Step It Up ECU: Comparing a 10,000 Step a Day Goal to a Small, Relative Step Goal in a Pedometer-Based Physical Activity Intervention

by

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Pedometers have been shown to be valid and effective tools for increasing physical activity, which is associated with improved overall health. While most research encourages participants to achieve 10,000 steps per day, there is little research conducted on the effectiveness of other types of step goals. The purpose of the present pilot study was to compare the effectiveness of a 10,000 step-a-day goal versus a small, relative, participant-selected step goal. Participants (N = 37) were primarily female (97%), obese (BMI *M* = 32.67, *SD* = 4.60), middle-aged (*M* = 43.49, *SD* = 9.14), borderline sedentary (*M* = 5497 steps/day, *SD* = 2964), Caucasian (59%) and African American (41%), university employees. Participants were randomly assigned to either a: 1) 10,000 daily step goal or b) small changes relative step goal (typically a 2,500-3,000 total step increase). Participants then engaged in weekly15-minute sessions over a 12 week period. Seven meetings were face-to-face and 5 were conducted via phone. Seventy-three percent of participants completed the study. Measures were given to assess depression, life satisfaction, and cognitive and behavioral self-management strategies. A repeated-measures ANOVA showed a significant main effect of time on step counts ($p < 0.001$), but no differences between groups ($p = 0.52$). Notably, participants in the relative goal group achieved their step goal increase of approximately 3,000 steps, while participants in the 10,000

step group did not meet their 10,000 goal on average. Cognitive and behavioral self-management strategies were related to higher step counts ($r = 0.57$, $p = 0.002$) and step count changes ($r = 0.43$, $p = 0.027$). Depressive symptoms ($p < 0.001$) and life satisfaction ($p = 0.016$) improved over the course of the study, but did not differ between groups. While these data are preliminary, they suggest that both goal types can increase step counts, but a relative step count and psychological and behavioral factors play an important role in goal achievement.

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CHAPTER 1: LITERATURE REVIEW

Overweight in the US

With overweight and obesity rates for children and adults steadily rising over the past three decades, unhealthy weight has reached epidemic proportions in the US. Currently, 67% of US adults are considered overweight, and 34.2% are considered obese (National Center for Health Statistics, 2009). These percentages are even higher for US minorities; 75.8% of Mexican American adults and 76.1% of non-Hispanic black adults are overweight, compared to 64.2% of Caucasian adults (Ogden et al., 2006). While these minority groups have disproportionately higher levels of overweight, rising rates of overweight have affected most all subgroups in the US, including both men and women (Lewis et al., 2000; Mokdad et al., 1999), African American, Caucasian, Hispanic, and other minority populations (National Center for Health Statistics, 2009; Ogden et al., 2006), and the young and the old (Mokdad et al., 1999; Ogden, Carroll, & Flegal, 2008).

Perhaps most troubling is the fact that obesity rates in the US have more than doubled between 1980 and 2000 (Flegal, Carroll, Ogden, & Johnson, 2002). This rising trend has led Healthy People 2010 to call upon Americans to increase the number of people achieving healthy weight to 60% and to reduce obesity rates to 15% by 2010 (Do, Hootman, Helmick, & Brady, 2011). Unfortunately, these aspirational objectives were not met, and it has been proposed that these goals will be readdressed yet again during Healthy People 2020. While recent years have heralded a considerable amount of media coverage related to the obesity epidemic (Hill, Catenacci, & Wyatt, 2005) and large-scale healthy weight interventions, obesity rates have yet to decrease (Ogden et al., 2006).

Overweight, Chronic Illness, and Mental Health

The need for Americans to reduce weight in the US is urgent. Overweight and obesity are highly correlated with chronic illness and have led to over 350,000 deaths in the year 2000 alone (Mokdad, Marks, Stroup, & Gerberding, 2004; Mokdad, Marks, Stroup, & Gerberding, 2005). Currently, obesity is the second leading cause of preventable death behind smoking (Hurt, Frazier, McClave, & Kaplan, 2011), and experts suggest that obesity may become the leading cause of preventable deaths in the US in the near future (Mokdad et al., 2004). In fact, the rate of obesity-related illness is so great that some predict it will lead to the first decline in life-expectancy since the turn of the century (Olshansky et al., 2005). The reason that unhealthy weight is correlated with mortality is complicated and multi-faceted. Because obesity leads to higher triglycerides, hypertension, and hyperlipidemia (Field, Barnoya, & Colditz, 2004), studies show that approximately a quarter of coronary heart disease deaths are attributed to overweight (Seidell, Verschuren, van Leer, & Kromhout, 1996). Overweight is also strongly associated with Type 2 diabetes due to its effects on insulin resistance. Abdominal fat is particularly predictive of type 2 diabetes; studies suggest that almost 80% of variance in insulin sensitivity can be accounted for by abdominal overweight (Carey, Jenkins, Campbell, Freund, & Chisholm, 1996).

Overweight is also closely related to cancer deaths due to hormonal and gastro-intestinal complications (Field et al., 2004). In a study of over 900,000 adults, men with a BMI over 40 had 52% higher cancer death rates, while women with a BMI over 40 had 62% higher death rates than normal weight individuals (Calle, Rodriguez, Walker-Thurmond, & Thun, 2003). Calle et al. estimated that overweight accounted for 14% of cancer deaths in men and 20% in women (Calle et al., 2003).

Finally, compromised quality of life has been associated with overweight. One British study illustrated that health-related quality of life is significantly lower in overweight individuals (Soltoft, Hammer, & Kragh, 2009). A review by Faith and colleagues (2011) illustrate that obesity is frequently predictive of increased depression, and in some cases depression even predicts obesity. Overall, obesity is related to as much as a 40% increase in depression in a non-clinical population; these rates may be even higher for young women (Chen, Jiang, & Mao, 2009). This increase in depression may be because obese individuals generally have significantly poorer health, have been shown to be discriminated against socially and professionally, and are more limited in their daily functioning (Field et al., 2004).

Judgment from the media and from those within one's social environment also can be extremely detrimental to the self-esteem of overweight individuals. Overweight people are often portrayed as lazy, undisciplined, comical, and/or unclean (Johnson, 2004). This barrage of negative feedback likely plays a large role in body image dissatisfaction, particularly in those with long-term obesity or individuals whose significant others contribute to this negative feedback (Sarwer, Wadden, & Foster, 1998).

Overweight and Cost

The costs of these significant physical and psychological symptoms of overweight have been particularly burdensome on the nation's economy. Research from over 45,000 employees suggests that medical expenditures related to overweight exceed $3,500 a year for women with a BMI between 35 and 39.5, compared to $2,000 a year for women with a normal BMI between 18.5 and 24.9 (Finkelstein, Fiebelkorn, & Wang, 2005). Further, obese women miss 5 to 8 work days a year, versus normal weight women who miss approximately three days. While male employees have significantly less medical expenditures and absenteeism, their costs follow a similar trend (Finkelstein et al., 2005). In 2001, medical costs for obese individuals was 37% higher than costs of normal-weight individuals (Thorpe, Florence, Howard, & Joski, 2004).

The Contributors of Overweight: Nutrition and Physical Activity

Considering the many physical, psychological, and economic implications of overweight, it is important to understand the contributors to the development of overweight. Research shows that genetics (Clement et al., 1996; Stunkard, Harris, Pedersen, & McClearn, 1990; Wang et al., 2009), insulin sensitivity and macronutrient metabolism (Swinburn, Boyce, Bergman, Howard, & Bogardus, 1991; Swinburn & Ravussin, 1994; Wang et al., 2009), low sympathetic nervous system activity (Astrup, 1995), and human evolution (Tataranni & Ravussin, 2004) may serve as factors in weight gain (Hill et al., 2005; Tataranni & Ravussin, 2004).

More controllable, behavioral factors that contribute to weight status are nutrition (i.e., energy consumed) and physical activity (i.e. energy expended). The most simplistic model that determines weight status is the energy balance equation; weight gain or loss is determined by the balance of energy consumed versus energy spent within one's body (Hill et al., 2005). In other words, to maintain body weight, one must use an equivalent amount of energy as what was consumed in a day. Using this model, obesity is generally considered the result of "chronic energy imbalance," or an "energy gap" (Heymsfield, 2009; Hill, Wyatt, Reed, & Peters, 2003). Thus, many researchers now agree that our nation's rapid development of a "dangerous food and physical activity environment" (Horgen & Brownell, 2004) is the reason behind the current obesity epidemic (Hill et al., 2003; Horgen & Brownell, 2004). Hill and colleagues (Hill, Peters, & Wyatt, 2009) propose that the energy gap can be reduced by increasing physical activity needed to burn energy and/or reducing calories consumed. These two elements have thus been the focus of most obesity treatment programs to date.

Physical Activity

Some researchers suggest that the current energy gap is a result of lack of physical activity in particular. Studies show that ancestral humans generally burned 1000 kcal daily via physical activity and consumed 3000 kcal a day, creating at 3:1 ratio of energy consumed/energy expended (Saris et al., 2003). Interestingly, current estimates suggest that modern sedentary people of wealthy first world countries typically consume only 2100 kcal a day while only burning only 300 kcal daily, creating a 7:1 ratio of energy consumed/energy expended. Thus, while energy consumption has decreased in modern times, physical activity has decreased over three-fold, creating an energy gap expanded by sedentary lifestyles. There is further evidence that sedentary lifestyles may be directly related to the obesity epidemic experienced over the past several decades. Research suggests that the 1980s heralded increased hours in front of the television, greater use of automobiles, and the development of computers and gaming systems (Saris et al., 2003). Considering that the rate of obesity has doubled between 1980 and 2000 (Flegal et al., 2002), this evidence seems to support that the sedentary lifestyle of US citizens may be at the core of weight gain in America.

Research utilizing accelerometers has shown a relationship between higher rates of obesity and lower rates of physical activity (Yoshioka et al., 2005). In fact, one study examined 15,239 men and women across the European Union and found that the odds ratio for obesity was 0.52 for highly physically active people versus sedentary individuals (Martinez-Gonzalez, Martinez, Hu, Gibney, & Kearney, 1999). Considering that most of these studies are based on self-report, the level of sedentary behaviors among obese individuals may be under-estimated (Irwin, Ainsworth, & Conway, 2001; Jakicic, Polley, & Wing, 1998; Levin, Jacobs, Ainsworth, Richardson, & Leon, 1999; Lichtman et al., 1992).

However, despite the strong relationship between physical activity and obesity, exploring potential causal links between low physical activity and the development of obesity are difficult. While some suggest that low physical activity leads to obesity, other studies illustrate that obesity predicts low physical activity (Cooper, Page, Fox, & Misson, 2000; Hemmingsson & Ekelund, 2007). In fact, a study of 6279 men and women found that the odds of developing obesity with moderate to high physical activity were .81 for women and 1.28 for men, while the odds of becoming inactive for those with high BMI was 1.91 for women and 1.50 for men (Petersen, Schnohr, & Sorensen, 2004). These data suggest that obesity may be a stronger predictor for inactivity than inactivity for obesity. However, it may be that weight status and physical activity are only significantly related for obese individuals. A stratified analysis of physical activity by weight status in 278 individuals illustrated that BMI accounted for 24% of physical activity variation for obese participants and only 2% of physical activity variation for non-obese individuals (Hemmingsson & Ekelund, 2007). Regardless of the directionality of this relationship, the important lesson for interventionists is that a strong relationship exists between obesity and low physical activity.

Physical Activity as an Independent Predictor of Morbidity and Mortality

Physical activity is not only linked to obesity; a lack of physical activity appears to also have direct health consequences regardless of weight. Exercise biologists argue that human bodies were not meant to function on low levels of physical activity. In fact, it has been argued that, until the Industrial Revolution, humans evolved as a highly physically active species and that inactivity has caused abnormal phenotypic expression of our genetic make-up (Booth, Gordon, Carlson, & Hamilton, 2000). This hypothesis appears to be supported by the physical activity literature. There are many studies illustrating the connection between physical inactivity and an increased risk or increased severity of a myriad of ailments, including cancer (Lee, 2003), heart disease (Franco et al., 2005), stroke (Krarup et al., 2007; Stroud et al., 2009), diabetes (Jonker et al., 2006), and even late-life cognitive function decline (Lautenschlager et al., 2008). In fact, the American Heart Association has identified sedentary lifestyle as the fourth leading cause of coronary artery disease (Fletcher et al., 1992). In lieu of this research, some theorists suggest that obesity itself does not necessarily lead to health concerns; The "fit but fat" theory suggests that regardless of weights status, if one has high cardiovascular fitness, one may still be considered "healthier" than a sedentary lean person. In fact, 9% of US adults could be considered obese yet at no increased risk for health concerns, and 17% of adults are overweight and yet have high cardiovascular fitness (compared to 30% of normal weight participants; Duncan, 2010).

Physical inactivity has also been directly related to mortality independent of weight status. The American Association of Retired Persons Diet and Health Study conducted by the National Institute of Health followed 252,925 women and men over the age of 50. Participants who completed regular moderate activity (30 minutes most days of the week) had a 27% decrease in mortality risk and those who completed vigorous exercise for 20 minutes three times per week had a 32% decrease in mortality risk. This significant trend was found in normal weight, overweight, and obese subgroups (Leitzmann et al., 2007). This relationship is consistent in elderly populations. Studies of individuals over 70 years old found that physical activity lowered risk of mortality by 30-32% (Gregg et al., 2003; Manini et al., 2006). These trends seem to hold true for physical activity and chronic illness; the American Cancer Society has attributed one-third of cancer-related deaths to a combination of poor physical activity and nutrition (Kushi et al., 2006). Some researchers estimate that physical inactivity leads to approximately one-third of all colon cancer, coronary heart disease, and type 2 diabetes deaths (Powell & Blair, 1994).

Physical Activity and Psychological Outcomes

Finally, physical inactivity appears to have an impact on psychological factors. One cross-sectional Finnish study that followed 727 young men found that leisure-time physical activity levels were related to all levels of health-related quality of life, including physical functioning, mental health, vitality, general overall health, and low co-morbidity (Hakkinen et al., 2010). Further research shows that physical activity is linked to lower levels of depression (Daley, 2008; Dunn, Trivedi, & O'Neal, 2001; Paluska & Schwenk, 2000), reduction of some types of anxiety (Paluska & Schwenk, 2000; Strohle, 2009; Strohle et al., 2009), and improved mental health in general (Asztalos, De Bourdeaudhuij, & Cardon, 2009) using a variety of physical activity intensity levels. Notably, a study of menopausal women who “mall walk” found that walking the mall regularly is associated with higher satisfaction with life according to Deiner’s “Satisfaction with Life Scale” (SwLS) than those who do not walk (Owens, 2007). Another 12 week study assessing a physical activity intervention in congenital heart disease patients found significant changes in the SwLS after exercise intervention (Dua, Cooper, Fox, & Graham-Stuard, 2010). Future studies should focus on better understanding the relationship between life satisfaction and physical activity.

While it is believed that the relationship between physical activity and mental health status is a complex relationship involving developmental, psychological, and neurobiological factors (Strohle, 2009), there is significant research to suggest that the modality of improvement is neurochemical in nature (Dishman et al., 2006). Exercise appears to facilitate neuro-generative and neuro-protective processes. Further, exercise enhances nervous system adaptation that protects against mood disorder while affecting neurotransmitters such as serotonin, which plays a large role in disorders such as depression (Dishman et al., 2006). These discoveries have led to studies that suggest that exercise may be effective in the treatment of mild to moderate mood disorders (Strohle, 2009). A recent review paper illustrated that there is a link between exercise interventions and decreased depression, lower anxiety, and increased psychological well-being. Further, exercise is comparable to antidepressants in mild to moderate depression (Carek, Laibstain, & Carek, 2011).

Physical Activity Recommendations

Considering the extensive literature on the value of physical activity for physical and mental health and well-being, various organizations have encouraged certain physical activity standards. Currently, the American College of Sports Medicine (ACSM), the American Heart Association (AHA), and the American Cancer Society (ACS) recommend that individuals engage in moderate physical activity (such as a brisk walk) for at least 30 minutes a day on five or more days of the week or 20 minutes of vigorous activity (such as jogging) for at least 20 minutes on three days of the week (Haskell et al., 2007; Kushi et al., 2006). Recommendations jump to 60-90 minutes most days to maintain weight loss (Phelan, Roberts, Lang, & Wing, 2007). The recommendations of the Institute of Medicine (IOM), released in 2001, are even more stringent: As much as 90 minutes of moderate intensity activity everyday of the week (Institute of Medicine, 2005). These recommendations are based on the physical activity literature and the significant health benefits associated with long-term, regular, moderate to vigorous exercise. Importantly, it has been shown that there is benefit from both exercising continuously and pursuing exercise in 10-minute bouts.

Challenges to Current Recommendations

However, some researchers have begun to question whether this is an appropriate recommendation for activity promotion in overweight and obese individuals. These recommendations may be unrealistic for those who carry excess weight because physical activity can be challenging for this population. Obese individuals have reported that physical activity results in many aversive problems, include chaffing, feeling out of breath, anxiety related to exercising in public, joint pain, feelings of incompetence, and overall discomfort (Hemmingsson & Ekelund, 2007). Fear may be another barrier to physical activity adherence in obese adults. A recent study suggests that young adults whose fear was measured at 4 minute intervals during a treadmill exercise experienced a significantly high level of fear when they had a high body mass and high anxiety sensitivity compared to at-rest controls (Smits, Tart, Presnell, Rosenfield, & Otto, 2009). Yet another obstacle that obese exercisers must often face is stigma. Research shows that women who have experienced stigmatization due to overweight in the past have more body dissatisfaction and are more motivated to avoid exercise (Vartanian & Shaprow, 2008). Finally, these trends may be partially due to the fact that US citizens live in an environment that is non-conducive to maintaining physical activity (Owen, Humpel, Leslie, Bauman, & Sallis, 2004; Sallis et al., 2006).

Another study conducted on 57 obese women examined the levels of exhaustion and pain obese participants experience when walking (Mattsson, Larsson, & Rossner, 1997). Though the pace of walking was self-selected, on flat ground, and indoors, the percentage of VO2 max of obese women during walking was significantly higher than non-obese controls. Considering that a similar study found that four minutes of walking causes 70% of obese individuals to reach their VO2 max (Mattsson et al., 1997), it is not surprising that obese women are more likely to experience over-exertion, walk significantly more slowly, and report pain compared to non-obese controls when attempting to follow guidelines over 20 times this long. This leads one to question whether the physical activity guidelines are appropriate, realistic, or safe for this population. Recent research suggests that these goals may not even be realistic for normal-weight individuals. One study found that only 26% of normal weight participants met the 2002 IOM recommendations (compared to 13% of overweight/obese participants; Davis, Hodges, & Gillham, 2006).

Overall, only a quarter of all adults reported meeting the ACSM recommendations and 29% reported having no physical activity at all (Centers for Disease Control and Prevention (CDC), 2001). Considering that these data are based on self-report it is likely that these rates are even lower. More objective accelerometer data show that, contrary to reports, less than 5% of people achieve the ACSM recommendations (Troiano, Berrigan, Dodd, Masse, Tilert, & McDowell, 2008). Further, inactivity rates are even lower when surveying only African American and Latino adults (Pratt, Macera, & Blanton, 1999). These dismal statistics highlight the urgent need for a critical evaluation of our current physical activity recommendations and behavioral change strategies.

Dose-Response Trends Regarding Physical Activity

Fortunately, research is beginning to illustrate that less structured, less intense, or less frequent physical activity can still make a significant difference in health outcomes and weight reduction. In the American Association of Retired Persons Diet and Health Study, it was shown that participants had a 19% decrease in death risk of when physically active even when the participants did not meet the recommended levels of physical activity (Leitzmann et al., 2007). Another study of 235 individuals over a six-month period showed that a lifestyle physical activity program designed to increase activity throughout the day can help individuals increase their physical activity and cardio-respiratory fitness as well as a structured exercise program (Dunn et al., 1998), suggesting that structured programs of a certain intensity and time are not necessary to elicit positive health changes. Further, the Physicians Health Study illustrated that exercising only once a week caused men to have a 36% reduced risk for developing non-insulin dependent diabetes mellitus (Manson et al., 1992).

While the risk reduction for these chronic illnesses are not as high as the risk reduction one would experience with more moderate of vigorous exercise most or all days of the week, it does illustrate that significant health improvement can result from even modest amounts of physical activity. This is probably because exercise appears to have a dose-response relationship with abdominal obesity (Slentz et al., 2005), cardiorespiratory fitness (Church, Earnest, Skinner, & Blair, 2007), weight (Slentz et al., 2004), and perhaps even depression (Dunn et al., 2001). In other words, because mild and moderate physical activity can have correlated and significant effects on health outcomes, pursuing activity levels less than the national recommendations has been shown to still be beneficial for health and weight outcomes for overweight and obese individuals. Perhaps Slentz and colleagues explain this relationship best: “Some exercise is better than none, and more is better than less” (Slentz, Houmard, & Kraus, 2009, pp. S28-29).

How to Measure Physical Activity

It has been demonstrated that physical activity, even at varying amounts and intensities, is an important indicator of overall health. However, in order to achieve physical activity changes, one must be able to measure and track activity change across time. Generally, doubly labeled water is considered the “gold standard” of measuring energy expenditure (Ainslie, Reilly, & Westerterp, 2003). However, doubly labeled water can be an unrealistic measure; purchasing the isotopes and equipment could cost as much as $1800 per participant and fails to offer detailed information on the type, intensity, or duration of physical activity (Irwin et al., 2001).

Most typically, self-report measures are used to measure physical activity. While self-report measures are the easiest method of measuring physical activity research (Aittasalo, Miilunpalo, Kukkonen-Harjula, & Pasanen, 2006; Boutelle & Kirschenbaum, 1998; Carels et al., 2005; Helsel, Jakicic, & Otto, 2007), these measures also have limitations. Research shows that individuals (particularly obese individuals) tend to over-estimate their amount of regular physical activity (Irwin et al., 2001; Jakicic et al., 1998; Levin et al., 1999; Lichtman et al., 1992) and that over-estimating exercise is related to poorer outcomes in weight loss programs. In fact, one study showed that 45% of overweight women over-report exercise, and that this predicted poor weight loss outcomes across time (Jakicic et al., 1998). Further, research shows that people tend to over-report recording behaviors and report having recorded at inaccurate times (Burke et al., 2006). This may be due to the social desirability theory, which states that individuals over-report culturally positive behaviors in order to improve self-esteem (Irwin et al., 2001).

Pedometers

A reliable and accurate alternative tool to these two measurement types is the pedometer. The pedometer is a small device (generally the size of one's palm) that is worn at the hip and records the number of steps taken in a day. Pedometers are relatively inexpensive and allow the participant to measure not only planned, prescribed physical activity but free-living activity as well. Research shows that the demonstrated effect size of physical activity change using pedometers is moderate to high for adults (ES = 0.72; Kang, Marshall, Barreira, & Lee, 2009).

Most pedometers are created to count a step after a particular vertical force limit has been reached (Tudor-Locke & Lutes, 2009). While limitations to the pedometer include the inability to record non-ambulatory energy expenditure, limited intensity readings, the variability of validity between different brands and types of activity, and difficulties recording at very slow speeds (Corder, Brage, & Ekelund, 2007), pedometer records are strongly correlated with accelerometers and amount of time engaged in observed activity and moderately correlated with heart rate and indirect calorimetry (Tudor-Locke, Williams, Reis, & Pluto, 2002). Further, research shows that the self-monitoring encouraged by pedometers, particularly when followed by feedback, leads to improved outcomes in both weight-loss and adherence (Tudor-Locke & Lutes, 2009).

The pedometer can serve as more than a measurement device. Pedometers have also been shown to be effective motivational tools (Merom et al., 2009; Tudor-Locke & Lutes, 2009). One study used both qualitative and quantitative measures to determine the motivational mechanisms of pedometers. Results suggest that the pedometer particularly serves as an external cue that leads to behavior change (Gardner & Campagna, 2009).

Gardner and colleagues found that the ability to self-monitor provided by pedometers also allows for goal setting, which is an important factor in social cognitive theory (Bandura, 2004) and has been demonstrated to be an effective mechanism in physical activity interventions (Shilts, Horowitz, & Townsend, 2004). In fact, research shows that pedometers predict the least amount of activity change if participants simply record their steps and the highest amount of activity change if they set a goal and record their steps (Kang, Marshall, Barreira, & Lee, 2009). Further, a recent meta-analysis of goal setting related to health behavior change illustrated that 8 of 13 studies related to physical activity and/or nutrition interventions had more positive results when using goal-setting (Shilts et al., 2004). After assessing the goal-setting practices of 664 workers in a physical activity intervention, researchers showed that the more goal-setting constructs used (based on goal-setting theory), the greater the increase in physical activity (Dishman, Vandenberg, Motl, Wilson, & Dejoy, 2009). One systematic review of pedometer use illustrated that having a step goal was the largest predictor of step increases (Bravata et al., 2007). Thus, goal-setting is an important process when using pedometers in physical activity interventions.

Pedometer Goals: 10,000 Steps a Day

While pedometers and goal-setting have been shown to be powerful tools for physical activity behavior change, questions still remain as to the number of steps one should strive to reach in a day in order to achieve physical activity change (Tudor-Locke & Lutes, 2009). Currently, the typical step goal is 10,000 steps a day (Tudor-Locke & Bassett, 2004) and this recommendation is often used in research (Lindberg, 2000). The 10,000 steps per day recommendation appeared to originate from Japanese walking club promotions in the 1960s (Tudor-Locke & Bassett, 2004). This recommendation has likely continued to gain international popularity due to the fact that it has been shown to lead to significant health benefits, roughly corresponds to physical activity recommendations, and is an easy-to-remember, concrete goal that focuses on behavior (Tudor-Locke & Bassett, 2004).

Research has shown that meeting 10,000 steps a day has many long-lasting health benefits. Ten thousand steps per day is related to improvement in BMI, body fat, waist circumference, and HDL in overweight and obese individuals (Schneider, 2006) when participants adhere to the step count recommendation. Another study sampled 730 industrial workers and found that 83 of them walked 10,000 steps or more a day. This level of walking led to lower blood pressure and sympathetic nerve activity, particularly for hypertensive patients (Iwane, Arita, Tomimoto, Satani, Matsumoto, Miyashita, et al., 2000). These recommendations appear to also be affective for diabetic indicators: a study following inactive women with a family history of type 2 diabetes were encouraged to reach 10,000 steps a day during an 8-week walking program. These women were able to increase their steps by 85% and achieve 9,200 steps per day, which led to improved glucose tolerance and blood pressure (Swartz, Strath, Bassett, Moore, Redwine, Groer, et al., 2003). Thus, it is evident that setting a 10,000 steps per day goal may have many health benefits.

However, some studies have since challenged the notion that 10,000 steps a day goal is equivalent to a 30-minute a day “moderate intensity” physical activity goal because 1) it does not measure intensity, 2) some people who pursue 30-minutes of activity still do not meet 10,000 steps per day, and 3) it does not consider non-walking activities (Tudor-Locke, Ainsworth, Thompson, & Matthews, 2002; Wilde, Sidman, & Corbin, 2001). These findings raise questions as to the validity of the 10,000 steps per day goal. This debate is further complicated by the fact that, while at least 10,000 steps per day appears to maximize benefits, some research using the 10,000 steps per day goal suggest that this may be a difficult target for many to reach.

While the research varies greatly based on recruitment population when reporting average step counts (4,000-7,500 steps per day; Bravata, 2007; Choi, Pak, Choi, & Choi, 2007), it is evident that there is a significant step deficit between average steps and the 10,000 step goal. While Choi and colleagues suggest pursuing sports activities and home activities to reduce this gap, it may be that even with these suggestions achieving approximately twice the amount of physical activity in a day for many is unlikely. For example, one study found that even when achieving 30 minutes of walking every day, less than half of sedentary women were able to reach a 10,000 step per day goal (Wilde, et al., 2001). Another study of 45 women of various baseline step count levels found that participants with low to medium baseline step counts were significantly less likely to achieve a 10,000 steps per day goal (Sidman et al., 2004).

These step counts for obese participants are likely even lower than those reported in previous research. One study found that obese individuals walk an average of 2,000 fewer steps per day compared to average-weight individuals (Raedeke, Focht, & King, 2010). Further, a study of 10 morbidly obese individuals found that participants walked only 3,763 +/- 2,223 steps per day in total (Vanhecke, Franklin, Miller, deJong, Coleman, & McCullough, 2009). The 10,000 step recommendation would thus require morbidly obese individuals to increase their steps by almost three times their typical amount in order to achieve their goals, despite known limitations to achieving physical activity in heavier individuals.

Goal Acquisition

While it may be difficult for many to reach a minimum of 10,000 steps per day, it is well known that the more steps one accumulates the more health benefits they will receive, and achieving 10,000 steps or more would thus maximize these benefits. One may then question why a 10,000 step goal would not be given to everyone in hopes that they will increase their step count to the closest attainable amount. The answer may lie in the importance of goal acquisition. The fact that the 10,000 steps per day goal is difficult to achieve, particularly for the obese, the elderly, and the sedentary, may have implications for motivation, self-efficacy, optimism, or over-all success.

Performance accomplishment is an important part of self-efficacy and future goal achievement and research suggests that improving goal achievement may increase self-efficacy and, in turn, future health behaviors (Lee, Arthur, & Avis, 2008; van de Laar & van der Bijl, 2001). Studies have shown that it can be disappointing for participants to fail in achieving their

10,000 steps per day goal, and that this could impact motivation to exercise (Korkiakangas, Alahuhta, Husman, Keinanen-Kiukaanniemi, Taanila, & Laitinen, 2010). One study assessing 43 individuals showed that participants assigned to a 10,000 steps per day goal (as well as members assigned to thirty minutes of activity) reported lower self-efficacy (Samuels, Raedeke, Mahar, Karvinen, & DuBose, 2011).

Self-efficacy is impacted by many factors that in turn strengthen goal acquisition. Self-efficacy theory (Bandura, 1997) states that self-efficacy is related to self-management techniques such as problem solving, planning, cognitive restructuring, and perceiving benefit to physical activity. In fact, some propose that self-management mediates the relationship between self-efficacy and goal acquisition (Bandura, 1997). This has been supported by research with adolescents (Dishman et al., 2005). This was done using a modified measure of health behaviors: the Modified Health Behavior Survey (mHBS; Dishman et al., 2005).

Alternative Approaches

Similar to the research on physical activity recommendations, research on step count goals has found that relative, smaller goals may have important health benefits, perhaps in a dose-response relationship. One meta-analysis found that, while 10,000 steps per day had the greatest effect size, relative goals had similar effect sizes across time (Kang et al., 2009). For example, one study assessing moderate exercise during a 24 month period found that increasing one’s step counts by 2,000 to 3,000 steps per day can improve cholesterol and overall lipid profiles (Sugiura et al., 2002) and even meet activity recommendations if pursued at a moderate pace. Further, it has been suggested that increasing walking by just one mile a day (approximately 2,000 steps) may lead to weight maintenance over time (Hill et al., 2003).

Some researchers suggest that it is more reasonable and effective to assist sedentary individuals in pursuing a lower amount of activity that can be enjoyable, attainable, long-term and still beneficial for one's health (Sidman et al., 2004; Wilde et al., 2001). One notable study by Sidman and colleagues (2004) compared a traditional 10,000 steps per day goal versus a personal step goal using pedometers. Results showed that the women walked a similar number of steps despite the goal type, and that baseline step counts appeared to be a stronger determining factor of post-test step counts than goal type.

Alternative Goal Setting

But what is a reasonable goal? One meta-analysis of nine studies found that the average step increase across the interventions was between 2,000 and 4,000 steps (Richardson et al., 2008). Another meta-analysis of 8 randomized controlled trials and 18 observational trials using pedometers found that participants were able to increase their daily step counts by a little over 2,000 steps per day (Bravata et al., 2007). Further, one study illustrated that individuals achieve similar changes, despite whether they were assigned to a 10,000 step per day goal or personal goal (Sidman, Corbin, & Le Masurier, 2004). Thus, research suggests that, despite the original goal, most individuals in a physical activity intervention program increase their steps by 2,000-3,000 above baseline (Sidman et al., 2004), suggesting that regardless of goal participants tend to increase a predictable amount. Further, research shows that a CBT approach that utilizes relative, client-selected, modifiable goals is associated with a greater increase in step count and a significant increase in self-efficacy compared to controls who utilized pedometers and recording alone (Raedeke, Focht, & King, 2010).

These findings have led to a new theoretical framework for physical activity interventions called the Small Changes Model (SCM; see figure 1; Lutes & Steinbaugh, 2010). This model builds on Social Cognitive and Decision Theories (Sbrocco, Nedegaard, Stone, & Lewis, 1999) and is unique because throughout the intervention all goals are 1) relative to baseline (pre-program) activity, 2) selected by participants instead of assigned by lifestyle coaches to maximize goal ownership, 3) are small and manageable in order to reduce the feelings of burden and failure in a participant, and 4) modified throughout the program based on the participant's needs (for examples of goals see Table 1). SCM also utilizes problem-solving theory (Perri et al., 2001) to assist the participants in coping with challenges that arise when pursuing their goals through a cognitive behavioral theory (CBT) approach. Self-efficacy and self-management strategies also play a role in small changes theory, which utilizes problem solving, planning, goal-setting, and cognitive restructuring to increase self-efficacy and improve goal acquisition.

Two studies have shown SCM to have promising implications for physical activity interventions. When used for a weight loss program targeting nutrition and physical activity, 60 participants increased their daily step count significantly (M = +2,937) and lost approximately 5% total body weight. Notably, after a three-month follow-up period where participants had no contact with study staff or access to their pedometers, they were able to maintain 100% of their weight loss and daily step count (M = +3,154) that was achieved relative to baseline at the end of the treatment (Lutes et al., 2008). More recently a telephone based SCM treatment program for a significantly sicker, heavier, and inactive group of military veterans resulted in a 4% body weight decrease and a step increase of 786 steps per day (Damschroder, Lutes, Goodrich, Gillon, & Lowery, 2009). While this study produced significantly smaller step count changes, it is important to note that these veterans made an 18% increase in step counts according to baseline steps (4471+/-2315 steps per day). Further, the self-selected goals and dual nutrition-physical activity treatment approach means that the veterans may have also focused more on nutrition than physical activity throughout the study, making fewer changes in step counts.

The purpose of the present study is to utilize the SCM framework to compare a 10,000 steps per day goal to a self-selected goal anchored to baseline step counts using a pedometer. This study is designed to examine differences in step counts, goal acquisition, and self-management techniques between the two goal types. Specifically, we hypothesize that the relative goal group will experience higher rates of goal-achievement, higher self-management, and, over time, equivocal daily step counts compared to the 10,000 steps per day goal group. According to SCM, the ability to create one's own goals and pursue small, relative changes will allow the participant to have more goal ownership, achieve goals more easily, experience greater goal achievement, and perhaps even reduce depression, ultimately motivating the participant to continue to increase step counts, whereas participants with a lofty, pre-set goal of 10,000 steps per day may become discouraged, lack self-efficacy, not utilize self-management skills, and not maintain activity change long-term.

CHAPTER II: METHOD

Participants

Participants were primarily female (97%), obese (BMI *M* = 32.67, *SD* = 4.60), middle-aged (*M* = 43.49, *SD* = 9.14), borderline sedentary (*M* = 5497 steps/day, *SD* = 2964), predominantly Caucasian (59%) and African American (41%), university employees (N = 37). This sample has an uneven gender representation simply because few men responded to our advertisements during recruitment. Future interventions should consider ways to be more appealing to male populations. Participants were matched based on BMI and randomized to the two groups. Participants were randomly assigned to either a: 1) 10,000 daily step goal or b) small changes relative step goal. There were no differences in BMI, step counts, psychological measures, or demographic measures between groups at baseline. Of the 37 participants, 10 were lost to follow-up. There were no differences in completers and non-completers except for age: Those who remained in the study were significantly older ($p = .009$). The only significant difference between the 10,000 step group and the relative group was income. The relative group made statistically higher income than the 10,000 step group ($p = 0.05$). For a more thorough examination of baseline factors between groups as well as between completers and non-completers, see Tables 2 and 3.

Study Design

This study was reviewed for human subject protection by the University and Medical Center Institutional Review Board (see Appendix A). Participants were recruited using a university email listserv, advertisements in the campus newspaper, and flyers distributed throughout East Carolina University's campus. While university faculty and staff were targeted through these recruitment techniques, community members unaffiliated with ECU were also welcome to enroll. Interested individuals were directed to an online survey where they were asked to read a brief synopsis of the study and complete a short screening questionnaire to determine eligibility.

In order to be eligible for this study, potential participants were required to be: 1) between the ages of 21 and 60 years old, 2) willing and able to participate in a physical activity program, 3) overweight according to BMI (greater than 25 kg/m^2), and 3) below the current physical activity guidelines as defined by the ACSM. All participants were also required to complete the Physical Activity Readiness Questionnaire (Par-Q) in order to demonstrate that they were physically capable of maintaining regular physical activity. Finally, participants were required to have less than a score of 20 on the Beck Depression Inventory-II (BDI-II) to assure that participants were not suffering from a moderate level of clinical depression which could greatly lessen their motivation to complete the pedometer program.

The qualifying participants were contacted via telephone and asked to attend a one-hour meeting where they were briefed on the study requirements, given the informed consent, and trained in using pedometers and the step count recording booklets. Participants were then asked to record their baseline step counts for a minimum of three days without changing their usual behavior. This time frame was based on previous research (Damschroder et al., 2010) and participants were asked to include one weekend day into their records. Participants were then randomly assigned to either a 1) 10,000 daily step goal or, or b) SCM small, relative, participant-chosen daily step goal (gradually increasing weekly step counts resulting in approximately a 2,000-3,000 step increase compared to baseline at treatment completion) over a 12 week period. Weight status was controlled between groups through matched-sample randomization. Participants met individually each week with a lifestyle coach for 15 minutes to plan goal achievement strategies and problem-solve challenges. Seven meetings were face-to-face and 5 were conducted via phone. For a more detailed outline of participant involvement in the study, see the consort guidelines in Figure 2.

Both groups received identical treatment information throughout the 12 weeks. Weekly meetings were led by a trained lifestyle coach and each participant wore a pedometer to monitor physical activity and recorded her step count daily. During weekly meetings, participants were provided materials on cognitive and behavioral topics relating to physical activity changes (e.g. cognitive distortions, slips and lapses, communication, and social support). They also learned to problem-solve, anticipate challenges, and set goals for the coming week.

The only difference between groups was goal type. The 10,000 steps per day goal group had one set goal that they were asked to achieve every day, regardless of their current step count, environmental challenges, or attitudes toward step change. For example, this meant that some participants with a baseline of approximately 3,000 steps were asked to triple their daily walking times. In contrast, the SCM step goal group was able to choose their own goals based on their personal situations and pursue goals in small increasing increments. Participants were encouraged to keep their weekly step goal changes within 250-750 steps and were advised to not further increase their future goal until they confidently mastered their current goal. Thus, while participants in the SCM group may have initially smaller step count changes, they were encouraged to increase throughout the study.

Assessments

At baseline, participants completed step count records, height and weight assessments, waist circumference, the Physical Activity Readiness Questionnaire (PAR-Q), the Satisfaction with Life Scale (SwLS), and the Beck Depression Inventory, Second Edition (BDI-II). At the end of the 12 weeks, participants were asked to complete these measures again along with a modified Health Behavior Survey (mHBS) to measure self-efficacy.

Height and Weight. Trained lifestyle coaches took each height and weight measurement. Participant's height was measured using a height rod on a spring scale to the nearest 0.05 cm. Weight was measured in kilograms on a Health-O-Meter Body Fat and Hydration Monitoring Scale (Sunbeam Products, Boca Raton, Fl., USA) to the nearest 0.1 pound. Participants were measured without shoes and jackets. BMI was calculated using these measurements.

Waist Circumference. Waist circumference was measured for each participant at baseline and post-test assessment periods. Measurements were taken one inch below the naval on bare skin with the participant's arms held out to the side. All measurements were acquired using a Gulick tape measure (Power Systems, Knoxville, Tn., USA) to the nearest 0.1 centimeter. Measurements were taken by the same trained research assistant at both baseline and post-test to assure reliability.

Physical Activity Readiness Questionnaire (PAR-Q). Participants were asked to complete 7 yes or no questions designed to assess the ability to safely pursue exercise (Adams, 1999). Participants who endorsed any physical activity risks were asked to seek approval from their physician before being enrolled in the study.

Satisfaction with Life Scale (SwLS). Participants were asked to complete a 5-item questionnaire measuring life satisfaction using a 1-7 Likert scale (1 = strongly disagree, 7 = strongly agree; Diener, Emmons, Larson, & Griffin, 1985). The score may range from 5 to 35 points. Higher scores indicate higher life satisfaction. This measure has been shown to have strong internal consistency ($\alpha = .87$) and test-retest reliability. Further, past research shows that significant changes have been found in the SwLS scale after physical activity (Dua et al., 2010; Owens, 2007).

Beck Depression Inventory, Second Edition (BDI-II). Participants were asked to complete the BDI-II at baseline and post-test. The BDI-II is a 21-item questionnaire used to measure depression levels (Beck & Steer, 1984). The BDI-II is based on the diagnostic criteria outlined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV). Each question of the BDI-II can be rated on a scale from 0 to 3. Scores from 0 to 13 are considered indicative of minimal depression, 14-19 is indicative of mild depression, 20-28 is indicative of moderate depression, and 29 and over is indicative of severe depression.

Modified Health Behavior Survey (mHBS). In order to measure self-efficacy, participants were asked to answer 8 items using a 1-7 Likert scale. This modified measure was derived from self-management theory and assesses cognitive and behavioral strategies used to increase physical activity (Dishman et al., 2005). Higher scores indicate a higher level of self-efficacy in relation to physical activity.

Statistical Analyses

Data were analyzed using the Statistical Package for the Social Sciences (SPSS for Windows, Version 17 SPSS Inc, Chicago, IL), with statistical significance set at $p < .05$. Both Intent to Treat and Completers only groups were examined for the primary outcome and step changes were determined using the average step count of the first and last week of treatment. If there were less than three days recorded in the final week, then the previous week was used. Descriptive statistics were used to describe the age, race, weight, and BMI of the participants. Repeated measures multivariate analysis of variance (ANOVA) were used to assess step count and weight differences across the sample. In addition, Pearson's product moment correlations were calculated between self-efficacy and change in step count and self-efficacy and goal completion rates. Independent-samples t-tests were used to assess for difference in means of variables. Finally, initial levels of depression, body satisfaction, and life satisfaction were correlated with change in step counts to determine any differences in goal completion based on baseline factors.

CHAPTER III: RESULTS

The primary outcome of this study was step counts (see Table 3). The average step count for all completers was 5307 (SD = 2581), and these steps increased across the treatment to an average of 8261 (SD = 2633). A repeated-measures ANOVA showed a significant main effect of time on step counts across time for all completers $F(1,24) = 41.57$ $p < 0.001$), but no step count differences across time between the 10,000 step group (M = 8645, SD = 2068) and the relative group (M = 7813, SD = 3207; $F(1,24) = 0.450$, $p = 0.51$). Intent-to-treat analyses were also assessed in which the 10 participants who did not complete the study were included using their baseline step counts in lieu of post-step counts. Despite this, there was still a significant increase in step counts according to a repeated measures ANOVA ($F(1,31) = 0.44$, $p < 0.001$). As could be expected, there was no significant time by group interaction ($F(1,31) = 0.004$, $p = 0.95$).

Height and weight were collected across treatment in order to calculate BMI (kg/m^2). According to repeated measure ANOVAs there were no changes in BMI over the course of treatment ($F(1,24) = 0.97$, $p = 0.34$) and no significant group by time interaction ($F(1,24) = 0.027$, $p = 0.87$). However, Pearson Product Moment correlations show that a reduction in BMI was significantly related to posttest step counts ($r = 0.39$, $p = 0.05$) and an increase in steps ($r = 0.42$, $p = 0.03$). Interestingly, higher post BMI was related to using the incorrect step goal ($r = 0.64$, $p = 0.002$) as well as a decrease in BDI score ($r = 0.43$, $p = 0.035$). For a complete list of correlations, see Table 4. Unlike BMI, there was a significant reduction between baseline waist circumference (M = 107.26, SD = 13.88) and posttest waist circumference (M = 103.02, SD = 11.77) across time ($F(1,24) = 16.44$, $p < 0.001$). However, there was no difference in waist circumference change between groups across time ($F(1,24) = 0.44$, $p = 0.52$).

Regarding psychological measures, life satisfaction (see Figure 3) significantly improved from an average of 21.84 (SD = 8.79) at baseline to 25.64 (SD = 7.53) posttest ($F(1,23) = 6.83$, $p = 0.016$). However, life satisfaction (see Figure 3) was not significantly different between groups ($F(1,23) = 0.39$, $p = 0.54$). While baseline BDI scores (see Figure 4) were low and this population sample did not meet scores high enough to indicate depression (M = 8.64, SD = 5.79), BDI scores nonetheless significantly dropped posttest (M = 3.44, SD = 3.25), illustrating a significant time interaction ($F(1,23) = 19.58$, $p < 0.001$). Change in BDI was not different between groups ($t = 0.33$, $p = 0.12$) and there was no difference in BDI scores between groups across time ($F(1,23) = 0.98$, $p = 0.33$). However an improvement in BDI across the study was related to higher posttest BMI ($r = 0.43$ $p = 0.04$).

Self-management, an important component to self-efficacy theory and the small changes approach, was measured by the mHBS. Scores were not different between groups ($t = 0.65$ $p = 0.52$). However, self-management skills were significantly related to posttest step count ($r = 0.57$, $p = 0.002$) and change in step counts ($r = 0.43$, $p = 0.027$). Self-management skills were not related to depression ($r = -0.015$, $p = 0.94$) or life satisfaction ($r = 0.32$, $p = 0.12$).

Out of the 12-week program (approximately 90 days) participants recorded an average of 80.12 days (SD = 10.18), illustrating acceptable compliance throughout the study. When assessing these records, it is surprising that there was no significant difference in rate of goal achievement between the two groups using either a independent measures t-test ($t = -1.10$, $p = 0.28$) or a chi-squared analysis ($C(1, N = 26) = 1.25$, $p = 0.26$). However, there is a definite trend in the data: only 29% of the 10,000 group reached their overall goal of 10,000 steps, while 50% of the relative goal group reached a 3,000 step increase relative to baseline. It is likely that a more powerful, larger sample may have detected significance between groups in goal achievement.

However, it is difficult to determine if participants utilized the correct goal throughout the study. A manipulation check showed that participants often made their own goal despite their group assignment: Those in the relative group sometimes aimed for 10,000 steps, while those in the 10,000 group reported that they often used small, relative goals to work towards a 10,000 step goal. On a 1-7 Likert scale, with 7 indicating that the participant always used the other group's goals and 1 indicating that they always used their own group's goal, participants averaged 5.14 (*SD* = 2.10).

CHAPTER IV: CONCLUSIONS

While goal setting and pedometer usage have been shown to be effective strategies to increase physical activity (Tudor-Locke & Lutes, 2009), the literature is unclear as to which goal types are most effective. Further, while it is evident that certain psychological and behavioral components are important to goal acquisition (namely depression, life satisfaction, and behavior management techniques) it is unclear how these elements are related to certain goal types. The primary goal of this study was to compare step changes from a 10,000 steps per day goal with a small, relative, self-selected goal type as recommended by the Small Changes Approach. Further, depression, life satisfaction, goal achievement, and behavior management techniques were assessed. It was predicted that step counts would increase to a similar degree throughout treatment, but that the relative group would achieve their goals more frequently and would have higher satisfaction with life, better behavioral management techniques, and perhaps even lower depression as a result. In turn, these factors may improve long-term outcomes, although this prediction is beyond the scope of this pilot study.

Consistent with past research, this study found that step counts significantly increased when utilizing a pedometer-based physical activity approach using either 10,000 steps or a relative goal. This increase is likely due to a myriad of factors promoted by the Small Changes Model that lead to increased physical activity, including self-monitoring and recording, wearing a pedometer daily, receiving weekly support, and learning self-management skills (Lutes et al., 2008). The significant relationship between self-management and step count in particular illustrates the importance of promoting self-management skills in physical activity interventions.

Further, the Small Changes Model also encourages utilizing a supportive, client-centered approach to behavioral management, which likely had a positive influence on behavioral outcomes (Lutes & Steinbaugh, 2010). In fact, client-centered support may have also contributed to the significant improvement of depression and life satisfaction of participants throughout the study. Considering these data it is possible that step counts increased equally despite goal type because this supportive model of treatment delivery and significant psychological improvement may be a powerful impetus for change even beyond goal-type.

Not unexpectedly, both groups increased step counts to an equal degree. Research has shown that steps typically increase 2000-3000 steps per day from baseline (Bravata et al., 2007), regardless of goal type. It may also be that whatever group step-count differences that might have been revealed were overpowered by the supportive behavioral-focused treatment sessions and self-management techniques. However, this does not mean that step goal is irrelevant. Considering that half of the relative group achieved their goals versus 29% of the 10,000 step group suggests that over time and with a larger sample, it may be that those with higher goals (i.e. 10,000 steps per day) find it more challenging to succeed if their goal is outside of the 2000-3000 step range. This may have implications for self-efficacy, which in turn may reduce long-term maintenance of behavior changes.

Because depression and life satisfaction are known to be related to increased physical activity (Owens, 2007), the improvements in both of these factors over the course of the study has important implications for client's future success. However, a confounding variable may be the time of year: While the initial assessments occurred in April, final assessments occurred during the summer time, when many may have been taking summer vacations and working part-time at the university. Interestingly, depression and life satisfaction were not related to step counts or changes. This may be due to the fact that average baseline depression was particularly low and there was little variation in depression or life satisfaction between participants, masking any potential effects that larger differences might show.

While BMI did not significantly reduce across participants, there was a significant relationship between BMI, step count change, and posttest step counts. This not only illustrates a dose-response effect between step counts and BMI but implies that relative improvement (step change) itself may have a positive impact on BMI. It is expected that this trend would continue long-term and, as is predicted in the small changes model, those that can maintain their changes (even small ones) across time will benefit from significant BMI reduction. Importantly, waist circumference did significantly decrease across study participants in both goal groups. This has important implications for the impact of walking interventions on chronic illness, as central adiposity is a significant predictor of chronic co-morbidity (Field, Barnoya, & Colditz, 2004).

Considering that almost half of this successful treatment was delivered via phone, this study suggests that telephone interventions may be effective in disseminating physical activity treatment. This may prove to be a cost-effective alternative treatment modality, particularly in rural locations where transportation can be challenging. Further, the fact that significant step changes resulted from weekly 15-minute sessions suggests that participant accountability may benefit more from frequency of encounters than duration of encounters.

Limitations

Limitations to this study include a small sample size. Effect sizes suggest that significant results may have been more likely if a larger sample size was recruited. This sample was also homogenous and included primarily middle-class women employed by the university, which reduces generalizability. The significant lack of male participants is likely due to the fact that men are less likely to seek out weight loss treatment (Field, Barnoya, & Colditz, 2004) and suggests that future studies should target recruitment of male participants particularly. Further, a control group would have allowed researchers to determine whether changes across time were due to intervention or confounding variables.

The most significant limitation to this study is the finding that participants frequently used the other group's goal designation as their own. In other words, members of the 10,000 steps per day goal reported that they frequently used small, relative goals to gradually increase steps to achieve 10,000 steps. Likewise, some members of the relative goal reported that they were always striving to make 10,000 steps, even though their daily step count may have not reflected this. Utilizing different goals may have neutralized any significant differences between groups and may have impacted participants' perceptions of achievement. This in combination with the supportive and therapeutic sessions may have alleviated feelings of failure that may otherwise be expected when a participant failed to achieve a 10,000 step goal repeatedly.

While the attrition rate for this study appeared elevated (27%), it is important to note that drop-out rates in weight management programs range from 10-80% (Gill et al., 2012). Attrition was equal across groups (five participants dropped from each group). Monetary incentive and a longer consent process may have improved completion rates. Completion rates may have been improved by the fact that consent was taken after the initial interest meeting and meetings were first held face-to-face in order to establish rapport and accountability. While the relative short nature of the program likely contributed to the completion rate, the lack of long-term follow-up is a distinct limitation of this study.

Discussion

Results from this study suggest that both a 10,000 steps per day and a small, relative goal type produce significant yet similar step count changes over time. This increase was associated with improved psychological measures (namely depressive symptoms and life satisfaction). Longer-term studies with a larger participant pool that utilize a follow-up model and a control group are necessary to confirm these findings.

If replicated, this study has several important implications for future interventions. First, this study highlights the importance of utilizing a client-centered, supportive approach along with behavioral management techniques and suggests that this may be effective above and beyond goal type. Also, this study illustrates the effectiveness of a small dose (15-minute session) phone based intervention that may reduce costs and treatment burden. Further, this study provides a foundation upon which to improve future research. Upcoming investigations should carefully monitor “actual” participant goals to assure that they are not confounding their designated group goal. Further, future studies may benefit from including more psychological outcomes, such as self-efficacy, which is a construct that is closely tied with goal acquisition and related to some of the measures included in this study. Finally, future studies should focus on assessing the constructs and factors outlined within the Small Changes Model because this model may be an effective alternative treatment guide when creating physical activity interventions. Armed with this information, physical activity interventionists may address the sedentary problem in the US by utilizing interventions that are supportive, client-centered, behavioral, and goal-directed.

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Appendix A.

University and Medical Center Institutional Review Board
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600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Emily Steinbaugh, BA, Dept of Psychology, ECU—104 Rawl Building

FROM: UMCIRB LCK

DATE: March 27, 2009

RE: Expedited Category Research Study

TITLE: "Step It Up ECU: A Pedometer Study"

UMCIRB #09-0284

This research study has undergone review and approval using expedited review on 3.27.09. This research study is eligible for review under an expedited category because it is on collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. It is also a research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
The Chairperson (or designee) deemed this **Department of Psychology, ECU** sponsored study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.
The above referenced research study has been given approval for the period of **3.27.09** to **3.26.10**. The approval includes the following items:

- Internal Processing Form (dated 1.9.09)
- Informed Consent (March 2009) (received 3.25.09)
- Program Satisfaction Questionnaire
- Eligibility & Demographic Survey Monkey Forms

- Baseline Survey Monkey Forms
- Step it up ECU Intervention Forms
- Post Intervention Evaluation
- ECU Listserv Announcement for Recruitment
- Recruitment Flyer

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

UMCIRB #:

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UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
REVISION FORM

UMCIRB #: 09--0284 **Date this form was completed:** 4/13/09
Title of research: Step it up ECU: A pedometer-based physical activity intervention
Principal Investigator: Emily Steinbaugh, B.A
Sponsor: Lesley Lutes, Ph.D.

Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored project revisions requiring review by the convened UMCIRB committee):

Fund	Organization	Account	Program	Activity (optional)

Version of the most currently approved protocol: on file
Version of the most currently approved consent document: on file

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:
X☐ East Carolina University
☐ Pitt County Memorial Hospital, Inc
☐ Heritage Hospital
☐ Other
☐ Beaufort County Hospital
☐ Carteret General Hospital
☐ Boice-Willis Clinic

The following items are being submitted for review and approval:
X☐ Protocol: version or date submitted
☐ Consent: version or date
X☐ Additional material: version or date Self-efficacy questionnaire

Complete the following:
1. Level of IRB review required by sponsor: ☐ full X☐ expedited
2. Revision effects on risk analysis: ☐ increased ☐ no change ☐ decreased - modified
3. Provide an explanation if there has been a greater than 60 day delay in the submission of this revision to the UMCIRB.
4. Does this revision add any procedures, tests or medications? X ☐ yes ☐ no If yes, describe the additional information:
5. Have participants been locally enrolled in this research study? X☐ yes ☐ no
6. Will the revision require previously enrolled participants to sign a new consent document? ☐ yes X☐ no

Briefly describe and provide a rationale for this revision There are 3 proposed revisions to the study given recruitment/participant interest and investigators added interest in self-assessment.

1. We are requesting that the Body Mass Index (BMI) cut off be increased to 45 from 40. Given that the study does not involve any intensity of activity, it is extremely unlikely that any adverse events will come from trying to increase daily step taking. Given the statistics of obesity in North Carolina, approximately a greater % of morbidly obese individuals are likely and that they will be African American. Given that our interest is to serve a good variety of staff and faculty at East Carolina University, and given that there is no intensity recommendations for this study, we feel that it is appropriate to increase the BMI range to 45.
2. We have found several individuals that answered yes to some questions on the physical activity readiness questionnaire (PAR-Q). Originally, we suggested that anyone who answered yes to any question would not be eligible to participate. However, upon gathering additional information, several participants indicated that they did have high blood pressure, or had some symptoms after being placed a medication, and are now either being treated with medication or were taken off a medication and are identified as being in good health. We are requesting that we seek additional information following a yes answer on the par-q and if it is determined that the individual is being medically monitored and risks are being managed, that they be allowed to proceed (e.g. patient is on blood pressure medication and is well managed). Further, for individuals that are identified to have a chronic health condition that could elevate risk (e.g. heart disease,

mitral valve prolapsed, BMI above 45 with elevated age), that participants seek a written release from their doctor to participate in the study. Participants will be sent a copy of the consent form along with a medical release form that (attached) asking the physician to provide a release to participate in the study.

3. Lastly, we would like to add a self-report questionnaire that assesses individuals self-efficacy for reaching their daily step count goal prescribed in the study. This will be a week #1 vs. week #12 assessment measure (attached).

PhD LESLEY LUTES 4/13/09

Principal Investigator Signature Print Date

Box for Office Use Only

The above revision has been reviewed by:

☐ Full committee review on ________ ☑ Expedited review on 4/24/09

The following action has been taken:

☑ Approval for period of 4/24/09 to 3/26/10

☑ Approval by expedited review according to category 45CFR 46.110

☐ See separate correspondence for further required action.

S. Wesley Nifong MD 4/24/09

Signature Print Date

CONSENT FORM

You are being asked to participate in a research study. This form provides you with information about the study and seeks your authorization for the collection, use, and disclosure of your protected health information necessary for the study. The Faculty Advisor (the person in charge of this research) or the Principal Investigator will also describe this study to you and answer all of your questions. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. Your participation is entirely voluntary.

1. TITLE OF THE RESEARCH STUDY

Step It Up ECU: A pedometer study

2. PRINCIPAL INVESTIGATOR, FACUTLY ADVISOR & CONTACT INFORMATION

Principal Investigator:	Emily Steinbaugh, BA
Faculty Advisor (and contact information):	**Lesley D. Lutes, Ph.D.**
Institution:	East Carolina University
Address:	223 Rawl Building, Greenville, NC 27858
Phone Number:	(252) 328-1374
Lab Phone Number:	(252)328-4874
Email:	lutesl@ecu.edu

3. SOURCE OF FUNDING

The Department of Psychology and the Harriot College of Applied Sciences is providing funding to Dr. Lutes through her start-up funds.

4. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

Increased weight and obesity are major health problems in the United States. One of the major contributing factors to weight gain is physical activity. According to recent reports, less than 20% of Americans are getting the amount of daily recommended activity levels to help maintain optimal health, stop weight gain, or to promote weight loss. Recently, pedometers (a simple device worn at the hip or in the pocket) have been developed and tested as a way to help people become more active by taking "more steps" everyday. A lot of people have often heard that 10,000 steps a day is optimal. However, this has never actually been tested in comparison to other goals

_____ Participant's initials

such as having someone increase their daily step-goal relative to their current daily step counts.

The primary purpose of this study is to learn better ways to help individuals become more active in order to help them manage their weight more easily. An important goal of the study is to find out what types of goals are most beneficial in helping individuals increase their daily physical activity. The study will also look at the ways that the different types of goal setting affect weight, waist circumference, and psychological feelings.

5. WHAT WILL BE DONE IF YOU TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in a research project that will extend over 12 weeks. The study will include about 60 men and women. If you agree to participate, you will first have a number of tests performed on your to see you are eligible to take part in the study. If you are eligible, these tests will be repeated after the 12-week treatment program.

The different tests and measures are below.

Questionnaires

You will be asked to fill out some questionnaires that ask you about yourself, including your health, your eating and exercise habits, and your thoughts and feelings. You will be asked to complete all of these questionnaires on a computer in our computer lab. These questionnaires will take about 30 minutes to complete.

Height, Weight, and Waist

A trained research team member will meet with you to take your height and weight in our lab. This will be done as privately as possible so that no one else will be able to see your weight and height measure. The team member then will take you into a private room to measure your waist with a tape measure around the skin on your waist.

Physical Activity Baseline Record

A trained research team member will show you how to put on and use a pedometer in order to record your daily physical activity over the next seven days using an activity log. After 1 week you will return to present your pedometer and activity record.

Randomization

After all the tests are completed, the principal investigator and faculty advisor will look at the results to find out if it is safe for you to take part in this study and that you meet all of the eligibility requirements. During your return visit, a member of the research team will tell you which group you have been randomized to. Random assignment is like rolling dice to decide which group a person is assigned to. You will not get to choose which group you are assigned to and the researchers will not get to choose which group you are assigned to. A computer will make your assignment.

The two groups are described below:

Group A: 12-weeks of a physical activity program with a 10,000 steps per day goal
Group B: 12-weeks of a physical activity program with relative goals to increase steps per day based on their baseline step count (>3,000).

Physical Activity Programs

Participants in both groups will receive a 12-week treatment program with a graduate student interventionist. You will meet individually with your interventionist 6 times in person and 6 times over the phone for a total of 12 visits in total. Each one-on-one meeting will take approximately 20-30 minutes with your lifestyle coach at a time that are agreed upon by you and your lifestyle coach. The goals of the 12 weeks program are to increase your daily physical activity.

The only difference between the two groups is the goal that is set.

Group A: This group will have a 10,000 step a day goal from week 1 of the program

Group B: This group will set weekly goals to increase their step counts relative to their baseline for a total of approximately 3,000 steps more per day compared to their baseline step count.

6. WHAT ARE THE POSSIBLE DISCOMFORTS AND RISKS

The risk of having heart problems during the treatment program is very low since the program is not promoting moderate or high intensity activity. Rather, the sole goal of the program is to increase daily step counts. However, there is a very low injury risk of muscle strain and soreness that may follow increased physical activity, but it usually lasts only a short while and generally does not get in the way of normal activity. Overall, we anticipate that this study poses no potential risks beyond those of mild physical activity done in daily life. However, in the event that you are uncomfortable with any element of the study, please notify an investigator. You are not required to complete any element of the study that causes you discomfort.

7. POTENTIAL BENEFITS

Participation in the study will provide an opportunity to increase your physical activity, which has been linked to lower risks for heart disease and diabetes and greater well-being. Participants who complete the program will also be offered a free pedometer at the end of the 12-week program. IN addition, the information learned from this study may help improve the future treatment of physical activity of overweight men and women.

8. WILL THE PROGRAM COST YOU ANYTHING?

It will not cost you anything to take part in this study.

9. WILL YOU RECEIVE COMPENSATION FOR TAKING PART IN THIS STUDY?

You will not receive any monetary compensation for participating in this study. However, you will receive a pedometer at no cost. A pedometer is a device that keeps track of how many steps you have taken each day.

10. WHAT IF YOU ARE INJURED BECAUSE OF THE STUDY?

The policy of East Carolina University and/or Pitt County Memorial Hospital does not provide for payment or medical care for research participants because of physical or other injury that result from this research study. Every effort will be made to make the facilities of the School of Medicine and Pitt County Memorial Hospital available for care in the event of injury, but these costs will have to be paid by your or your insurance provider.

11. WHAT OTHER OPTIONS OR TREATMENT ARE AVAILABLE IF YOU DO NOT WANT TO BE IN THIS STUDY?

Participation in this study is voluntary. You are free to refuse to be in the study, and your decision will not affect the health care you receive at East Carolina University or Pitt County Memorial Hospital either now or in the future. Other options for physical activity programs include the student recreation center, other research studies in the exercise science department, or other community programs such as viquest, curves, or gold's gym.

12. WILL MY CONFIDENTIAL INFORMATION BE PROTECTED?

Any information that is obtained in connection with this study will remain confidential, will be known only to the study investigators, and will be disclosed only with your permission. No names or other personally identifying information will be included in any analyses or reports that result from this study. All data files will be kept securely locked in the investigator's laboratory and destroyed six years following the study. An electronic database with all participants' information will be kept confidential but will not contain any identifiable information other than a pre-determined participation identification number.

13. CAN YOU WITHDRAW FROM THIS RESEARCH STUDY?

Participating in this study is voluntary. Refusal to participate will not involve penalty or loss of benefits to which you are otherwise entitled. Therefore, you can withdraw at any time during the study, for any reason, without penalty to current or future benefits.

14. PERSONS TO CONTACT WITH QUESTIONS

The investigators will be available to answer any questions concerning this research, now or in the future.

You may contact the primary investigator, Dr. Lesley Lutes, via email at lutesl@ecu.edu or contact her directly at (252) 328-1374.

Investigator Emily Steinbaugh may be contacted via email at eks0613@ecu.edu.
Investigator Marissa Errickson may be contacted via email at mae0312@ecu.edu.

If you have questions about your rights as a research participant, you may call the Chair of the University and Medical Center Institutional Review Board at phone number 252-744-2914.

CONFLICTS OF INTEREST

This study is funded by East Carolina University, which is supporting the costs of this research. Neither the research site, nor Dr. Lesley Lutes will receive any financial benefit based on the results of this study.

CONSENT TO PARTICIPATE

Step It Up ECU: A Pedometer Study

I have read all of the above information, and have received satisfactory explanations in areas I did not understand. (A copy of this signed and dated consent form will be provided to the participant if desired).

____

Participant's Name **(PRINT)** Signature Date Time

PRINCIPAL INVESTIGATOR: I confirm that the participant has read the contents of this consent document, the participant has indicated all questions have been answered to his or her satisfaction, and the participant has signed the document.

____

Person Obtaining Consent **(PRINT)** Signature Date Time

____

Principal Investigator's Name **(PRINT)** Signature Date Time

____
Participant's initials

Table 1. Examples of Small Changes Goals.

Original Behavior	Goal	Plan
5000 steps	5500 steps	When needing to use the restroom at work, participant planned to use the restroom on the third floor and walked each hall on her way to the restroom and back
2000 steps	2250 steps	Participant called family members three times a week on her cell phone and decided to walk around the building while she talked
6000 steps	6500 steps	Participant volunteered to drop off mail to the administration office neighboring her work place every day for her boss.
4000 steps	4500 steps	Participant walked around the baseball field as she waited for her son to finish baseball practice three days a week instead of sitting in the bleachers

Figure 1. The Small Changes Model (SCM).

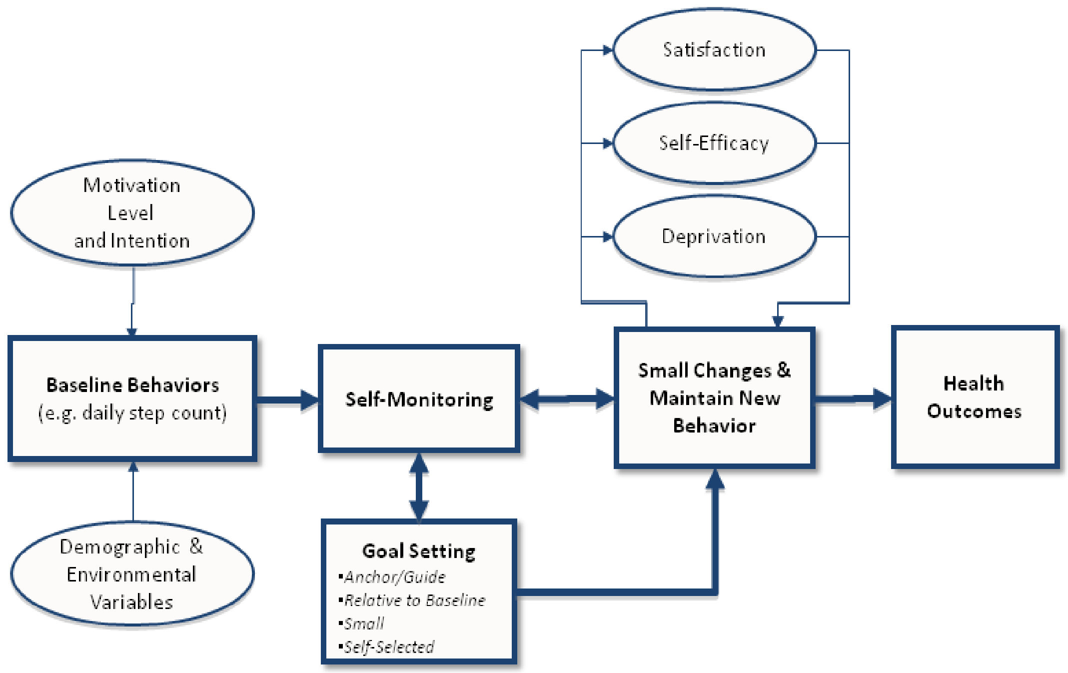

Table 2. Step It Up ECU Baseline Characteristics between Groups.

N = 37	All Participants	10000 Group M(SD)	Relative Group M(SD)	Difference *p*-Value Between Groups
Age	43.49(9.14)	42.05(8.67)	45.18(9.66)	0.403
BMI	32.67(4.60)	32.84(4.39)	32.47(4.97)	0.525
Race (%)				
Caucasian	59.0%	52.6%	66.7%	0.056
African American	41.0%	46.4%	33.3%	
Years of School	16.95(2.79)	16.20(2.21)	17.82(3.19)	0.309
Step Counts	5497(2964)	6024(2359)	4937(3486)	0.423
Income*	$46,250($20,146)	$38,750($15,438)	$55,000($22,038)	0.05*
SwLS	22.81(7.94)	21.11(7.41)	24.71(8.30)	0.18
BDI	8.34(5.82)	8.83(7.82)	7.82(5.65)	0.62

Note. *Indicates that the change is significant at the $p < .05$ level.

Table 3. Step It Up ECU Baseline Characteristics of Completers versus Non-completers.

Demographic	Completers M(SD)	Lost to Follow-up M(SD)	Difference *p*-Value
Age*	44.00(10.15)	41.89(4.94)	0.009*
BMI	33.11(4.58)	31.28(4.65)	0.36
Race (%)			
Caucasian	59.3%	60.0%	0.16
African American	41.4%	40.0%	
Years of School	16.56(2.55)	17.89(3.44)	0.39
Step Counts	5652(3102)	4800(2335)	0.29
Income	$44,130($20,651)	$53,750($17,633)	0.49
SwLS	21.92(5.85)	26.63(8.62)	0.12
BDI	8.92(5.85)	6.88(6.06)	0.42

Note. *Indicates that the change is significant at the $p < .05$ level.

Figure 2. Consort Guidelines.

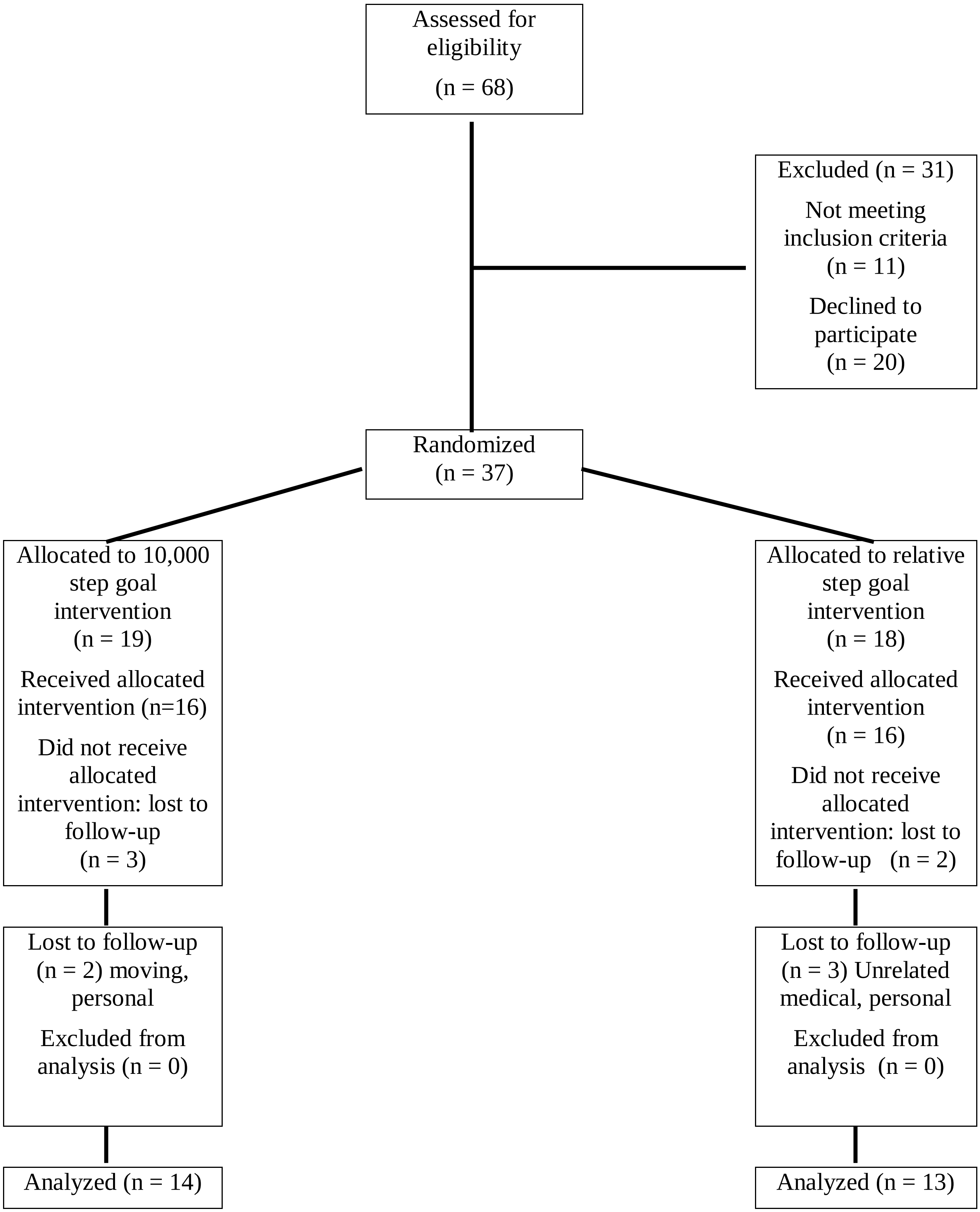

Table 4. Change in Step Counts

	Baseline	Posttest	Change	Difference
Intent to Treat	5497(2964)	7724(2915)	2401(2392)	$F(1,32) = 24.99$
10,000	6024(2359)	8222(2217)	2198(2284)	$p < 0.001$
Relative	4937(3486)	7194(3508)	2257(2419)	
Completers Only	5307(2581)	8261(2633)	2955(2323)	$F(1,25) = 42.07$
10,000	5977(2482)	8645(2068)	2669(2017)	$p < 0.001$
Relative	4525(2574)	7814(3208)	3288(2689)	

Note. *Indicates that the change is significant at the $p < .05$ level.

Table 5. Correlations between Factors.

	Change BDI	Post SwLS	Change SwLS	Post Steps	Change Steps	Behav. Manage.	Post BMI	BMI Change	Days Recorded
Post BDI	r = -0.29 p = 0.16	r = -0.044 p = 0.83	r = -0.25 p = 0.23	r = -0.019 p =0.93	r = 0.11 p = 0.61	r = -0.015 p = 0.94	r = 0.036 p = 0.86	r = 0.12 p = 0.56	r = -0.11 p = 0.61
Change BDI		r = -0.37 p = 0.071	r = 0.137 p = 0.52	r = -0.27 p = 0.19	r = -.077 p = 0.71	r = -0.18 p = 0.39	r = 0.43 p = 0.035*	r = -0.094 p = 0.71	r = -.13 p = 0.52
Post SwLS			r = 0.29 p = 0.15	r = 0.19 p = 0.38	r = 0.33 p = 0.10	r = 0.32 p = 0.12	r = -0.13 p = 0.52	r = 0.028 p = 0.89	r = 0.067 p = 0.75
Change SwLS				r = -0.20 p = 0.34	r = -0.094 p = 0.65	r = -0.27 p = 0.19	r = -0.033 p = 0.87	r = -0.23 p = 0.26	r = 0.015 p = 0.95
Post Steps					r = 0.46 p =0.017*	r = 0.57 p =0.002*	r = 0.077 p = 0.71	r = 0.39 p = 0.048*	r = -0.045 p = 0.83
Change Steps						r = 0.43 p =0.027*	r = 0.17 p = 0.41	r = 0.42 p = 0.034*	r = -0.36 p =0.068
Behav. Manage.							r = 0.16 p = 0.43	r = 0.29 p = 0.15	r = -0.002 p = 0.99
Post BMI								r = 0.28 p = 0.17	r = -0.097 p = 0.67
BMI Change									r = 0.11 p = 0.59

Note. *Indicates that the change is significant at the p < .05 level.

Figure 3. SwLS Scores: Life Satisfaction Change over Time

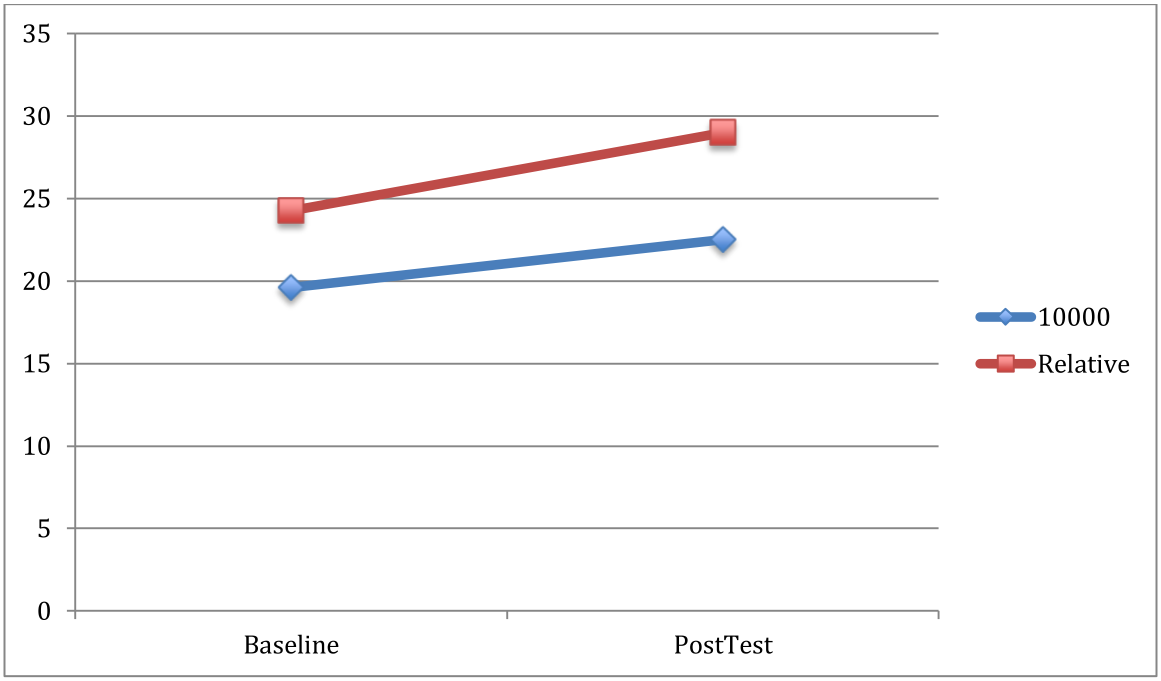

Figure 4. BDI Scores: Depression Change over Time.