese participants. Of three highlighted studies that focused on telephone-based

interventions on weight loss ranging from 17 weeks to six months, two of them gave evidence of significant moderate weight loss and body fat reduction (Sherwood et al., 2010; Tucker et al., 2008). Tucker and colleagues even managed to achieve a high compliance rate of 94% and records were also kept of each telephonic coaching session.

Transtheoretical Model for Behavior Change

Background

The Transtheoretical model (TTM) was originally developed at the University of Rhode Island Cancer Prevention Research Center in studying and observing how people quit smoking (Prochaska & Velicer, 1997). TTM integrates various theories and models of behavior, suggesting behavior change as a gradual process whereby individuals progress through a series of changes.

The TTM can be useful for guiding physical activity interventions. When a stage of change is determined, then the appropriate strategies can be applied that are most likely to help in progressing to the next stage. TTM consists of five stages of behavior change that people typically move through, although not always in a linear fashion:

Precontemplation

People have no intention to start exercising in the foreseeable future. People consider the disadvantages of exercising to be greater than the advantages. People tend to stay here very long without an intervention.

Contemplation

People have intentions to start exercising within the next six months. People at this stage are aware of the advantages of exercise, know exercise is good for them, and may feel they should be exercising, but are not ready to make a commitment to change. Unless there is a form of intervention, they remain in this stage for long periods of time.

Preparation

People intend to start exercising in the immediate future and consider the advantages of physical activity to be greater than the disadvantages. During this stage, people will be performing tasks that will prepare them to start an exercise program,

such as getting medical clearance, obtaining information about local exercise facilities and programs, or buying exercise equipment.

Action

People are exercising at recommended levels for health and fitness (usually defined as exercise on most days of the week at a moderate level for at least 30 minutes duration). Individuals in the action stage must work hard to avoid falling back into their old sedentary lifestyle.

Maintenance

People have been exercising at recommended levels for six months. Maintainers must still work to prevent lapsing into a sedentary lifestyle, but they don't find exercise as difficult to maintain as they did during the action stage.

Successful movement through the stages of change involves changing how people think about exercise, about themselves, and aspects of environment that influence exercise behavior. We can determine whether people are moving through the stages by looking at their decisional balance, self-efficacy towards physical activity, and changes in self-reported physical activity levels.

Evidence

Although attention to the TTM SOC framework has emerged in recent years in designing lifestyle modification with respect to physical activity, as well as tobacco cessation and alcohol dependence, a majority of studies have indicated lack of conclusive evidence for sustainable weight loss. A meta-analysis was conducted by a team of researchers assessing the effectiveness of dietary and physical activity interventions based on the Transtheoretical model to produce sustainable weight loss in overweight and obese adults. The trials under study lasted from six weeks to twenty-four months with a total of 3910 participants evaluated finding no conclusive evidence for weight loss, along with other outcome measures of health (Tuah, Amiel, Qureshi, Car, Kaur & Majeed, A., 2011).

Another study conducted within the primary care setting concluded that a telephonic and print contact based program based on the TTM SOC and some elements

of chronic disease care were not powerful enough to alter targeted behaviors among overweight primary care patients in an obesogenic environment compared to usual care (Logue et al, 2005).

One major limitation of the TTM SOC construct is that it may be useful for describing differences between people in different stages, but fail to reveal the mechanisms by which people change their activity behavior and progress across the stages. Another limiting factor to using the TTM SOC is that most people do not exhibit a stable progression through the stages. Many may skip stages or regress backward in a mixed order. Human functioning may also be considered too complex to be categorized into just a few distinct stages, but the premise is that it can still be useful to help people adopt a more physically active lifestyle.

Although the impact of the TTM SOC framework has yet to show significant and conclusive evidence for the effect on physical activity behaviors and weight loss success rates, it has been used in prominent physical activity interventions, particularly that of the ALED program, and may still be useful to allow participants to use as a guideline by which individual progress can be easily identified and understood.

Active Living Every Day (ALED)

Evidence

An intervention called Project Active directed by Dunn and colleagues compared the 24-month intervention effects of a lifestyle physical activity program with traditional structured exercise on improving physical activity, cardio-respiratory fitness, and cardiovascular disease risk factors (Dunn, Marcus, Kampert, Garcia, Kohl & Blair, 1999). The study recruited 235 men and women who were originally doing little to no exercise. Half of the population was committed to participating in a standard gym workout three to five times a week. The other half was part of the lifestyle group meeting in small groups and talking about ways to incorporate physical activity into their everyday lives. The results indicated that a lifestyle physical activity intervention is as effective as a structured exercise program in improving physical activity, cardio-respiratory fitness, and blood pressure. The same study however, failed to observe a

significant change in weight or difference in percentage of body fat reduction (Wilcox, Dowda, Leviton, Bartlett-Prescott & Bazzare., 2008).

A more recent internet-delivered version of the ALED directed by Carr and colleagues was also shown to increase physical activity levels by an average of 1384 steps per day ($p = 0.03$) compared to 8160 steps per day ($p = 0.14$) for the control group. Waist circumference (100.6 +-2.4 vs 96.6 +-2.7cm) and Coronary Risk Ratio (5.1 +-0.3 vs. 4.7 +- 0.3) decreased for the ALED internet group but not the control group.

Active for Life (AFL) was a study run by Wilcox and colleagues to measure increases in moderate to vigorous-intensity physical activity, total physical activity, and decreases in BMI between the Active Choices and ALED program after 4 years. With both interventions being ground in the Transtheoretical model and social cognitive theory, they were feasible for implementing in a variety of real-world settings and produced significant increases in physical activity among participants.

Programming

The telephonic coaching program based on Active Living Every Day (ALED) is one that encompasses the advanced aspects of a successful behavioral therapy program (Blair, Dunn, Marcus, Carpenter, & Jaret, 2011). ALED is designed to teach people the cognitive and behavioral skills necessary to become and stay physically active. It was originally developed by the Cooper Institute, Brown University, and Human Kinetics as a textbook that transformed research materials from Project Active into a guide for helping people to increase their physical activity. It was originally a 20 lesson course and most recently compacted into a 12 lesson course. Participants would meet once a week structured around the ALED textbook to discuss ways to identify and overcome barriers to physical activity. Participants would also receive the ALED textbook and a pedometer to be used outside of class to monitor the number of steps they take and motivate themselves to be more active. Each chapter also contains several assignments and worksheets to be completed by participants in the program as well.

Conclusion

The rising prevalence of obesity poses a grave threat to the health and economic condition of the United States. This is of concern because of the association with decreased life expectancy and numerous chronic conditions, which include cardiovascular disease, diabetes, hypertension, asthma, cancer, mental health, and lower quality of living. Furthermore, the burden of rising medical costs is also associated with obesity in the United States.

The primary goals for treating obesity are to prevent further weight gain, to reduce body weight initially by 5- 10 % from baseline to six months, and to maintain a lower body weight over the long-term. Strategies such as improved dietary habits restricting energy-dense intake and fat composition, pharmacological weight loss drugs, behavioral therapy, physical activity, or combination of these may reduce weight and other important health indicators such as excess abdominal fat tissue and above normal blood pressure associated with obesity. Recent literature suggests that at least 60 - 90 minutes a day of moderate-intensity physical activity may be necessary to achieve clinical weight loss and also prevent significant weight regain, assuming the inclusion of a caloric restricted diet. The achievement of 10,000 moderate equivalent steps per day is estimated to consume the same amount of daily time of required physical activity to achieve similar weight management goals as described by the relevant literature (Schneider et al., 2006).

Physicians and other health professionals have been identified as important sources of information to support those who hope to become more physically active. Facilitation of behavior change for physical activity to support weight loss, body fat reduction, and cardiorespiratory health may be further induced by telephonic coaching and pedometer step tracking from a health and fitness professional. Although there is minimal evidence in favor of the TTM SOC for increasing physical activity levels, it still serves as a useful framework for participants to recognize and understand processes of change for reaching their goals. Most of the pedometer-based tracking strategies, TTM SOC, and behavior change concepts are included in the Active Living Every Day

program that serves as the basis for the telephonic coaching intervention for physical activity for this study.

CHAPTER 3
METHODOLOGY

Study Design

The study applied a randomized controlled design, involving randomization of participants into the telephonic health coaching or the control group. The intervention lasted 24 weeks or six months. At baseline, all participants were enrolled and initiated clinical visits and appointments with the medical care team of Minnesota Center for Obesity Metabolism and Endocrinology (MNCOME). The intervention group was assigned to receive telephonic health coaching support from graduate student Mike Zambrana, along with a pedometer to be worn for the duration of the study trial. The telephonic coaching group participants were instructed to wear the pedometer each day during all waking hours and to schedule a preferred time for receiving on-going weekly coaching call. All participants provided written consent to participate in the study.

Population and Sample Source

The target population consisted of individuals who initiated participation with MNCOME for a new service year and matched the obesity category of either a BMI of 30 or greater kilograms per meter squared or at high risk waist circumference of over 40 inches for men and over 35 inches for women.. Led by Dr. Michael Gonzalez-Campoy and colleagues, MNCOME is a specialty clinic that offers medical care, patient education, and clinical research for weight management in treating obesity and for treating diabetes. MNCOME staff is composed of four health care providers (all of whom are certified endocrinologists), five certified diabetes educators, and five administrators. Each patient visit consists of a 20 minute office visit and up to one hour of education appointments on nutritional habits, brief physical activity overview, lab tests, and pharmacological review.

Inclusion criteria

New participants to MNCOME were targeted for recruitment, although participants with previous history of clinical visits were also encouraged to participate in the study. Each participant giving consent had to have either a BMI greater than or equal to 30 kg/m^2 or a man with waist measurement over 40 in. and women with waist measurement over 35 in. Participants must have been between ages 18 to 64 years old at the time of initiation into the study.

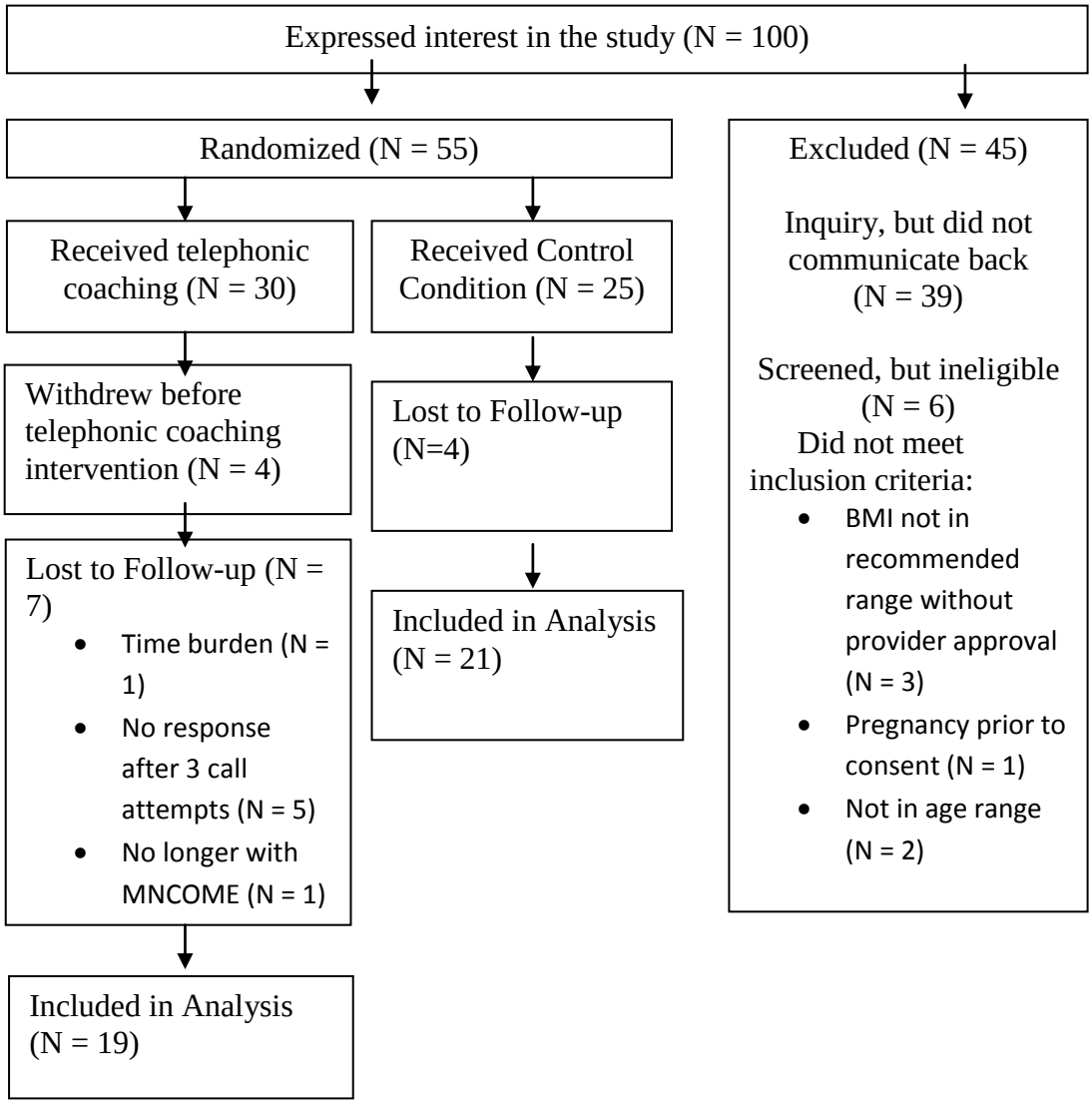
Exclusion criteria

Potential recruits who were younger than 18 or older than 64 years of age were excluded. Self-reported pregnancy prior to giving consent was also considered a criterion for exclusion.

Recruitment

Outreach calls and face-to-face advertisement towards the end of initial consultation appointments at MNCOME were made by the principle investigator for recruitment efforts. Recruitment call efforts terminated after three attempts for outreach calls and after two attempts following the face-to-face advertisement for each potential participant. A total of 100 potential recruits were contacted either by call outreaches or face-to-face advertisement with follow-up call outreaches throughout the recruitment effort of the study. The recruitment process lasted from March 2012 until October 2012. A total of 55 participants who initiated and gave consent to participate in the study were randomized to be included to either receive the telephonic coaching program or remain in usual care and service provided by MNCOME.

Figure 1: Flow of Participants



Effect Size and Power Analysis

Calculation of effect size and power was calculated post-intervention based on a convenience sample size of N = 40 participants. According to a recent meta-analysis on telephone-delivered interventions for physical activity behavior change and weight loss, an effect size of Cohen's d greater than 0.5 was to be anticipated, indicating a moderate or better intervention effect among 33 out of 51 trials conducted (Goode, Reeves, Eakin,, 2012).

Power was calculated by utilizing PS Power and Sample Size Calculations Copyright © 1997 – 2009 by William D. Dupont and Walton D. Plummer. Based on a final tally of 39 pair of data subject to analysis for weight change over six months, a mean difference of 0.7 lbs in the weight response of matched pairs with standard deviation of 15.82 lbs resulted in a Type 1 error probability for two sided test of $\alpha = 0.89$ and power β probability of 0.89 of detecting a true difference. The resulting Cohen's *d* and effect-size correlation *r* for between-group differences for the telephonic coaching and control groups were very minimal values of 0.04 and 0.02 respectively in comparison to the anticipated effect size of $r = 0.5$ for a weight-loss intervention.

However, when effect size calculations were made for within-group differences of both groups (N = 40) for weight loss over six-months, a resulting power β probability of 0.96, Type 1 error of $\alpha < 0.01$, and effect size of $r = 0.57$ and Cohen's $d = 1.4$ was found.

Procedures for Sample Randomization

Randomization for the study was operated by the use of the randomization form from Research Randomizer (version 3.0) by Urbaniak and Plous retrieved from http://www.randomizer.org. The site is designed for researchers and students to generate random numbers or assign participants to experimental conditions. It uses a JavaScript number generator to produce customized sets of random numbers.

In order to prevent an imbalance in the assignment to either the telephonic coaching or control group, a block design was implemented during randomization. Through the use of the Research Randomizer, the principle investigator generated a total of 60 random assignments, anticipating that participants would drop out from either the telephonic coaching and control group. Randomization was done by generating 30 sets, with 2 unique numbers per set of either a value of 0 or 1. The order by which participants established consent to participate in the trial as communicated by the staff at MNOME or by the principal investigator was translated into the order by which they were selected into the randomized assignment generated by Research Randomizer.

Figure 2: Research Randomizer Template

Participants were either called after an initial consultation with a MNCOME health care provider or were met face to face with either the principle investigator Mike Zambrana or secondary investigator Dr. Michael Gonzalez-Campoy upon initial visit.

Primary Variables and Instrumentation

All primary and secondary variables were conducted and measured by the nursing and lab staff members of MNCOME who were unaware of the treatment allocation with respect to this trial. The primary investigator was not involved in conducting the baseline and follow-up measures. All of the following variables were evaluated based on a single-blinded research method.

Weight Loss and Change in Body Mass Index

Weight was measure in pounds using the weight scale provided by MNCOME (Kennedy Scales, Inc. SN # 5662). In cases when participants did not come in for a

weigh-in, self report over the phone was used to determine changes in body weight. BMI was calculated afterwards relying on height measured in inches.

Changes in Abdominal Fat

Dual-Energy X-ray Absorptiometry (DXA)

Recent studies support the plausibility of estimating abdominal fat using the conventional whole body dual-energy x-ray absorptiometry (DXA) (Wells, J, and Fewtrell, M, 2006). DXA has some advantages over CT and MRI as a means of estimating fat distribution, including relative ease of access to systems, simplicity of measurements, relatively low cost, and minimal radiation exposure compared to CT (Park et al., 2002). DXA may be useful for tracking changes in abdominal fat during weight loss.

By using the DXA in the study, it is possible to quantify the size of the various body tissue depots, particularly estimate changes in abdominal fat mass (g), lean mass (g), Trunk/Limb Fat Mass ratio and index, estimated visceral adipose tissue (cm^2), and total body and truncal fat (%) induced by interventions such as caloric restriction and exercise. A value less than 100 is considered to be a normal result for estimated visceral adipose tissue according to MNCOME staff.

Total body composition results were measured with a whole-body DXA scanner provided by MNCOME (Hologic APEX Software Version 4.0 Model: Discovery Wi. SN# 82455). Participants were responsible for scheduling and arriving to the appointment to have their DXA analysis done sharing no cost with MNCOME. The only exclusion that prevented a participant from having body composition measured via DXA was a state of pregnancy prior to the test.

Waist Circumference

Waist circumference was measured by a standard tape measure using inches as the unit of measure. The tape measure was applied to the top of the hip bone and brought all the way around. A high risk waist circumference is a man with waist measurement over 40 inches and women with waist measurement over 35 inches.

Secondary Variables

Blood Pressure

Blood pressure was measured by a conventional method of utilizing a Stethoscope and Sphygmomanometer and placing around the upper arm. High blood pressure is defined as means systolic blood pressure ≥ 140 mm Hg or mean diastolic blood pressure ≥ 90 mm Hg. Obesity and hypertension are co-morbid risk factors for the development of cardiovascular disease.

Ethical Considerations

Prior to initiating any contact with potential participants from MNCOME, approval to conduct human research was obtained from the University of Minnesota Institutional Review Board. I also completed human subject research training via the Collaborative Institutional Training Initiative and Health Insurance Portability and Accountability Act (HIPPA) Training through the University of Minnesota.

During the initial presentation of the potential participation for my study either face-to-face or over the phone, I described the following to each participant: the study purpose, voluntary nature of the study, confidentiality protection, benefits and risks associated with being more physically active beyond a state of rest, the format of the telephonic coaching program, and where to address questions and/or complaints. Each participant was allowed up to one week to review the written Informed Consent (Appendix B) and encouraged to contact me with questions. Participants were recruited into the study once they signed and dated the Informed Consent document.

Confidentiality for Recording of Telephonic Coaching Calls

Confidentiality of participant identity as it relates to the recording of the telephonic coaching calls was stated at the beginning of each recorded coaching call. The following statement was made:

"Our call will be recorded for the purposes of this research study. At all times your specific identity will not be known. And we can terminate the call at any point if you prefer that we do so"

Procedures for Intervention Programming and Data Collection

MNCOME Standard of Medical Care

Adherence to the weight management service of MNCOME by all participants of the study first included an initial appointment by a team comprised of medical professionals who treat and acknowledge weight as an endocrine disease. Through quarterly follow-up appointments, the endocrinologists, dieticians, and educators of MNCOME all helped guide and encouraged participants to make realistic choices for a healthier lifestyle to reach weight loss goals. Anthropometric and metabolic health evaluations and assessments were conducted, along with addressing lifestyle modification in the pursuit of weight loss through dietary, pharmacological, and physical activity therapies. The goal established by MNCOME for each participant was to help stop any further weight gain, and continue to work on losing 5-10% of initial weight as recommended.

Active Living Every Day Programming

After each MNCOME treatment participant was informed of their assignment through a phone call and randomized into the treatment group, they were then each delivered worksheets adapted from the Active Living Every Day program. All twelve chapters of the Active Living Every Day guidebook were covered by the coach with relevant topics addressed and discussed with participants. Each chapter was covered every other week to match the duration of the treatment intervention of 24 weeks. Weekly coaching calls were made from week 1 until week 11 with the intent of also checking progress made with daily step counts from the use of the pedometer. Bi-weekly calls were made at week 12 and thereafter until the end of the program with the acknowledgement that progress would be made by participants in being held accountable to keep track of daily step counts.

Control participants were informed by a telephone call by the principal investigator that their control status was based on randomization. They were also instructed to continue active participation with MNCOME and to have their weight,

blood pressure, and DXA analysis complete upon entry into the study and at the end of the six month study period.

Daily Step Tracking and Goals

Participants were given a physical activity prescription that led towards a goal of accumulating of at least 10,000 steps per day. Participants who were part of the coaching program were responsible for reporting their average daily step count for the previous week. A mechanical pedometer and daily step log sheets were distributed to each participant that was part of the coaching program. These materials were donated by the St. Jude Medical and American Heart Association Midwest Affiliations. After the day of consent was received, they were delivered within 4- 7 business days.

Coaching Calls

All treatment participants were given the opportunity to confirm a preference for day of the week and time of day to receive a regular weekly and bi-weekly coaching call from the primary investigator. The coaching calls and distribution of pedometers alongside was the intervention exposed only to treatment participants of the study. Each call was recorded using the Olympus Digital Voice Recorder VN-8100 PC. Length of calls ranged from as little as five minutes to as much as twenty-six minutes. The length of each call depended on the information covered within each chapter of the ALED guidebook and participant feedback and update of step tracking progress.

For the twelve calls that took place in which the ALED chapter was addressed every other week, the coach was responsible for:

1) Reviewing and summarizing the key points of each chapter of ALED
2) Initiate discussion and participation around the activity alerts found throughout each chapter.
3) Checking on progress made and confirming a goal with step tracking from the use of the pedometer.
4) Discussing barriers and strategies around barriers found in either getting the 10,000 daily step goal and their personalized average daily step count.

For all of the other twelve calls, the coach was responsible for:
1) Checking on progress made through average daily step count reporting and confirming a goal for the upcoming week with step tracking from the use of the pedometer.

MNCOME Follow-up Appointment Protocol

After the initial visit, follow-up appointments were made on a quarterly basis. During each follow-up appointment with MNCOME, certified educators were able to conduct a progress assessment of diet and physical activity recall for both control and treatment group participants They discussed and promoted the importance of a balanced diet based on the USDA MyPlate recommendations and from the American Heart Association guidelines for dietary therapy for proper weight loss which included:

1) Low-calorie diet up to approximately 1,500 calories a day
2) Total Fat composing 30 percent or less of total calories
3) Carbohydrates composing 50% or more of total calories with the majority coming from soluble fiber and fruits and vegetables.
4) Protein composing approximately 15% of total calories with the majority derived from plant sources and lean sources of animal protein.

The education provided by MCNOME staff directed awareness to the energy value of different foods, reading and identifying nutrition labels to determine caloric content and food composition, food preparation, food composition, reducing portion sizes, and avoiding consumption of high-calorie foods.

Figure 3: MNCOME Progress Assessment Sample

Progress Assessment #1 – MNCOME Participant 5/1/12

Dietary recall

Breakfast: 2 eggs and turkey sausage or an omelet. Coffee plain

Lunch: varies, eating out 70% of the time. Salad from Bruegger's, Jimmy John's sub, Chinese chicken and mushroom with fried rice (3/4 cup)

Dinner: protein, carbohydrates, occasional vegetables, likes asparagus and grows her own

Snacks: afternoon: Greek yogurt or pickle/ham/low fat cream cheese roll up. Blueberries or other fruit

Beverages: water, at least 64 ounces of diet soda daily, coffee in the am

Atypical meal times / skips meals: No

Eating environment: restaurant, work, home

Diet low in: vegetables, calcium, fruit

Physical Activity Recall

Current (purposeful activity in minutes): mowing grass (once per week), moving landscape rocks recently, previously was going to uplift 2 times per week.

Initial Stages of Change for Physical Activity

A questionnaire was delivered to both treatment and control participant with the purpose of evaluating and assessing stage of change with respect to adopting physical activity as a habit and behavior. A request was made for the questionnaire to be filled out and returned alongside the process of obtaining consent in order to compare participant readiness and motivation in becoming more physically active prior to randomization. The process of consent to participate in a trial with the intention of receiving support to obtain more physical activity kept the range of possible responses within stage 2 (giving it a thought now and then but not doing it) and 5 (maintaining the recommended levels of physical activity of 150 minutes per week for six months or more).

Study Hypotheses

The following primary hypotheses were formed and developed prior to the data collection and used to guide the final analysis.

1. Exposure to the telephonic coaching service that involved the application of the Active Living Every Day model and pedometer-based tracking and reporting received by the treatment participants would result in statistically significantly greater difference in weight loss measured in pounds than among the control participants who were not exposed after six months.

2. Exposure to the telephonic coaching service that involved the application of the Active Living Every Day model and pedometer-based tracking and reporting received by the treatment participants would result in statistically significantly greater abdominal fat reduction measured by DXA percentage results and measured by changes in waist circumference in inches than among the control participants who were not exposed after six months.

3. Exposure to the telephonic coaching service that involved the application of the Active Living Every Day model and pedometer-based tracking and reporting received by the treatment participants would result in statistically significantly greater improvement in systolic and diastolic blood pressure than among the control participants who were not exposed after six months.

4. The rate of participation of the coaching calls will elicit a statistically significant strong direct correlation with the rate of weight loss in pounds within the treatment group after six months.

5. The rate of participation of the coaching calls will elicit a statistically significant strong direct correlation with the rate of abdominal body fat reduction as

measured by DXA percentage results and measured by changes in waist circumference in inches within the treatment group after six months.

6. The rate of participation of the coaching calls will elicit a statistically significant strong direct correlation with the rate of systolic and diastolic blood pressure reduction within the treatment group after 6 months.

7. A greater percentage of participants exposed to the telephonic coaching service will achieve the 5-10% initial goal weight than among the control participants who were not exposed after six months.

Statistical Analysis

All data and tests were used to determine statistical significance for outcomes with a level of significance for $p < 0.01$. Comparisons were made measuring the difference between baseline and follow-up clinical outcomes within each group (post-intervention minus pre-intervention results) and between the telephonic coaching and control groups over a period of six months. SAS Version 9.3 was used for the analysis and all analyses were performed by the primary investigator.

In order to evaluate the first three hypotheses, the mean difference ± standard error of the mean difference of the selected variable between the treatment (n = 19) and control groups (n = 21) was computed using a paired t-test statistical procedure. The selected variables under consideration were body weight and BMI units, body and truncal fat percentage, waist circumference, estimated visceral adipose tissue, and systolic and diastolic blood pressure.

In order to evaluate hypotheses four, five, and six, a Pearson's correlation regression procedure was computed to measure the strength of the relationship between number of coaching calls completed by the telephonic coaching participants (n = 19) and rate of weight loss (lbs) after six months. The selected variables under consideration were body weight, abdominal body fat percentage, waist circumference, systolic and diastolic blood pressure change over six months. A coefficient *r* closer to a

value of 1.0 represents a strong relationship and a value closer to 0 represents a weak relationship.

In order to evaluate the final hypothesis, a percentage of those participants who achieved the initial 5-10% weight loss goal after six months would be taken from the telephonic coaching and control group.

CHAPTER 4

RESULTS

Table 1 illustrates the clinical characteristics evaluated for the MNCOME participants on selected variables prior to randomization. Of the forty participants who were randomized into either a treatment or control group, thirty-six were female (90%), thirty-six were of white racial status (90%), and about more than half were married. The average age of the participant study population was close to 42 years, with approximately 2 years of standard error. The youngest participant was 19 years old and the oldest was 65 years of age. Thirty-eight of the 40 participants spoke English, with two participants only able to communicate in the Spanish language, resulting in one in each trial group. The primary investigator conducting the telephonic coaching calls was capable and able to communicate fluently in the Spanish language in order to accommodate any language barrier which allowed for diversity inclusion into the study.

Table 1: Baseline Demographic and Clinical Characteristics of the Study Population

	All	Telephonic Coaching Group	Control Group
	N = 40	N = 19	N = 21
Gender, % female	36 (90%)*	16 (84%)	20 (95%)
Race, % white	36 (90%)	17 (89%)	19 (90%)
Marital Status, % married	22 (55%)	11 (59%)	11 (53%)
Ethnicity, % Not Hispanic	30 (75%)	15 (79%)	16 (76%)
Language, % English	38 (95%)	18 (95%)	20 (95%)
Age, years	42.2 ± 1.9**	41.9 ± 2.8	42.5 ± 2.5
Weight, pounds	244.9± 11.4	226.6 ± 11.3	261.3 ± 18.6
BMI, kg/m²	40.0 ± 1.4	37.6 ± 1.5	42.2 ± 2.3
Waist Circumference, inches	46.5 ± 1.3	44.4 ± 1.5	48.3 ± 2.1
Blood Pressure			
Systolic, mmHg	123.3 ± 2.2	120.6 ± 3.2	125.7 ± 2.9
Diastolic, mmHg	77.3 ± 1.5	76.0 ± 2.3	78.6 ± 1.9
Healthy Eating Assessment Completion***	1.2 ± 0.3	1.5 ± 0.5	1.0 ± 0.3
Initial Stage of Change	2.9 ± 0.2	2.7 ± 0.3	3.0 ± 0.3
Stage of Change: 3 or under (% 3 or under)	26 (74%)	12 (70 %)	14 (77%)

*Values are represented as number of participants (percent of total number of participants).

**Values are represented as mean value ± standard error, unless otherwise indicated.

***Evaluated throughout the six-month intervention for all participants

The average initial weight was greater for the control group (261 lbs) by an average of 35 lbs than for the treatment group (226lbs) even with prior random assignment. Average BMI was greater by default by an average of approximately 5 points for the control group (42.2 kg/m^2) than the treatment group (37.7 kg/m^2). Average waist circumference, blood pressure, and initial stage of change were all slightly greater for the control group than the treatment group at baseline. The number and proportion of participants that did not meet the current recommendations for moderate level of physical activity of 150 minutes a week was compared for both groups. Out of all 35 participants who completed in the initial stages of change questionnaire, 26 were considered sedentary with 12 (70%) of the treatment group and 14 (77%) of the control group. The MNCOME Progress Assessment was completed on average for a greater amount of visits for the treatment group (1.5) than the control group (1.0) throughout the six-month study duration.

Table 2 shows the baseline body composition characteristics measured by the DXA scan for a total of 24 participants who volunteered to have this measured pre and post trial. The DXA body fat percentage results were very close between the telephonic coaching (n = 14) and control group (n = 10) with an average difference of 1.0% for total body fat and 0.1% for truncal body fat being higher for the control group. Analysis of the estimated visceral adipose tissue was limited to a total of n = 5 due to limited capabilities of the DXA scan serviced at MNCOME to measure this variable during the early stages of the intervention trial period. The estimated visceral adipose tissue evaluation was available by DXA scan in the month September of 2012.

Table 2: Baseline Body Composition Characteristics measured by Dual-Energy X-ray Absorptiometry of the Study Population

	All	Telephonic Coaching Group	Control Group
	N = 24	**N = 14**	**N = 10**
Total Body Fat, %	44.8 ± 4.0	44.9 ± 1.0	45.9 ± 1.4
Truncal Fat , %	44.6 ± 5.1	44.6 ± 1.0	44.5 ± 2.0
	N = 5	**N = 4**	**N = 1**
Estimated Visceral Adipose Tissue, cm^2	271.4 ± 52.9	228.8 ± 40.4	442.0

*Values are represented as mean value ± standard error, unless otherwise indicated.

Tables 3 and 4 illustrate the within-group differences for all selected variables, comparing pre-trial and post-trial results for the telephonic coaching and control groups after six months. Based on a statistical criterion of $p < .01$, statistically significant differences were observed only for weight lost over six months represented as absolute difference in lbs and also as a percentage lost of the initial weight, and by default BMI change for both groups. Although the control group lost an average of 15.4lbs, more weight lost than the telephonic coaching group of 14.7lbs over six months, the coaching group lost a higher percentage of initial weight of 6.5% than the 5.9% for the control group. This difference may have been due to the higher initial weight observed in the control group than the telephonic coaching group at baseline of the study intervention. Among all other selected variables in Table 3 and 4, including body composition results measured by the DXA scan, apparently with-in group differences were far from observing statistical difference from baseline to post-trial.

The results can be viewed upon in another manner considering that the final hypothesis seeks to discover whether a greater proportion of obese participants would achieve the 5-10% weight loss goal after six months in the telephonic coaching than the

control group. The results show that a greater percentage of obese participants in the control group (13 out of 21, 61%) achieved the initial 5 – 10% weight loss goal after six months than the telephonic coaching group (8 out of 18, 45%).

Table 3: Within-Group Study Outcomes for Weight, Waist Circumference, and Blood Pressure after Six-Months

	Group (N)	Mean ± SE	T-Statistic	p-value
Weight Change, lbs*	Telephonic Coaching (N = 18)	-14.7 ± 3.4	-3.71	P = 0.0020*
	Control (N = 21)	-15.4 ± 3.2	-4.75	P = 0.0001*
Weight Change, % of Initial Weight	Telephonic Coaching (N = 18)	-6.5 ± 2.0	-3.71	P = 0.0020*
	Control (N = 21)	-5.9 ± 1.2	-4.75	P = 0.0001*
BMI Change, kg/m^2	Telephonic Coaching (N = 18)	-2.4 ± 0.6	-3.70	P = .0017*
	Control (N = 21)	-2.5 ± 0.5	-4.80	P = .0001*
Waist Circumference Change, inches	Telephonic Coaching (N = 14)	-0.7 ± 2.7	-0.26	P = .8001
	Control (N = 19)	-2.7 ± 1.1	-2.48	P = .0230
Blood Pressure Change				
Systolic, mmHg	Telephonic Coaching (N = 13)	0.46 ± 5.7	0.08	P = .94
	Control (N = 19)	-0.63 ± 3.9	-0.02	P = .87
Diastolic, mmHg	Telephonic Coaching (N = 13)	4.1 ± 2.8	1.50	P = .16
	Control (N = 19)	3.6 ± 1.8	1.96	P = .06

Table 4: Within-Group Study Outcomes of Total Body Fat Percentage, Truncal Fat Percentage, and Estimated Visceral Adipose Tissue after Six-Months

	Group (N)	Mean ± SE	T-Statistic	p-value
Total Body Fat Change, %	Telephonic Coaching (N =10)	1.3 ± 1.3	0.99	P = 0.340
	Control (N = 8)	0.9 ± 1.1	0.84	P = 0.430
Truncal Fat, %	Telephonic Coaching (N = 10)	1.2 ± 1.6	0.74	P = 0.477
	Control (N = 8)	0.9 ± 1.7	0.54	P = 0.603
Estimated Visceral Adipose Tissue, cm^2	Telephonic Coaching (N = 2)	-26.0 ± 8.0	-3.25	P = 0.190
	Control (N = 1)	-57.0	NA	NA

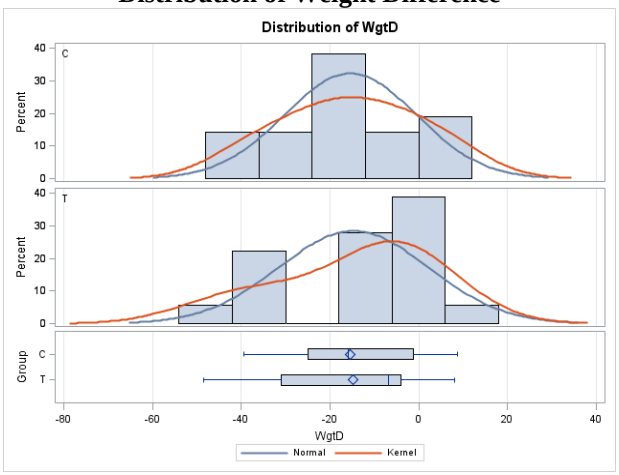
There were no significant between-group differences based on statistical criterion of $p < .01$ on any of the selected baselines for the telephonic coaching group compared to the control group after six months. Furthermore, the results from Table 5 reveal that the control group participants who were not exposed the supplemental telephonic coaching program succeeded in achieving a greater absolute mean difference on all selected variables, although far from observing statistical significance with lowest p-value equal to 0.268 for change in estimated visceral adipose tissue over six months. The distributions of the two-tailed paired t-tests for the selected variables after six months are shown in Figure 4.

Table 5: Between-Group Difference of Selected Variables after Six-Months

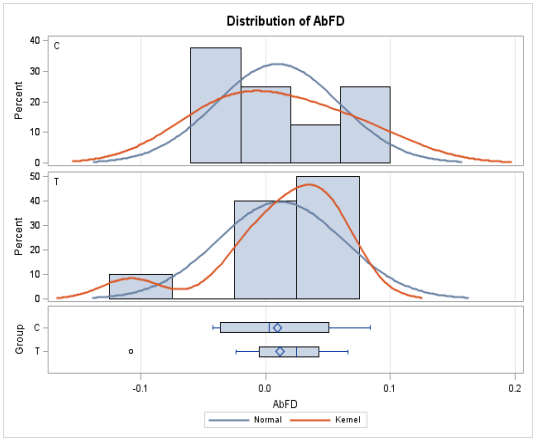
	Difference in Mean for Telephonic Coaching Group – Control Group	**95% Confidence Interval**	**p-value**
Weight Loss, lbs	-0.70 ± 5.0	-11.00 to 9.60	P = 0.891
BMI Change, kg/m²	-0.18 ± 0.8	-1.85 to 1.47	P = 0.822
Body Fat Change, %	-0.4 ± 1.8	-4.2 to 3.4	P = 0.823
Truncal Fat Change, %	-0.2 ± 2.4	-5.2 to 4.8	P = 0.924
Estimated Visceral Adipose Tissue Change, cm²	-31 ± 13.8	-145.1 to 11.31	P = 0.268
Waist Circumference Change, inches	-2.03 ± 2.6	-7.41 to 3.33	P = 0.447
Blood Pressure Change			
Systolic, mmHg	-1.09 ± 6.7	-14.81 to 12.63	P = 0.8719
Diastolic, mmHg	-0.52 ± 3.2	-7.08 to 6.03	P = 0.8713

Figure 4: Distribution of Between-Group Differences of Selected Variables after Six-Months

Distribution of Weight Difference



Distribution of Abdominal Fat Difference



Distribution of Waist Circumference Difference

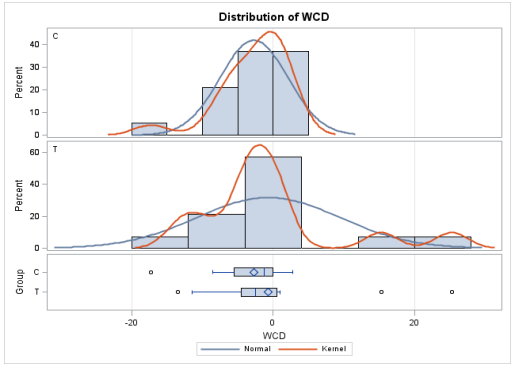
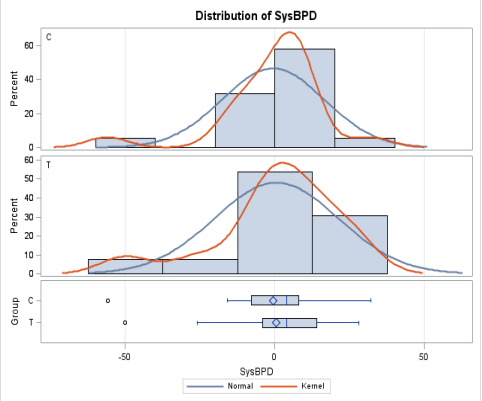
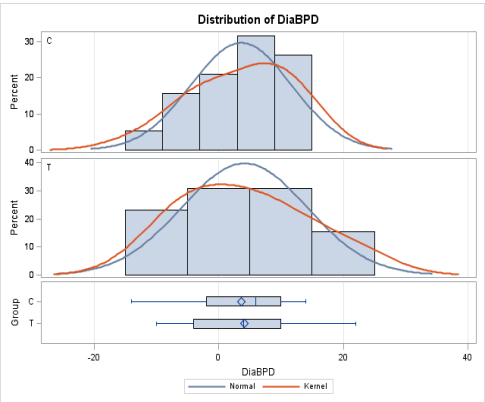


Figure 4: Distribution of Between-Group Differences of Selected Variables after Six-Months

Distribution of Systolic Blood Pressure



Distribution of Diastolic Blood Pressure



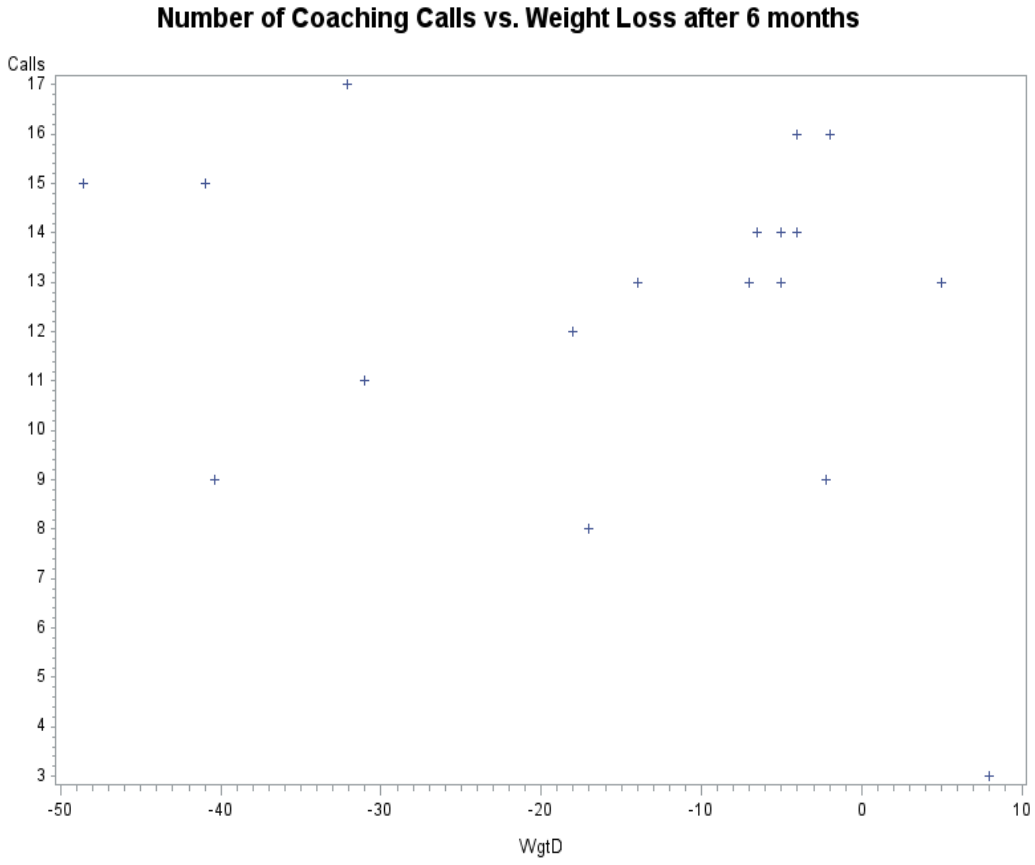
The results of the Pearson's regression two-tailed tests failed to reach statistical significance and indicated a weak relationship between the number of coaching calls completed by the telephonic coaching participants and the within-group difference for all of the selected variables under consideration such as body weight (r = -0.220), abdominal body fat percentage (r = 0.433), waist circumference (r = 0.095), systolic (r = 0.059) and diastolic (r = -0.258) blood pressure change after six months exposure. The Pearson's test assumed that a coefficient r closer to a value of 1.0 represents a strong relationship and a value closer to 0 represents a weak relationship. The results can be seen in Table 6. Graphical representation of the Pearson's correlation tests can be seen in Figure 5.

Table 6: Correlations among Selected Variables and Number of Completed Coaching Calls for the Telephonic Coaching Group after Six-Months

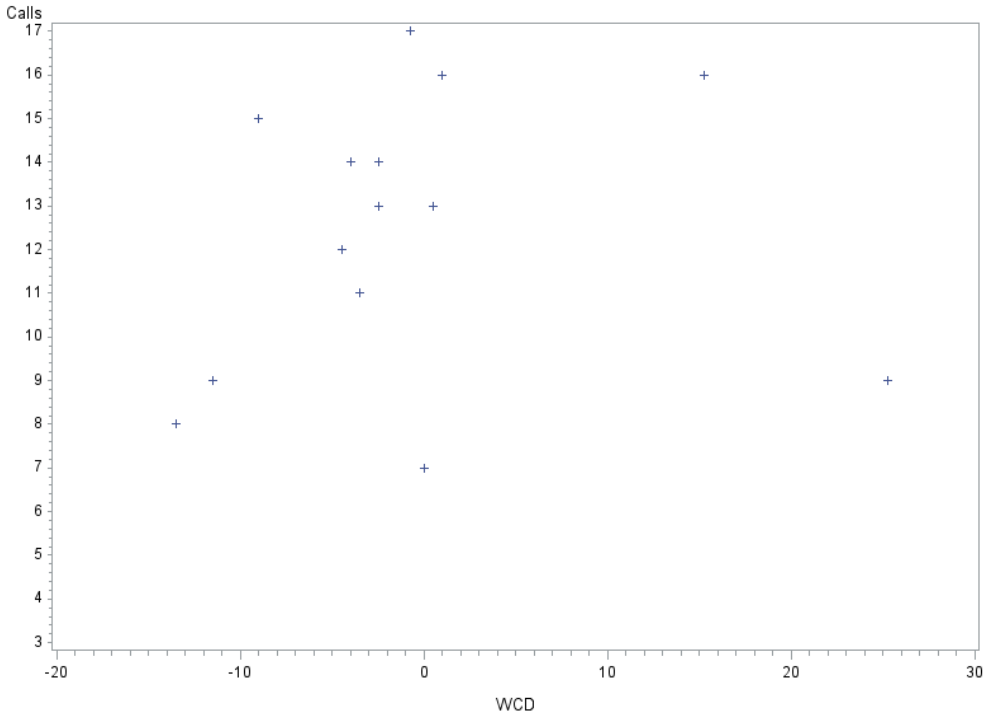
	Number of Completed Calls (min = 3, max = 17)	
	Pearson's Correlation Coefficient *r*	**p-value**
Weight, lbs	-0.220	0.380
Truncal Fat, %	0.433	0.211
Waist Circumference, inches	0.095	0.748
Systolic Blood Pressure, mmHg	0.059	0.846
Diastolic Blood Pressure, mmHg	-0.258	0.3945

Note: All variables were two-tailed tests.

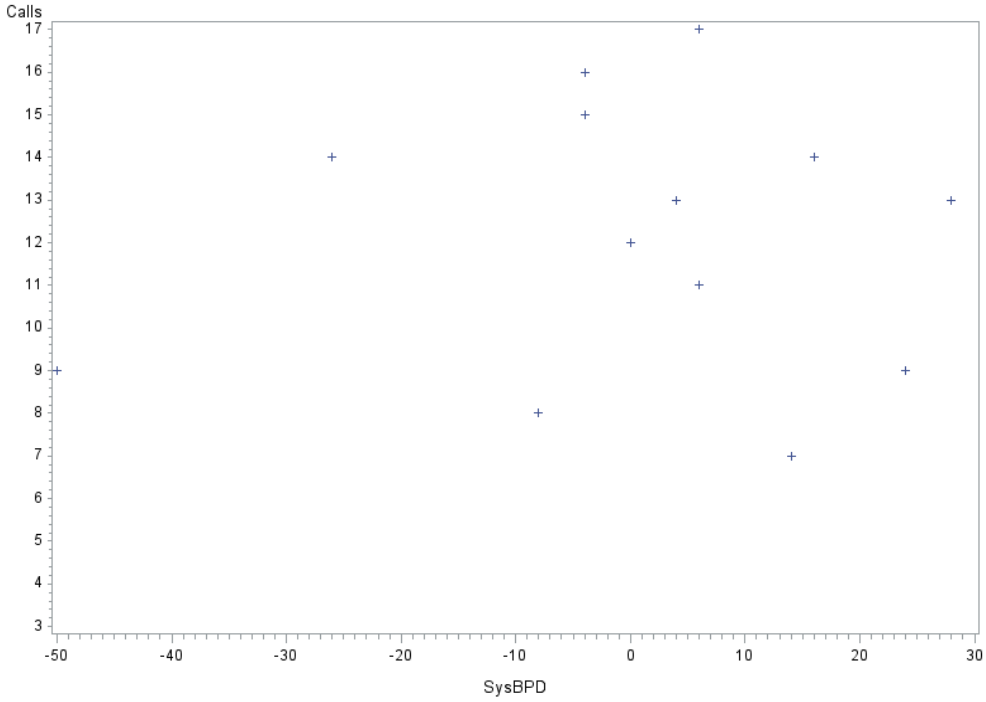
Figure 5: Scatter-plot of Number of Completed Calls vs. Outcome of Selected Variables for Telephonic Coaching Participants after Six-Months



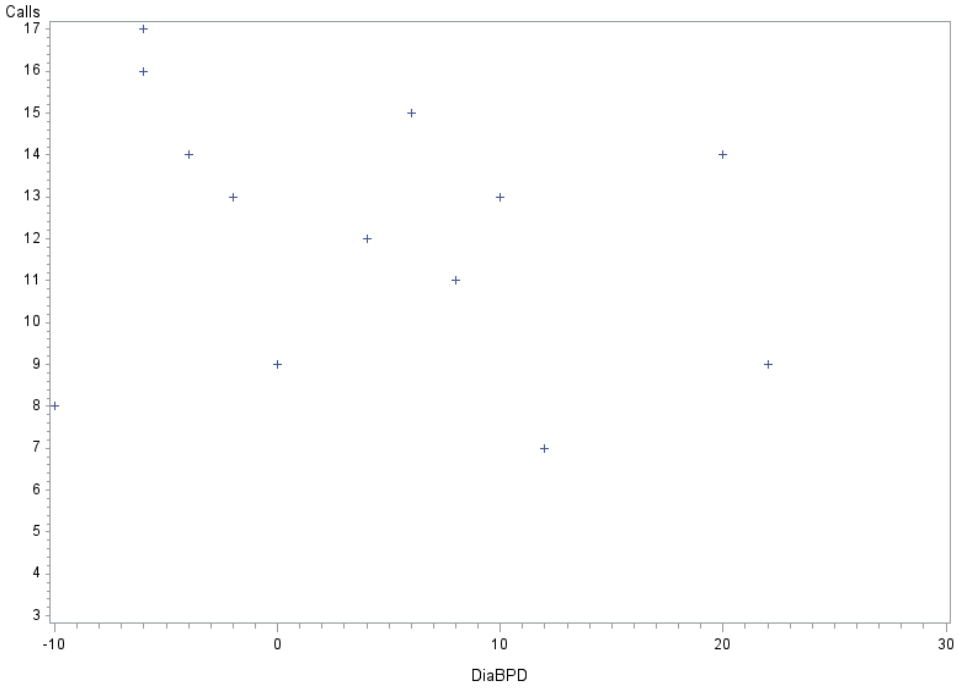
Number of Coaching Calls vs. Waist Circumference Difference after 6 months



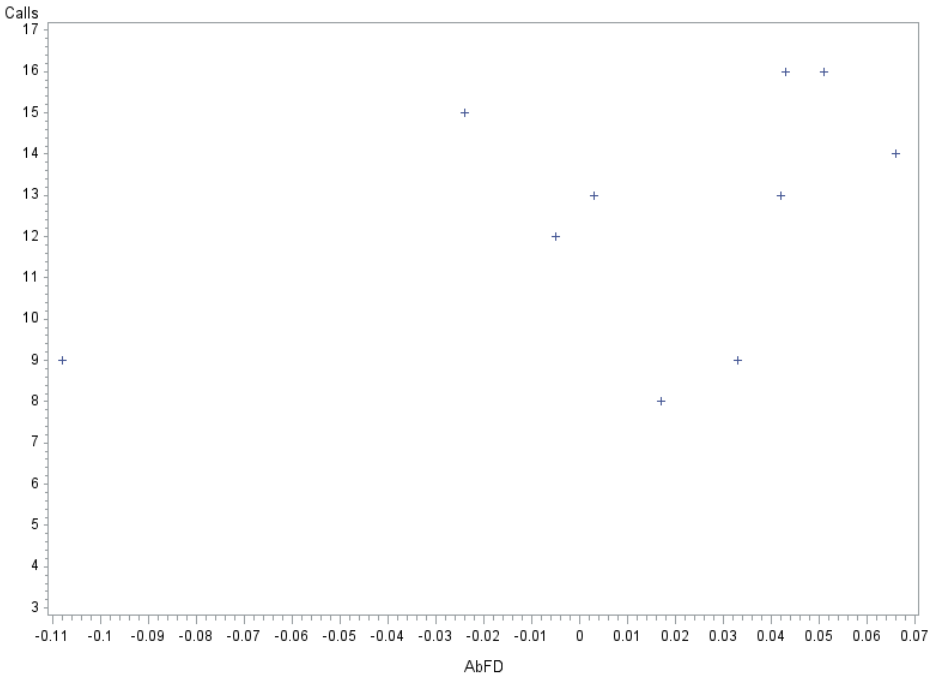
Number of Coaching Calls vs. Systolic Blood Pressure Difference after 6 months



Number of Coaching Calls vs. Diastolic Blood Pressure Difference after 6 months



Number of Coaching Calls vs. Truncal Fat Difference after 6 months



Average Daily Step Count

Sixteen out of the 19 participants who were part of the telephonic coaching program reported their average daily step count using the mechanical pedometer until the study completion of a six month period. Adherence was defined as reporting steps for 70% or 12 out of the 17 coaching call opportunities given throughout the study period. The average daily step count was self-reported to be 8214, with a minimum count of 3268 steps and maximum count of 11,816 steps. Only four out of the nineteen participants completed an average daily step count of over 10,000 steps per day throughout the six-month intervention period as recommended and suggested by the literature on physical activity for cardiovascular and metabolic health.

CHAPTER 5
DISCUSSION

These results demonstrate that an adequate adherence to the support of a telephonic coaching service framed on the ALED programming principles when added to the specialty medical practice of MNCOME failed to achieve a statistically significant difference for all selected outcome variables than adherence to MNCOME medical services alone over six-months. However, a statistically significant within-group difference was achieved for the telephonic coaching group (n = 19) and control group (n = 21) from baseline to a period of six-months for a mean weight loss of 14.7 and 15.4 lbs respectively. In fact, a greater percentage of initial weight loss was achieved by the telephonic coaching group of 6.5% than the control group of 5.9% after six-months. BMI changed were also evaluated and decreased by an average factor of 2.4 kg/ m^2 (6.3%) and 2.5 kg/m^2 (5.9%) respectively. The BMI changes if expressed as a percent decrease for both the telephonic coaching and control groups surpass the recommended population wide decrease of 5% that could help prevent thousands of obesity-related disease cases in many states as previously suggested in the review of economic costs associated with obesity (Voelker, 2012).

There are several implications that can be made based on the weight loss findings of this trial. Higher morbidity in association with overweight and obesity has

been observed for hypertension, coronary heart disease (CHD), stroke, and cancer. Although the direct and independent association of weight and blood pressure has not been significantly demonstrated in this trial, it has been shown in numerous cross-sectional studies, including the large international study of salt (INTERSALT) carried out in more than 10,000 men and women (Dyer, Elliot, 1989). In the INTERSALT study, it was found that a 22 lb higher body weight is associated with a 3.0 mm Hg higher systolic and 2.3 mm Hg higher diastolic blood pressure. According to the NHLBI Education Initiative, there is enough evidence to suggest that increased physical activity to increase cardio-respiratory fitness reduces blood pressure independent of weight loss, but was not shown or powerful enough to be investigated in this study.

Weight loss produced by lifestyle modifications has been shown to reduce serum triglycerides, increase HDL-cholesterol, produce reductions in total cholesterol and LDL-cholesterol, as well as reduce the risk of diabetes in obese patients within a multitude of previous RCT research but was not addressed in this particular study due to low compliance to potential laboratory tests.

Considering that the general goals of weight loss and management of obesity to prevent further weight gain, to reduce body weight by 5-10% of initial weight, and to maintain a lower body weight over the long term, it appears that the contribution of services provided by MNCOME and the telephonic coaching program have achieved success on the first two of the three criteria. As previously stated, an effect size of $r = 0.57$ validates within-group differences of both groups ($n = 40$) for weight loss over six-months, a resulting power β probability of 0.96, Type 1 error of $\alpha < 0.01$. However, a limited sample size of $n = 40$ and a low effect size range of ES = 0.022 to .0444 over six-months for mean changes and standard deviation of the primary variables may have impacted the insignificant finding and in drawing further conclusions for between-group differences after six-months.

Based on the results, it can also be confirmed that over the six-month time frame, both groups succeeded in preventing any further increases in body weight, body and abdominal fat expressed as a percentage, waist circumference in inches, and blood pressure values. For a potential future study, diligent effort and time should be devoted

to recruit and retain a much greater sample size and prolong the study beyond a period of six months in order to find significant findings for weight loss, body fat reduction, and blood pressure improvement for long-term weight loss and maintenance.

Limitations

Several limitations were discovered during and after the study trial. First, all research study MNCOME participants who volunteered to be in this experimental program had to initially score at least a level 2 stage of change and were more motivated to accomplish more physical activity than the general population of patients who partake in the medical services of MNCOME who were not interested. Therefore, the impact of the telephonic coaching program on physical activity and weight loss may fail to answer questions related to engaging those who are not motivated to participate at all (level 1 stage of change).

A second limitation was that the principal investigator who initiated the telephonic coaching study trial for weight loss and who was also responsible for delivering the intervention may have more time, motivation, expertise, and willingness to deliver such an intervention in comparison to the level of engagement that would be brought by a neutral professional setting.

There was also inconsistent exposure of the telephonic coaching program among participants with respect to seasonal variation throughout the recruitment and intervention period among treatment participants and controls. Since the timeframe of recruitment and participation by study participants ranged from March 2012 until April 2013, participants enrolled and completed physical activity in different seasons which translates to inconsistent opportunities and access to be more active outdoors.

There were also missed phone call opportunities for the telephonic coaching group participants, occurring on average 35% of the time. Although this was to be expected, missed coaching calls lead to missed opportunities to apply the telephonic coaching support service through the ALED program and for review and accountability to achieve the daily step goal for weight loss. For future research, texting and e-mailing may pose a more conducive communication process.

An important limitation of this program was self-report of daily step counts over the phone. Also physical activity levels were not formally captured pre or post-intervention in order to detect differences in energy expenditure throughout the trial. Although we can detect differences in body fat and weight loss, we cannot detect whether the coaching program was in actuality more effective in facilitating changes in physical activity in terms of energy expended more than the control group.

This study trial also was limited to a relatively small sample size (n = 40), with a resulting effect size range of $r = 0.022 – 0.044$, which is miniscule compared to most physical activity and weight loss trials for obesity.

Also, failure to maximize compliance and quality assurance of monitoring diet and physical activity progress beyond self-report may have also hindered the quality of the results and outcomes of this particular trial.

There was missing data when conducting the statistical analysis at the end of the trial on several selected variables including weight (n = 1), body composition measured by the DXA (n = 22), waist circumference (n = 7), blood pressure (n = 8), and estimated visceral adipose tissue (n = 37). For the purpose of this trial, a missing value is defined as value that is not available and that would be meaningful for analysis if it was observed.

Laboratory tests that could have been included but were not followed upon at the end of the trial were total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, fasting glucose, triglycerides, leptin, adiponectin and c-peptide blood levels. These were not included due to a very low compliance to return for testing after six-months during the post-trial period of data collection for all telephonic coaching and control group participants. The rationale for including these blood tests was to analyze the impact that weight loss, body fat loss, and physical activity may have on these values after six months of telephonic coaching or control group exposure. Therefore, conclusions may not be adequately drawn for the particular health risk questions as originally proposed and addressed in the review of the literature on the metabolic impact of weight loss for obesity.

Finally, it may be possible that the participants of the study who were recruited and classified as obese may or may not have demonstrate previous success in managing their current weight. An assessment of previous history of weight loss efforts and trials, as well as pattern of weight gain should be assessed and controlled for in future studies.

Future Studies

It may be important to understand a participants' perspective of the extent whether confidence gained in achieving physical activity goals can contribute to confidence developed in forming new dietary habits when seeking to initial weight loss to reduce obesity. From a coach's perspective during this trial, it was brought to my attention from several participants as noted in the recorded calls, that the success in achieving additional daily steps actually motivated them to seek success for all other realms of weight management, including dietary and pharmacotherapy. As stated by the NHLBI Obesity Education Initiative, much of the current research on weight loss trials conclude that simply reducing dietary fat, along with reducing dietary carbohydrates would be needed for an acceptable weight loss. Most of these trials fail to acknowledge the readiness one would need to have in order to develop the skills and confidence to comply with and incorporate those practices successfully. There may be an advantage to behavior coaching to support the participant, especially in the context of what they feel ready and confident to accomplish.

An adherence to a 10,000 step per day goal and the impact it may have to weight loss, body composition, and cardiovascular health warrants future attention. This study only achieved adherence to the 10,000 step per day goal among four of the nineteen intervention participants, a sample selection that would not carry a sufficient conclusion. Future studies should also address the factors that impact adherence to pedometer-based walking programs.

It might also merit further study to see the impact of adhering to telephonic coaching for improvements in physical activity not only on body and truncal fat composition, but also further analysis on estimated visceral adipose tissue which is a strong risk indicator for cardiovascular disease. With a sample of n = 5 for that

particular variable, this study failed to achieve the statistical capacity to qualify that as a finding which may merit future attention.

CHAPTER 6
CONCLUSION

The results of the study indicated that both telephonic and control groups achieved a statistically significant within-group difference from baseline to a period of six-months for a mean weight loss of 14.7 and 15.4 lbs respectively, but not for all other variables under consideration. A greater percentage of initial weight loss was achieved on average by the telephonic coaching group of 6.5% than the control group of 5.9% over the course of six-months. However a greater percentage of the control group (61%) achieved the 5-10% weight loss goal than the telephonic coaching group (44%) suggesting that the telephonic coaching program may not serve as a more useful supplement to the weight loss therapy provided by MNCOME. The findings of the study however, failed to find a statistically significant difference for between-group differences for all variables under consideration after six months, concluding lack of any additional benefit than the standard level of MNCOME service alone.

At the present time, this is the only study that has managed to combine pedometer-based self-monitoring with an added support of a telephonic physical activity coaching based on the ALED when added to the clinical services of MNCOME for the purpose of treating obesity. Additional studies should be made with a much larger initial sample size of $n > 240$ that would enable a much greater power than 0.22 from this study and a lower level of statistical significance closer to $p = 0.01$ in order to clarify whether the program enhances the goals of a weight management program to reduce obesity. Improvements in dietary habits and physical activity levels may reduce obesity within the context of lifestyle intervention through telephonic coaching, but may be proven by a much more effectively run randomized controlled trial in the future.

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Appendix A: Questionnaire for Physical Activity

Physical Activity Stage of Change Questionnaire

Name:

1) Assessing stage of change

Regular physical activity includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as these activities.

	Yes	No
1. I am currently physically active		
2. I intend to become more physically active in the next 6 months		
For activity to be REGULAR, it must add up to a total of 30 minutes or more per day and be done at least 5 days per week. For example, you could take one 30-minute walk or take three 10-minute walks for a daily total of 30 minutes.		
	Yes	No
3. I currently engage in regular physical activity		
4. I have been regularly physically active for at least 6 months		

Scoring algorithm
If (question 1 = 0 and question 2 = 0), then mark as stage 1
If (question 1 = 0 and question 2 = 1), then mark as stage 2
If (question 1 = 1 and question 3 = 0), then mark as stage 3
If (question 1 = 1, question 3 = 1, and question 4 = 0), then mark as stage 4
If (question 1 = 1, question 3 = 1, and question 4 = 1), then mark as stage 5

2) Pros and cons of becoming more active

Your pro's of becoming more active	**Your con's of becoming more active**
1.	*1.*
2.	*2.*
3.	3.

3) Outcome Expectations for Exercise

The following are statements about the benefits of exercise (walking, jogging, swimming, biking, stretching, or lifting weights). Circle the number representing the degree to which you agree or disagree with these statements. 1 = strongly disagree, 5 = strongly agree

1. Makes me feel better physically	1	2	3	4	5
2. Makes my mood better in general	1	2	3	4	5
3. Helps me feel less tired	1	2	3	4	5
4. Makes my muscles stronger	1	2	3	4	5
5. Is an activity I enjoy doing	1	2	3	4	5
6. Give me a sense of personal accomplishment	1	2	3	4	5
7. Makes me feel more alert mentally	1	2	3	4	5
8. Improves my endurance in performing my daily activities (such as personal care, cooking, shopping, light cleaning, taking out garbage)	1	2	3	4	5
9. Helps to strengthen my bones	1	2	3	4	5

4) Physical Activity History

If you do not currently participate in physical activity, answer these questions:

1. How long has it been since you did regular physical activity or exercise?
    a. Less than 6 months
    b. More than 6 months but less than 1 year
    c. More than 1 year but less than 2 years
    d. More than 2 years but less than 5 years
    e. More than 5 years but less than 10 years
    f. More than 10 years
    g. I have never been regularly physically active

If you currently are physically active, answer the following questions

1. How many days per week are you physically active?_____.
2. Approximately how many minutes are you physically active each time?_____.
3. How long have you been physically active at this level?_____.
4. What activities do you do? _____

Answer the following questions whether or not you are currently physically active

1. As an adult, were there ever times when you were physically active regularly for at least 3 months and then stopped being physically active for at least 3 months?
2. If yes, then how many times?_____.
3. Regarding the most recent time, why did you stop your activity? (Please check as many as apply.)

Lack of time because of:

___Work or school
___Household duties
___Children
___Social activities
___Spouse

___Lack of money
___Lack of facilities
___Lack of physical activity planner
___Lack of interest in physical activity
___Health problems
___Injury
___Season or weather change
___Personal stress
Other:_____

Appendix B: Consent Form

CONSENT FORM

"A Comprehensive Approach to Weight Loss Management for Obesity: Application of a Telephonic Physical Activity Coaching Intervention"

You are invited to participate in a research study evaluating the effects of receiving a telephone physical activity coaching program for weight management program. You were selected as a possible participant because of your recent participation under the care and supervision of the Minnesota Center for Obesity, Metabolism and Endocrinology (MNCOME). We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Michael Zambrana, a candidate for the degree of Master of Science in Exercise Physiology at the University of Minnesota School of Kinesiology.

Study Purpose

The purpose of the study is to determine whether telephonic counseling made up of weekly phone calls from an activity coach and a pedometer will help achieve clinical weight loss and lower body fat and waist circumference over six months. This will be done among you and those who are under the care of Dr. Michael Gonzalez-Campoy at the Minnesota Center for Obesity, Metabolism and Endocrinology.

Study Procedures

If you agree to participate in this study, we would ask you to do the following:

- Complete your physical examination and laboratory testing required by the Minnesota Center for Obesity, Metabolism and Endocrinology. This will include participating in the Dual Energy X-Ray Absorptiometry (DEXA) assessment for body composition.
- You will be randomly assigned to either:
    1) Treatment Group – receiving the weekly coaching calls in addition to your normal service of care from MNCOME staff
    2) Control Group – receiving only normal service of care of weight management provided through MNCOME.
- If assigned to the treatment group you will:
    1) Receive weekly physical activity coaching and counseling over the phone

2) Receive a step tracking tool called a pedometer. You will be asked to wear it every day by attaching it to your waistband (belt or clothes)
3) Receive weekly log sheets on which to enter in the amount of steps reported by the pedometer at the end of each day.

- You will also be required to complete an updated version of Stages of Change for Physical Activity Questionnaire at the beginning and end of the study to evaluate possible changes in health behaviors towards walking and physical activity over the duration of the study.
- The length of time for participation will be six months
- Clinic visits will be made every three months or as required by MNCOME

Risks of Study Participation

There are minimal risks in participating with the physical activity coaching call such as possible discomfort in the encouragement of completing a daily walking routine. There may also be potential increase in risk of injury to muscle, skeletal, and heart health from physical activity as compared to a state of complete rest. However, this moderate level of physical activity is also suggested by the counseling services of the Minnesota Center for Obesity, Metabolism, and Endocrinology.

Benefits of Study Participation

If you are assigned to the telephone intervention group, you may lose weight more quickly than those in the standard treatment group, but this is not guaranteed. There may be no direct benefit to you for participating in the study. However, the results of the study may be useful in designing weight loss programs for others in the future.

Alternatives to Study Participation

The alternative to study participation is to continue to pursue weight management counseling from the staff at MNCOME.

Study Costs/Compensation

If selected into the treatment group, you may incur the telephonic fee costs corresponding to the coaching calls necessary to complete weekly for 15 minutes for up to 24 weeks. You will not be paid or reimbursed for this potential fee that may be incurred.

MNCOME will cover the costs of conducting the DEXA scan analysis for body composition for the purpose of this research study.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may be reviewed by departments at the University of Minnesota with appropriate regulatory oversight. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University of Minnesota policy for protection of confidentiality.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Michael S. Zambrana and Dr. Michael Gonazalez-Campoy. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact Michael S. Zambrana at 516-668-5062 and Dr. Michael Gonzalez-Campoy at 651-262-5785. You may also contact Stacy Ingraham, the graduate advisor of the student Michael S. Zambrana at 612-626-0067.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at *Fairview Research Administration, 2433 Energy Park Drive, St. Paul, MN 55108.*

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____

Date_____

Signature of Person Obtaining
Consent_____

Date_____

Appendix C: Recruitment Flyer

VOLUNTEER FOR A RESEARCH STUDY: WEEKLY TELEPHONIC PHYSICAL ACTIVITY COACHING CALLS

Congratulations on your recent enrollment under the care of Dr. Michael Gonzalez-Campoy and the staff at the Minnesota Center for Obesity, Metabolism, and Endocrinology (MNCOME).

In addition to the individualized care that you will be receiving from MNCOME, you are invited to participate in a research study evaluating the effects of physical activity counseling intended to promote your weekly physical activity goals as part of your comprehensive weight management program. The study is being conducted by graduate student Michael S. Zambrana from the University of Minnesota, a candidate for the degree of Master of Science in Exercise Physiology and Dr. Michael Gonzalez-Campoy, director at MNCOME.

If you have any further questions or would like to participate in the study please contact:

Michael S. Zambrana at 516-668-5062 or e-mail at zambr015@umn.edu
Dr. Michael Gonzalez-Campoy at 651-262-5785

If you decide to partake in the research study, please mail in your Consent and HIPPA forms signed and dated, along with your Physical Activity Stage of Change Questionnaire within the enclosed envelope to the following address:

Michael S. Zambrana
315 10th Ave SE
Minneapolis, MN 55414

Please consider a one week time frame to respond with your decision.

Appendix D: Worksheets from Active Living Every Day

Personal Time Study			
Date: _____		Day of week: _____	
Time Slot	**Tasks/activities**	**Physically active? (record minutes)**	
		Yes	**No**
8 am to 12pm			
12pm to 4pm			
4pm to 8pm			
**Total Time ---> **		**_____minutes**	**_____minutes**

***IDEA* Activity Sheet**
I - Identify the barrier that keeps you from being active.
D - Develop a few creative solutions (the more the better).
E - Evaluate your list. Write the solution you're willing to try. Write down
precisely how and when you will actually put it into action.
A - Analyze how your plan is working / worked. If your plan worked well, give it five stars.
If it only deserves two stars, write down how it could become a five-star plan.
If a plan bombed completely, look back at your list of solutions and try again.
A plan that doesn't work really points to a solution that will work. Don't give up!

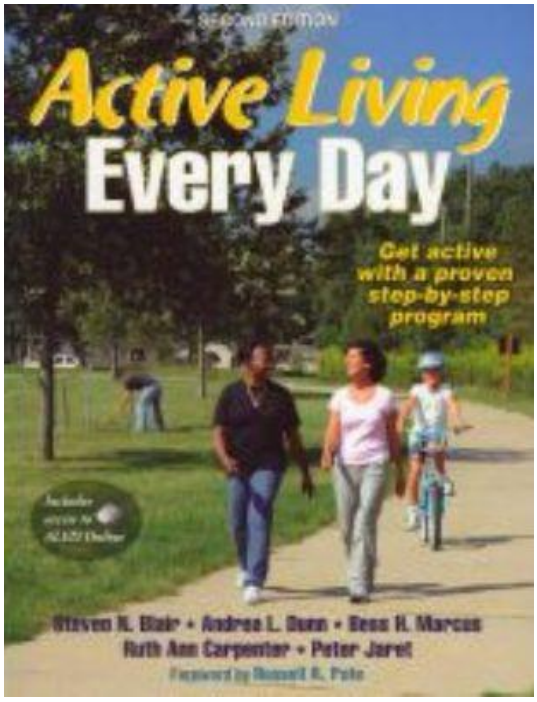
Accentuating the Positive **Activity Sheet**
Read the following negative messages. Circle the ones that you've said to
yourself. Then write down at least one counterargument that accentuates
the positive.
1. I don’t' want to do anything when I feel tired or down in the dumps
2. I don't know how to get started
3. I don’t have anyone to be active with me.
4. I can't find the time in my busy schedule.
5. I'm going on vacation

***New Opportunities for Activity* Activity Sheet**		
Parks (local, state, national)	Location	Comments
Walking, hiking, hiking trails	Location	Comments
Recreation centers	Location	Comments
Activity Clubs	Location	Comments
Other	Lcoation	Comments

***My Personal Successes* Activity Sheet**
Habits I've Changed
1
2
3
4
5
Things that helped me succeed
1
2
3
4
5
Obstacles that got in my way
1
2
3
4
5

Appendix E: ALED Official Description of Background and Purpose

Official Description and Background of Active Living Every Day (ALED)
Description of Book: Adding regular physical activity to your week can make a huge difference in your health. Move more and you'll have more energy, less stress, a reduced risk of chronic diseases such as diabetes and heart disease, a healthier weight, and better sleep quality. And those are just a few of the benefits. If you've decided that you want to lead a more active life, *Active Living Every Day, Second Edition*, offers you all the tools you need to take the first steps toward success. *Active Living Every Day, Second Edition*, is more than just a book. It's a step-by-step plan for building a healthier life. With *Active Living Every Day*, you'll learn how enjoyable physical activity can be—even if you've never been active before—and how easy it is to add activity to your day. You'll create your own activity plan based on your preferences and lifestyle, and you'll be encouraged to choose activities that you like and that fit easily into your routine. You'll even learn how everyday activities, like housecleaning and gardening, can count toward your weekly physical activity goals. Along the way you'll develop confidence by building on small successes and overcoming obstacles—methods that have proven effective in producing lasting change. The advice and participants' stories in the book and the supplementary online tools offer support and guidance to help you achieve your activity goals. Making important lifelong changes takes commitment. With the right structure and encouragement, those changes can be easier to accomplish. Let *Active Living Every Day, Second Edition*; show you how building on small successes can add up to healthy, life-changing habits.



Appendix F: Data Sheets

ID #	Group:	Initial Visit	Stage of Change	Weight 1	Height 1	BMI 1
2	Control	3/21/12	4	266.6	69.8	38.5
5	Control	3/28/12	5	236.0	64.8	39.6
8	Control	4/9/12	2	281.0	71.0	39.2
9	Control	3/23/12	2	329.5	67.8	50.5
10	Treatment	3/23/12	2	343.1	72.0	46.5
11	Treatment	4/4/12	2	268.6	72.8	35.7
12	Control	4/4/12	2	254.0	65.5	41.6
13	Control	4/9/12	3	542.2	76.0	66.0
16	Control	7/20/12	3	182.7	63.5	31.9
18	Treatment	5/30/12	5	292.0	63.0	51.7
19	Treatment	5/1/12	2	282.0	66.0	45.5
20	Control	5/30/12	2	212.0	67.0	33.2
21	Treatment	6/1/12	5	170.0	61.5	31.6
22	Control	5/30/12	2	147.0	61.3	27.5
25	Treatment	7/1/12	5	191.0	63.5	33.3
27	Control	7/9/12	3	238.0	62.0	43.5
28	Treatment	7/9/12	2	229.5	69.0	33.9
29	Treatment	6/26/12	2	224.0	63.5	39.1
30	Control	7/5/12	5	213.0	66.5	33.9
31	Treatment	6/27/12	3	247.0	64.8	41.4
32	Control	8/10/12	.	186.3	61.3	34.9
33	Treatment	7/5/12	2	280.0	65.8	45.5
34	Control	7/30/12	.	268.8	68.5	40.3
35	Treatment	10/21/12	.	231.0	63.0	40.9
36	Control	8/22/12	.	201.0	64.0	34.5
37	Treatment	8/13/12	2	238.0	63.5	41.5
38	Control	8/22/12	2	218.0	67.8	33.4
41	Treatment	8/28/12	5	196.0	63.0	34.7
42	Control	8/29/12	2	276.0	64.0	47.4
43	Treatment	8/23/12	2	212.0	65.0	35.3
44	Control	8/20/12	2	205.5	60.0	40.1
45	Control	8/27/12	2	262.3	65.3	43.3
47	Treatment	9/5/12	3	160.0	63.0	28.3
49	Control	8/29/12	2	239.0	62.5	43.0
51	Control	9/5/12	5	367.3	63.8	63.5
52	Treatment	9/14/12	5	169.0	62.5	30.4
53	Treatment	8/31/12	3	201.5	64.0	34.6
54	Control	9/7/12	2	362.0	64.3	61.6
55	Treatment	8/22/12	3	179.2	64.0	30.8
56	Treatment	9/19/12	2	192.4	63.0	34.1

ID #	Total Calls Completed	Average Daily Step Count	Study End Date
2	-	-	6/7/12
5	-	-	9/28/12
8	-	-	6/1/12
9	-	-	9/23/12
10	17	3268	9/23/12
11	15	10185	10/4/12
12	-	-	10/4/12
13	-	-	10/4/12
16	-	-	1/20/13
18	8	10900	11/30/12
19	13	7000	12/5/12
20	-	-	11/30/12
21	16	9943	12/1/12
22	-	-	11/30/12
25	3	7725	1/1/13
27	-	-	1/9/13
28	14	7216	1/9/13
29	14	8200	1/3/13
30	-	-	1/5/13
31	16	7400	12/27/12
32	-	-	2/10/13
33	12	5000	1/23/13
34	-	-	1/30/13
35	15	11816	4/21/13
36	-	-	2/22/13
37	11	7217	2/13/13
38	-	-	3/22/13
41	13	8308	2/28/13
42	-	-	2/29/13
43	13	10294	2/23/13
44	-	-	2/20/13
45	-	-	2/27/13
47	14	8050	3/5/13
49	-	-	2/29/13
51	-	-	2/28/13
52	13	8900	3/14/13

ID #	Total Calls Completed	Average Daily Step Count	Study End Date
53	7	N	2/28/13
54	-	-	3/6/13
55	9	N	2/22/13
56	9	N	3/19/13

ID #	Blood Pressure1	Waist Circumference 1	Visceral Adipose Tissue 1	Truncal Fat % 1	Total Body Fat % 1
2	122/84	53.00	.		
5	116/72	40.25	.		
8	130/86	54.00	.		
9	156/90	54.75	.		
10	126/78	56.50	.		
11	122/74	49.50	.		
12	116/82	41.00	.	39.4%	39.6%
13	158/98	73.00	.		
16	110/78	45.00	.	37.0%	38.3%
18	128/74	55.50	.	52.7%	53.9%
19	110/70	41.50	.	41.5%	44.6%
20	122/68	42.50	.		
21	140/92	39.00	.	41.6%	41.9%
22	108/64	35.50	.		
25	120/86	37.50	.		
27	120/74	62.00	.	45.4%	47.1%
28	122/80	43.00	.		
29	140/60	47.00	.		
30	116/70	43.50	.	37.4%	38.7%
31	110/80	49.50	.	44.0%	45.0%
32	118/76	40.00	.		
33	110/70	50.50	.	47.2%	47.7%
34	130/90	45.00	.		
35	132/80	48.00	262.0	44.2%	41.5%
36	140/70	37.75	.	45.8%	45.4%
37	136/90	51.00	327.0	51.5%	45.9%
38	124/70	42.00	.	45.7%	46.0%
41	110/80	41.00	.	42.8%	44.7%
42	116/68	46.00	.	37.2%	42.5%

ID #	Blood Pressure1	Waist Circumference 1	Visceral Adipose Tissue 1	Truncal Fat % 1	Total Body Fat % 1
43	118/80	39.00	.	40.9%	43.2%
44	118/76	40.25	.	50.9%	49.0%
45	128/88	46.00	.	51.6%	49.3%
47	90/64	36.50	.	41.1%	40.8%
49	142/84	50.00	.		
51	130/82	60.00	.		
52	110/80	36.00	.	39.1%	39.5%
53	128/88	41.00	.	48.4%	49.6%
54	120/80	64.00	442.0	54.9%	50.6%
55	100/58	39.50	152.0	45.9%	44.9%
56	140/60	42.00	174.0	44.6%	46.1%

ID #	Blood Pressure 2	Waist Circumference 2	Visceral Adipose Tissue 2	Truncal Fat % 2	Total Body Fat % 2
2	130/82	47.00	.		
5	120/65	42.00	.		
8	132/98	45.50	.		
9	100/76	51.50	.		
10	132/72	55.75	.		
11	118/80	40.50	.		
12	124/92	41.00	.	38.7%	40.10%
13	190/92	73.00	.		
16	116/74	41.00	165	44.2%	42.30%
18	120/64	42.00	203	54.4%	55.20%
19	138/68	39.00	183	41.8%	46.60%
20	110/70	36.00	.		
21	136/86	40.00	179	45.9%	46.00%
22	116/68	30.00	.		
25	.	.	.		
27	116/82	44.75	.		
28	.	.	.		
29	114/80	43.00	.		
30	104/76	42.00	236	45.8%	44.60%
31	.	64.75	.	49.1%	49.60%
32	126/90	41.00	.		
33	110/74	46.00	145	46.7%	47.70%
34	.	.	.		

ID #	Blood Pressure 2	Waist Circumference 2	Visceral Adipose Tissue 2	Truncal Fat % 2	Total Body Fat % 2
35	.	.	228	41.8%	39.50%
36	124/78	37.00	119	41.7%	43.60%
37	142/98	47.50	.		
38	116/76	37.00	121	42.5%	43.90%
41	.	.	203	47.0%	48.90%
42	126/82	48.50	.		
43	122/90	39.50	.		
44	122/90	43.00	217	53.5%	50.40%
45	130/86	45.75	177	54.5%	52.20%
47	106/60	34.00	178	47.7%	47.40%
49	.	.	.		
51	126/90	60.00	.		
52	.	.	.		
53	142/100	41.00	.		
54	128/78	62.75	385	50.7%	47.40%
55	124/80	64.75	134	49.2%	46.80%
56	90/60	30.50	.	33.8%	37.20%

ID #	Weight 2	Height 2	BMI 2
2	254	69.8	36.7
5	220	64.8	36.9
8	263	71.0	36.7
9	301	67.8	46.1
10	311	72.0	42.2
11	220	72.8	29.2
12	216	65.5	35.4
13	541	76.0	65.8
16	183	63.5	31.9
18	275	63.0	48.7
19	277	66.0	44.7
20	173	67.0	27.0
21	168	61.5	31.2
22	127	61.3	23.8
25	199	63.5	34.7
27	213	62.0	39.0
28	223	69.0	32.9
29	220	63.5	38.4

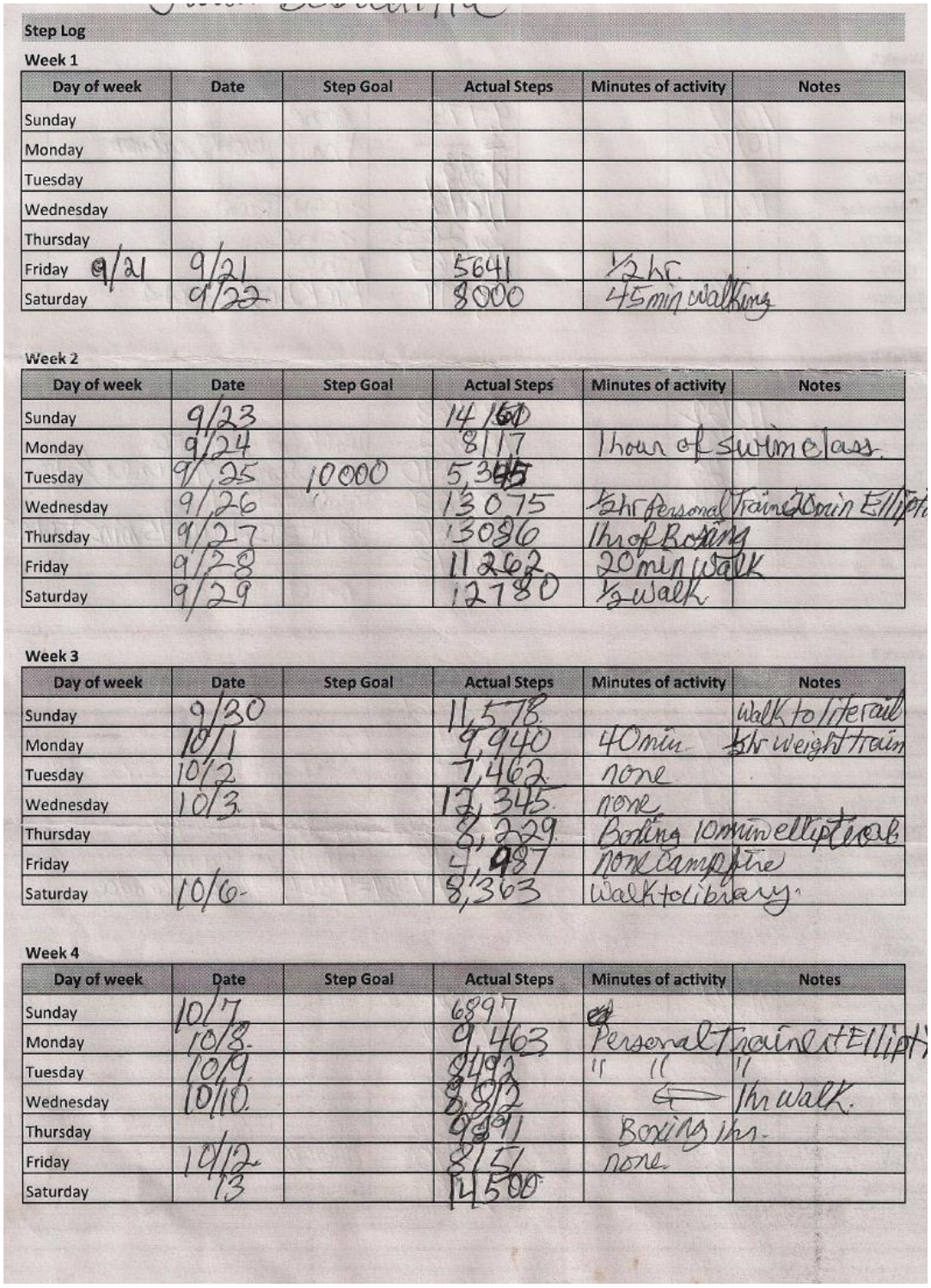
ID #	Weight 2	Height 2	BMI 2
30	213	66.5	33.9
31	243	64.8	40.7
32	186	61.3	34.9
33	262	65.8	42.6
34	277	68.5	41.5
35	190	63.0	33.7
36	188	64.0	32.3
37	207	63.5	36.1
38	181	67.8	27.7
41	189	63.0	33.5
42	271	64.0	46.5
43	198	65.0	32.9
44	184	60.0	35.9
45	244	65.3	40.3
47	155	63.0	27.5
49	226	62.5	40.7
51	376	63.8	65.0
52	174	62.5	31.3
53	N	64.0	0.2
54	328	64.3	55.9
55	177	64.0	30.4
56	152	63.0	26.9

	Telephonic Coaching Calls							
ID #	1	2	3	4	5	6	7	8
10	4/19	4/26	5/3	5/10	5/17	5/24	5/31	6/7
11	4/15	4/22	4/29	N	5/15	5/21	5/28	6/4
18	N	N	6/27	N	7/12	N	7/26	N
19	6/13	6/20	6/27	N	7/11	N	7/25	8/1
21	6/20	6/27	N	7/11	7/18	7/25	8/1	8/8
25	7/6	7/14	7/21	N	8/11	8/18	9/24	9/29
28	7/23	7/30	8/6	8/14	8/20	N	9/5	9/12
29	7/26	8/2	8/9	8/16	N	8/30	9/6	9/13
31	7/19	7/26	8/2	8/9	8/16	8/23	8/30	N
33	N	8/22	8/29	9/6	N	9/27	10/4	N
35	11/7	11/21	11/28	12/5	N	12/19	N	1/2
37	9/5	9/12	9/19	N	10/3	N	N	N
41	9/17	9/24	10/1	10/8	10/15	N	10/29	N
43	9/19	9/26	N	10/10	10/17	N	10/31	11/7

Telephonic Coaching Calls								
ID #	1	2	3	4	5	6	7	8
47	9/24	10/2	10/10	10/17	10/24	11/1	N	N
52	10/1	10/8	10/15	N	10/29	11/7	11/12	11/19
53	10/5	N	10/22	10/29	N	N	N	11/26
55	10/3	N	10/17	10/24	10/31	N	11/21	11/28
56	N	10/18	N	11/1	N	N	11/29	N

Telephonic Coaching Calls									
ID #	9	10	11*	13	15	17	19	21	23
10	6/14	6/21	6/28	7/12	7/26	8/9	8/23	9/6	9/20
11	6/11	6/18	7/1	7/16	7/16	7/31	8/20	N	9/12
18	N	8/16	N	8/30	N	10/11	10/25	N	11/29
19	N	N	8/22	8/29	9/19	10/17	10/31	11/21	12/5
21	8/15	8/22	8/29	9/12	9/26	10/10	10/24	11/7	11/28
25	10/6	10/13	N	10/27	N	11/13	11/26	12/3	1/2
28	9/19	9/26	10/17	10/31	N	N	12/5	12/19	1/2
29	9/20	9/27	10/18	11/12	N	11/29	N	12/20	1/3
31	9/13	9/20	10/4	10/18	11/1	N	11/29	12/13	12/27
33	10/26	N	11/12	N	11/28	12/13	12/27	1/9	1/23
35	1/9	N	1/23	2/6	2/20	3/6	3/26	4/10	4/24
37	10/31	N	11/28	N	12/19	1/2	2/6	2/20	3/6
41	11/12	N	11/26	12/10	N	1/2	1/16	1/30	2/13
43	N	11/21	11/28	12/12	12/26	1/9	N	2/6	2/20
47	11/21	12/5	12/19	1/2	1/23	N	N	N	3/14
52	11/26	N	12/10	12/26	N	N	2/6	2/20	3/6
53	12/3	N	12/17	N	N	N	N	2/18	N
55	12/5	N	12/19	N	N	N	1/30	N	N
56	12/13	12/20	1/3	N	N	2/7	2/21	N	3/6

Appendix G: Sample Daily Step Tracking Log by a Participant



Step Log

Week 1

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday 9/21	9/21		5641	1/2 hr.	
Saturday	9/22		8000	45 min walking	

Week 2

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	9/23		14 160		
Monday	9/24		8117	1 hour of swim class.	
Tuesday	9/25	10000	5345		
Wednesday	9/26		13075	1/2hr Personal Trainer 20min Ellipti	
Thursday	9/27		13096	1hr of Boxing	
Friday	9/28		11262	20 min walk	
Saturday	9/29		12780	1/2 walk	

Week 3

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	9/30		11,578		Walk to Interail
Monday	10/1		9,940	40min	1/2hr weight train
Tuesday	10/2		7,462	none	
Wednesday	10/3		17,345	none	
Thursday			8,229	Boxing 10min elliptical	
Friday			9,987	none Campfire	
Saturday	10/6		8,363	Walk to library.	

Week 4

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	10/7		6897		
Monday	10/8		9,463	Personal Trainer + Ellipti	
Tuesday	10/9		8493	" "	"
Wednesday	10/10		8,812	⇦	1hr walk.
Thursday			9991	Boxing 1hr.	
Friday	10/12		8154	none	
Saturday	13		14500		

Week 5

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	10/14		9,778	none	
Monday	10/15		[illegible]	1hr. Physical Trainer	
Tuesday	10/16		[illegible]		
Wednesday	10/17		[illegible]	½ pers. Train	
Thursday			8,263	none.	
Friday			11,763	none	
Saturday	10/20		17,899	Kickbox. class	

Week 6

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	10/22		8,468		
Monday	10/22		10,582	walk for groceries	
Tuesday	10/23		8,290	personal Trainer ½hr.	
Wednesday	10/24		9,102	walk to Foshay.	
Thursday	25		8,166	½hr pers. Train 15 min stairs	
Friday			3013		
Saturday			Forgot	mall	

Week 7

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday			~~forgot~~		
Monday	10/29		10814		
Tuesday	30		8000	personal Trainer ½hr	
Wednesday	31		6905		
Thursday	11/1		4083.	moved Willetta	
Friday	11/2		16,395	- Hockey Game	
Saturday	11/3		2000+7354=9354	Helped Randee	

Week 8

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	11/4		12770		
Monday	11/5		9574		
Tuesday	6		9301		
Wednesday	7		11300		
Thursday	8		6500		
Friday	9		12470	museum,	
Saturday	10		3,000		

Week 9

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	11/11	~~8,300~~	~~8,300~~	clean kitchen	
Monday	11/12	9,000	4,000		
Tuesday	Broken Pedometer				
Wednesday					
Thursday					
Friday					
Saturday					

Week 10

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday					
Monday					
Tuesday					
Wednesday	11/28	9,000	3,500	none	
Thursday	11/29	~~4,000~~	4,060	Boxing 2 hr.	
Friday	11/30		5,000		
Saturday	12/1		6,700		

Week 11

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	12/2		6800		
Monday	3				
Tuesday	4				
Wednesday	5				
Thursday	6				
Friday	7				
Saturday	8				

Week 12

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	12/9				
Monday	12/10				
Tuesday	12/11	7,000	3210	none	
Wednesday	12		7,000		
Thursday	13		7,044		
Friday	14				
Saturday	15				

Week 13

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	12/16				
Monday	17				
Tuesday	18				
Wednesday	19				
Thursday	20				
Friday	21				
Saturday	12/22				

Week 14

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	12/23				
Monday	24				
Tuesday	25				
Wednesday	26				
Thursday	27				
Friday	28				
Saturday	29				

Week 15

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	30				
Monday	31				
Tuesday	1/1/13				
Wednesday	1/2/13				
Thursday	1/3	7,000	8,000		
Friday	4		4,000		
Saturday	5		9135		

Week 16

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	6		7400		
Monday	1/7		6255		
Tuesday	1/8		5050		
Wednesday	1/9		6200		
Thursday	1/10		4000		
Friday	1/11		7300		
Saturday	1/12		600		

Week 17

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	1/12/12		500		
Monday	13		654		
Tuesday	14		~~455~~		
Wednesday	15				
Thursday	16				
Friday	17				
Saturday	18				

Week 18

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday	25				
Saturday	27				

Week 19

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	27				
Monday	28	2910.			
Tuesday	29	6263			
Wednesday	30	5000.			
Thursday	31	5900			
Friday	1	3000			
Saturday	2	3,000			

Week 20

Day of week	Date	Step Goal	Actual Steps	Minutes of activity	Notes
Sunday	2/3	3110			
Monday	2/4	2000			
Tuesday	2/5	4381			
Wednesday	2/6.	5520			
Thursday	7	0		Boxing 1hr	
Friday	8	7338			
Saturday	2/9	12607			