ACTIVE LIVING EVERY DAY Pedometer Feedback Based Physical Activity Intervention
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## Contents

ACKNOWLEDGEMENTS .................................................................................................................. 2

LIST OF TABLES AND FIGURES .................................................................................................. iii

ABSTRACT ........................................................................................................................................ iv

Chapter I ........................................................................................................................................... 1

- Introduction ................................................................................................................................. 1
- Statement of Problem .................................................................................................................. 6
- Purpose of the Study .................................................................................................................... 6
- Delimitations .............................................................................................................................. 7
- Hypothesis Statement ................................................................................................................ 7
- Definition of Terms .................................................................................................................... 8

Chapter II .......................................................................................................................................... 9

- Physical Activity .......................................................................................................................... 9
- Prevalence ..................................................................................................................................... 10
- Physical Activity and Chronic Disease ....................................................................................... 11
- Recommendations and Guidelines ............................................................................................ 13
- Objective measurements of PA .................................................................................................. 18
  - Pedometers ............................................................................................................................. 18
  - Accelerometers ....................................................................................................................... 21
- PA Surveys and QOL of Assessment ......................................................................................... 23
- Barriers to PA ............................................................................................................................. 25
- Pedometer Feedback Based PA Interventions ......................................................................... 26
- Summary ..................................................................................................................................... 42

Chapter III ...................................................................................................................................... 43

- Methodology ............................................................................................................................. 43
- Subjects ......................................................................................................................................... 43
- Procedures ..................................................................................................................................... 44
- Data Analysis .............................................................................................................................. 49

Chapter IV ....................................................................................................................................... 51

- Abstract ........................................................................................................................................ 53
# Table of Contents

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>54</td>
</tr>
<tr>
<td>Methods</td>
<td>59</td>
</tr>
<tr>
<td>Subjects</td>
<td>59</td>
</tr>
<tr>
<td>Results</td>
<td>63</td>
</tr>
<tr>
<td>Discussion</td>
<td>65</td>
</tr>
<tr>
<td>Figure Legend</td>
<td>75</td>
</tr>
<tr>
<td>References</td>
<td>82</td>
</tr>
<tr>
<td>Chapter V</td>
<td>84</td>
</tr>
<tr>
<td>Summary and Conclusions</td>
<td>84</td>
</tr>
<tr>
<td>Recommendations for further study</td>
<td>86</td>
</tr>
<tr>
<td>APPENDIX A</td>
<td>92</td>
</tr>
<tr>
<td>APPENDIX B</td>
<td>95</td>
</tr>
<tr>
<td>APPENDIX C</td>
<td>97</td>
</tr>
<tr>
<td>APPENDIX D</td>
<td>100</td>
</tr>
</tbody>
</table>
LIST OF TABLES AND FIGURES

FIGURE LEGENDS................................................................................................. 75

TABLE 4.1 Baseline Subject Characteristics.........................................................76

FIGURE 4.1 Average Steps/Day at Baseline and Follow-up..............................77

FIGURE 4.2 Individual PA Levels Throughout the ALED Intervention Period.....78

FIGURE 4.3 Distribution of PA Intensity Baseline and Follow-up......................79

TABLE 4.2 Comparison Between the Current Study and Carr et al.....................80

FIGURE 4.4 Weekday vs. Weekend PA Throughout the ALED Intervention Period..81
ABSTRACT

THESIS: Active Living Every Day Pedometer Feedback Based Physical Activity Intervention

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To demonstrate the dissemination of the Active Living Every Day (ALED) physical activity (PA) intervention program through a healthcare provider recruitment format. A total of 15 subjects were recruited from Delaware Co., IN and attended 6 mandatory visits over a 16-week period. After completion of baseline PA and risk factor profiles, patients were given the 12-week ALED program. PA was monitored using Omron HJ720-ITC pedometers. Reassessment of all PA and risk factor profiles were performed post intervention. No significant changes were observed for mean PA or percentage of time spent performing sedentary activities. Preliminary results suggest a healthcare provider delivery format is not an effective means for the recruitment of sedentary adults. Further subject recruitment is needed to draw conclusions on the effectiveness of the ALED program to increase PA and affect corresponding risk factor profiles.
Chapter I

Introduction

Physical inactivity is has been recognized by the American Heart Association (AHA) as an independent risk factor for cardiovascular disease, the leading cause of death in the United States for both men and women\(^1\). Physical inactivity is defined as, repeated failure to achieve recommended levels of physical activity as defined by published guidelines\(^2\). The most recent 2008 Physical Activity Guidelines for Americans suggest that everyone attain a minimum of 150 minutes of moderate to vigorous intensity exercise per week (30 minutes on 5 days per week) for greater than 3-months\(^1\). Examples of moderate intensity physical activity include; brisk walking, jogging, aerobic dance, swimming, bicycling, and certain types of yard work, housework, or gardening. These recommendations are consistent with those published by the American Heart Association (AHA) and the American College of Sports Medicine (ACSM)\(^3\).

The Center for Disease Control (CDC)\(^4\) in 2007 reported that of the U.S. population, only 48.8% are achieving sufficient amounts of physical activity (PA). This was defined as 30 minutes of moderate intensity activity on 5 days per week or 20 minutes of vigorous activity 3 days per week. Additionally, it was reported that 37.7% of the population is considered active but not currently achieving sufficient amounts of PA to meet current recommendations, and 13.5% were inactive, or achieving an average
of <10 minutes of moderate to vigorous activity per week. Indiana is no exception to these statistics and mirrors national inactivity levels with only 47.7% of the population achieving sufficient amounts of PA, 39.7% are achieving insufficient amounts of physical activity, and 12.7% are considered inactive\textsuperscript{4}. These statistics suggest that approximately 52.3% of Indiana residents are not achieving sufficient levels of PA to promote better health or avoid inactivity related morbidity and mortality\textsuperscript{5}. An epidemic is defined as a situation affecting or tending to affect a disproportionately large number of individuals within a population, community, or region at the same time\textsuperscript{6}. According to these criteria, physical inactivity has become an epidemic in the United States and around the world. Physical inactivity is a primary risk factor for many of the leading causes of morbidity and mortality, and rates continue to increase across the country. In 2003 the CDC reported a national average of 24.6% of Americans reporting no leisure time physical activity, by 2008 this number had risen to 25.4%\textsuperscript{4}.

Obesity is one outcome that has received a lot of public attention as it is the most visible health problem associated with physical inactivity. However, this is only one of many negative health related outcomes associated with this problem. Physical inactivity alone is considered to be a central risk factor for cardiometabolic diseases such as; heart disease, vascular diseases, stroke, and type II diabetes\textsuperscript{5}. This is a serious issue as cardiovascular disease continues to be the leading cause of death in the United States, with one death attributed to heart disease approximately every 25 seconds, or 39.0% of the total deaths each year\textsuperscript{7}. 
The health benefits of increased PA are now understood better than ever and include increased energy, increased mental capacity, cardiometabolic risk factor reduction, reduced risk of cancer, weight control, improved sleep quality, and greater independence. However, technological advances have made it easier and more convenient than ever before to remain inactive, with everyday conveniences such as cars, elevators, and internet that promote a sedentary lifestyle.

Walking has been suggested to be the most likely mode to increase PA, as it is appropriate for most individuals and carries little risk of injury. PA is defined as any bodily movement produced by skeletal muscles that result in energy expenditure. The goal of PA is to burn calories, prevent and improve medical conditions and increase one’s quality of life or ability to perform daily activities.

The amount of literature examining PA interventions and older adults has expended greatly in the past decade. Moderate short-term improvements have been consistently observed in programs utilizing behavior modification strategies as basis for PA intervention. Current research is in response to previous evaluations which have observed general health education alone does not appear to be an effective method for the promotion of PA in sedentary adult populations. The most effective interventions have included both cognitive and behavioral components. For example utilizing techniques such as self-monitoring along with goal setting has been shown to be effective in several studies. Additional techniques that have been used include problem solving, time management, and individual feedback. Long term adherence to PA interventions has been shown to be most effective in home and lifestyle modification based programs as
opposed to fitness center based programs\textsuperscript{3}. Technological innovations such as the internet and mobile messaging have helped to reduce the costs of these interventions and allow them to reach a much larger population. More research is needed to determine the effectiveness of interventions that target physical activity alone, versus those which also target other risk factor reductions.

Previous studies have shown healthcare based interventions can lead to short term increases in PA\textsuperscript{10,11}. In the most effective of these studies, physicians delivered the recommendation for greater PA while other members of the healthcare team were also involved in the recruitment process. Clinicians confront significant challenges when promoting PA to their patients such as; lack of personnel, reimbursement, and time. They need an available and cost effective method that has been validated in the clinical setting. It has been proposed that written prescriptions or intervention plans, in addition to advice, may enhance the effectiveness of these interventions. There is also a need for additional studies that focus on moderate intensity and lifestyle activities as opposed to vigorous training and short exercise bouts. Future research is also needed to determine ways to adapt interventions to community barriers and available resources.

The purpose of current research is to implement the previously evaluated Active Living Every Day PA intervention program through a new delivery format and in a more diverse subject population\textsuperscript{12,13}. Carr et. al\textsuperscript{14} conducted a study on the effects of the ALED program on sedentary and obese individuals in a predominantly rural region of Wyoming (12.5 people/square mile). The ALED program is a commercially available, internet based behavior change program that is based on the transtheoretical model of behavior
change along with the social cognitive theory. Several trials utilizing the instructor facilitated small group format have successfully shown increases in self-reported PA.

Participants were recruited to the study through advertisements and e-mail solicitation. Subjects were then randomized into one of two groups, a control group and an ALED intervention group. The specific aims of this study were to determine whether the ALED program increased physical activity to a similar extent as classroom-delivered programs, and traditional individualized exercise prescription programs. Also to determine if the ALED program increases physical activity and improves the cardiometabolic disease risk factor profiles in an overweight/obese and sedentary population.

Multiple linear regression analyses revealed a significant correlation between mean steps per day average and predicted change in steps for those in the ALED group only. This was the first known study to evaluate the ALED program using an objective measure of physical activity (Yamax SW-200). Smith and Carr et. al\textsuperscript{14}, found that of those participants completing the ALED program there was approximately a 30% compliance. Compliance was determined by total number of program modules completed throughout the course of the intervention. They found that subjects completing all outcome measures of the program were successful in increasing their PA by an average 17% and had an average reduction of 4% in central adiposity. The degree of baseline PA was found to predict the impact of the ALED program. They propose that the program may be most effective for those individuals who are the least active (< 7,000 steps/day). Exit surveys showed that they primary reason for non-compliance and
attrition rate was “lack of time”. Participants in the study were likely motivated volunteers from small geographically isolated communities with little access to other physical activity programs.

**Statement of Problem**

Physical inactivity has become an epidemic in the United States and around the world. In 2008 the CDC reported an all-time high, 51.2% of Americans, who were not achieving sufficient levels of PA. Guidelines have been published defining the recommended amounts of PA needed to attain significant health benefits\(^{15}\). These include the “Physical Activity Guidelines for Americans” published by the U.S. Health and Human Services in 2008. The problem is a lack of validated interventions that have been clinically shown to increase physical activity. The ALED program is one possible intervention strategy, but has yet to be validated in a sedentary population, through a clinical setting, or had its effect on cardiometabolic disease risk factors assessed.

**Purpose of the Study**

The primary purpose of this research is to demonstrate that ALED can be successfully implemented, in the higher density population of Delaware County, IN (299 people/square mile), to increase average steps/day and decrease sedentary time among an urban sedentary adult population. The secondary purpose of this study was to improve cardiometabolic risk factor profiles. This included LDL cholesterol, region % body fat, and waist circumference, along with increasing HDL cholesterol and lean muscle mass. Reproducing these results could provide clinicians with a feasible and powerful tool to reduce cardiometabolic disease risk in broader segments of the population. It is hypothesized that the ALED intervention will lead to a significant increase in steps/day
among participants corresponding with reduced minutes spent performing sedentary activities and waist circumference. Improvements in additional measured cardiometabolic disease risk factor profiles are not expected to be significant due to the short duration of the study and proposed lifestyle PA by the ALED program.

**Delimitations**

A total of thirty subjects participated in the ALED PA intervention study. The ALED intervention is a step-by-step plan towards achieving a healthier lifestyle. The program includes creating an activity plan based on the individual’s preferences, helping to schedule physical activity into a busy schedule, and learning how everyday activities can be counted towards achieving weekly PA goals. Subjects identified as sedentary by their primary care physician during a scheduled office visit, were referred to the ALED program as a possible means for increasing PA and health. Subjects were included if they were sedentary upon entry into the study, and free of any known cardiovascular disease or contraindications to increases in ambulatory activities. Sedentary status was determined by average weekly step counts and PA questionnaires. Change in PA patterns was determined by average weekly step counts and activity counts measured by Omron HJ720-ITC pedometer and Actigraph GT3X accelerometer at baseline and post 12 week intervention.

**Hypothesis Statement**

The hypothesis is that the Active Living Every Day physical activity intervention would increase the average number of steps/day, compared with those with average steps/day measured during the 2 week baseline assessment period. It is expected that an
increase in total steps/day will be associated with significant improvements in percentage of time spent performing sedentary activities, and waist circumference.

Definition of Terms

- **Physical Activity** – Any bodily movement produced by skeletal muscles that results in energy expenditure.
- **Exercise** – A planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness.
- **Pedometer** – A device designed to measure total number of steps while walking or running.
- **Accelerometer** – A device designed to quantify vertical acceleration and deceleration of the body, which is used to determine the intensity of work.
- **Activity Counts** – A unit of velocity portraying a relative vertical acceleration measured by an accelerometer.
- **Cardiometabolic Syndrome** – A combination of conditions, including high blood pressure, elevated insulin levels, excess body fat around the waist and abnormal cholesterol levels.
Chapter II

The primary objective of this study was to assess the effectiveness of the Active Living Every Day (ALED) internet delivery physical activity (PA) intervention program as it was implemented in Delaware County, IN (299 people/square mile). The program was designed to increase daily PA (steps/day) and decrease sedentary time among physically inactive individuals. The secondary purpose of this study was to assess the effects of the ALED-I program on cardiometabolic risk factor profiles. Profiles included LDL and HDL cholesterol, glucose, % body fat, and waist circumference. This chapter will include an in depth literature review 1) defining PA, 2) prevalence of physical inactivity, 3) effect of physical inactivity on health outcomes, 4) PA monitoring devices, and 5) pedometer feedback based PA interventions.

Physical Activity

PA is defined as any bodily movement produced by skeletal muscle that results in energy expenditure\textsuperscript{1}. PA in daily life can be categorized into sub groups; occupational, sports, conditioning, household, or other activities. All individuals perform PA in order to sustain life however; the amount is specific to personal choice and varies considerable between individuals and over time.

Benefits associated with PA have been documented as far back as ancient Greek medicine when Hippocrates and Galen advised “a lack of physical exercise was
detrimental to health”. This was further supported during the early days of the Enlightenment when the Italian physician Bernardi Ramazzini noted that “runners and messengers avoided the occupational health hazards seen in sedentary tailors and cobblers”. In 1915 Dr. FC Smith of the US Surgeon General’s office stated that “exercise is necessary for all except for those acutely physically ill, for all ages, for both sexes, in an amount just short of fatigue”.

Prevalence

Estimates of regular leisure-time PA vary between studies depending on the use of either subjective or objective measurements of PA. Subjective measurements, such as the International Physical Activity Questionnaire and Stanford 7-day Physical Activity Recall, are cost effective, easy to administer, and allow for the analysis of each individual’s perceived level of PA. For these reasons subjective measurements of PA are most commonly used when assessing large subject populations. However, due to their subjective nature subjective PA measurements are limited by factors such as error in recall, individual interpretation, and personal bias.

Utilizing computer-assisted personal interviews the National Health Interview Survey (NHIS) conducted by the CDC’s National Center for Health Statistics estimated in 2007 that 31.8% of US adults engage in regular leisure time PA. Regular leisure-time PA was defined as engaging in light or moderate intensity PA a minimum of 30 minutes a day, 5 days a week, vigorous intensity PA 20 minutes a day, 3 days a week, or an equivalent combination of both. It has been reported that participation in regular PA
was on the rise during the 1960’s, 70’s, and 80’s, but seems to have plateaued in recent years\(^1\). Numerical data was not provided to support these claims in the cited article.

The Behavioral Risk Factor Surveillance System reported that of those surveyed 32.6% of women reported no leisure time PA within the last month as compared with 28% of men\(^3\). Regular PA was defined as \(\geq 30\) minutes of moderate intensity PA on \(\geq 3\) days/week. Additionally, the 1990 NHIS survey showed a decline in reported PA with increasing age, with 19.3% of adults aged 18–24 years classified as sedentary, compared with 33.9% aged 65 and older\(^3\). Sedentary status was defined as reporting an average of \(\leq 10\) minutes/day of moderate intensity PA for \(> 3\) months. Currently a majority of U.S. adults (54.1%) do not engage in sufficient PA, as defined by the 2008 PA Guidelines for Americans, to meet the current public health recommendations\(^4\). The 2008 PA Guidelines for Americans are discussed in depth later in the chapter.

Physical inactivity is a global public health problem and has been identified as a national public health priority by the United States of America\(^5\). The annual cost directly attributable to inactivity in the United States was estimated at 24-76 billion dollars per year, or 2.4-5% of national healthcare expenditures\(^6\). As many as 250,000 deaths per year in the United States, or about 12% of total, are directly attributable to a lack of regular PA\(^7\). These statistics have led to sedentary behavior’s classification as one of the leading preventable causes of death.

**Physical Activity and Chronic Disease**

The notion that PA is an important component of a healthy lifestyle has been reinforced by scientific evidence linking PA to a wide variety of physical and mental
benefits. A linear does-response relationship has been shown between the amount of PA performed and the individual health status\textsuperscript{8}. Haskell et al.\textsuperscript{9} reported the strongest association between PA and cardiometabolic disease risk reduction was observed when the least active group became moderately active. Since that time additional studies designed to assess the effects of PA on cardiometabolic disease risk have shown the greatest improvements in those with the lowest initial PA status\textsuperscript{10-12}. PA has been related to substantial health benefits at any age and regardless of prior PA history.

Attaining the previously recommended amounts of moderate intensity (3-6 METS) PA has been shown to improve body composition, enhance lipid profiles, improve glucose homeostasis and insulin sensitivity, reduce blood pressure, increase autonomic tone, decreased blood coagulation, increased coronary blood flow, augment cardiac function, enhance endothelial function, and decrease systemic inflammation\textsuperscript{8}. All of these are related to a reduced risk of chronic disease and all-cause mortality. The American Heart Association named physical inactivity as an independent risk factor for cardiovascular disease after observing the relative risk of developing coronary heart disease in the least active group was 1.9 times greater than that of the most active group\textsuperscript{13}. This finding is similar to that of other risk factors such as smoking and hypertension. Physical inactivity has also been identified as a modifiable risk factor for other chronic diseases including but not limited to; diabetes mellitus, colon and breast cancer, and obesity\textsuperscript{14}.

Specifically, PA has been shown to have protective effects against the development of diabetes as well as being an effective treatment for those already
diagnosed with impaired fasting glucose and diabetes. Each increase in energy expenditure of 500 Kcal/day is associated with a 6% decrease in the incidence of type II diabetes, with greater effects shown for those at high risk for the development of diabetes.

Physically active men and women have shown a 30-40% reduction in their relative risk for colon cancer, and physically active women a 20-30% reduction in relative risk of breast cancer when compared with sedentary individuals. A review of epidemiological research has revealed additional protective effects when moderate intensity (>4.5 METs) PA is performed as compared with light intensity. It has been observed that among patients with cancer (breast/colon) higher amounts of self-reported PA are associated with a decreased recurrence of cancer and risk of death from cancer. One investigation revealed a reduction of 26%–40% in the relative risk of cancer-related death and recurrence of breast cancer among the most active women compared with the least active.

It is well known that obesity is an independent risk factor for cardiovascular disease, with a direct relationships observed between obesity and coronary heart disease, coronary death, and congestive heart failure. A 2003 consensus statement published by Saris et al. proposed 45-60 minutes of moderate intensity PA each day is required to prevent the transition from normal weight to overweight or obese weight classifications. Additionally, it was proposed that the equivalent of 60-90 minutes of moderate intensity PA per day was required for weight loss or maintenance of previous weight loss.

Recommendations and Guidelines
In the 1950’s a rapidly evolving scientific approach emerged around the idea that PA was related to significant health benefits. Scientific evidence produced during this time period lead to the promotion of many health-oriented PA and PF programs. However, there was still discrepancy as to what type of PA or exercise had the greatest benefits. In 1972 the American Heart Association published “Exercise testing and training of apparently healthy individuals: A handbook for physicians”, the first guideline with a focus on utilizing PA and exercise as a means for reducing the risk of developing cardiovascular disease \(^\text{20}\). This recommendation focused on the utilization of moderate to vigorous intensity exercise as a way to reduce the occurrence of cardiovascular disease in those that were “coronary prone”\(^\text{21}\). In 1978 the American College of Sports Medicine (ACSM) produced their first guidelines which outlined the recommended frequency and intensity of exercise for developing and maintaining fitness \(^\text{22}\). This publication represented a shift toward clinically focused approach aimed towards specific health outcomes. This position statement focused on the development and maintenance of cardiorespiratory fitness and body composition in healthy adults \(^\text{22}\). Specifically the ACSM recommended 15-60 minutes of aerobic exercise, 3-5 days per week, at an intensity of 60-90% of heart rate reserve (HRR) or 50-85% of maximum oxygen uptake (VO\(_2\)max). In 1990 the ACSM published an update to the 1978 recommendations. This update had a revised title which specified that the aim was to improve and maintain cardiorespiratory and muscular fitness \(^\text{23}\). The new recommendations were in response to research supporting health-related benefits at lower intensities than those previously recommended for improvements in fitness. The position stand stated “ACSM recognizes the potential health benefits of regular exercise performed more frequently, and for a
longer duration, but at lower intensities than presented in this position statement\textsuperscript{24}. The recommendations remained very similar; recommended duration was increased to 20-60 minutes per session as compared to the previous 15-60 minutes, and the recommended intensity changed from 60-90\% HRR to 60-90\% of maximal heart rate (HRmax)\textsuperscript{21}. A specific recommendation was added in regards to resistance training; one set of 8-12 repetitions of 8 different exercises 2 days/week.

Additional epidemiological studies were published throughout the 1990’s that supported the ACSM claim that health benefits could be achieved at lower intensities that previously established\textsuperscript{25-29}. Epidemiological research relies solely on observational data analysis, but can lead to the development of experimental studies used to identify cause and effect relationships between a defined variable and disease outcome. It was also noticed at this time that a majority of the American population was not meeting the current recommendations for PA and a large portion remained sedentary. This lead to the realization that greatest public health benefits may be attained by motivating the most sedentary individuals to a more active state\textsuperscript{24}.

In 1995 the ACSM and CDC published national PA and public health guidelines\textsuperscript{1}. These guidelines were also endorsed by the AHA. The ACSM and CDC suggested all healthy adults accumulate a minimum of 30 minutes of moderate intensity PA on most, preferably all days of the week. The ACSM and CDC provided brisk walking as an example of moderate intensity PA. A brisk walk of 2 miles or approximately the equivalent of 200 Kcal per day was determined to be sufficient intensity and quantity for health benefits. The purpose of these guidelines was to provide a clear, concise, public
health message to encourage increased participation in PA. At this time the 1995 Dietary Guidelines for Americans and 1996 Surgeon General’s report on Physical Activity and Health also included advice on benefits of PA\textsuperscript{30,31}.

The 1995 Dietary Guidelines for Americans stated “nearly all Americans need to be more active, because a sedentary lifestyle is unhealthful. The guidelines recommend an accumulation of 30 minutes or more of moderate physical activity on most, preferably all, days of the week\textsuperscript{30}. The Surgeon General’s report stated all individuals, independent of age or gender, can obtain significant health benefits by performing a moderate amount of physical activity on most, if not all, days of the week. Examples of sufficient moderate intensity activity were; 30 minutes of brisk walking or raking leaves, 15 minutes of running, or 45 minutes of playing volleyball. The guidelines also stated that those able to maintain a regular activity that is of longer duration or more vigorous activity are likely to experience greater health benefits than those meeting the minimum guidelines\textsuperscript{31}.

In 2007 the ACSM and AHA published updated PA guidelines\textsuperscript{32}. The purpose of this report was to update and clarify the 1995 recommendations which outlined the specific types and amounts of PA required to improve and maintain health\textsuperscript{30}. These guidelines were published by a panel of scientists that included physicians, epidemiologists, exercise scientists, and public health specialists. The new publication included a separate recommendation for older adult populations, those aged 65 years or older, or those between the ages of 50-64 years with clinically significant chronic conditions or functional limitations\textsuperscript{33}. Chronic conditions and functional limitations are
defined as those that require regular medical treatment, or impair the ability to perform physical activity, respectively. The primary recommendation published in the 2007 guidelines recommended adults aged 18-65 years should attain moderate intensity aerobic PA (3 – 6 METS) for a minimum of 30 minutes on five days/week, or vigorous intensity aerobic PA (> 6 METS) for a minimum of 20 minutes on 3 days/week. For older adults and those with chronic conditions and limitations the recommendation for aerobic physical activity is 50-85% of oxygen uptake reserve (VO2R). This guideline suggests moderate intensity PA is equivalent to a rating of 5-6 on a 10 point rating of perceived effort scale, with vigorous activity approximately equal to a 7-8. The guidelines also state that a combination of moderate and vigorous activity can be performed to meet the same quantity of PA. The 2007 guidelines also included recommendations for older adults that included strength training at least 2 days/week along with flexibility and balance exercises that promote and maintain health and physical independence.

In 2008 Physical Activity Guidelines for Americans was published. This was the first comprehensive guidelines on PA ever issued by the federal government. The intended use of these guidelines was to be a “primary source of information for policy makers, physical educators, health providers, and the public in amount, type, and intensity of PA needed to achieve health benefits across the life span”. The 2008 Physical Activity Guidelines for Americans stated to attain substantial health benefits, all apparently healthy adults should perform at least 150 minutes of moderate intensity, a minimum of 75 min/week of vigorous intensity aerobic PA or an equivalent combination of moderate and vigorous intensity PA. In order to accumulate the recommended
minutes of PA each bout must be ≥ 10 minutes in duration, bouts failing to meet this requirement shall not be counted towards an individual’s daily PA. It is also noted that there are additional health benefits when achieving 300 minutes per week of moderate, or 150 minutes/week of vigorous intensity aerobic PA. There are also resistance training recommendations for moderate to high intensity strengthening activities that involve all major muscle groups on 2 or more days per week. The guidelines stress the fact that some activity is always better than none if you are unable to meet the current recommendations. The 2008 guidelines also include a section for older adults and those with chronic disease conditions. Specifically, older adults unable to perform 150 minutes of moderate-intensity aerobic activity a week due to chronic conditions, they should be as physically active as their abilities and conditions allow. Activities that improve strength and balance are recommended, especially for those at a greater risk for falls. Individuals falling in these categories should understand their disease conditions and how they affect their ability to perform regular PA along with consult their health-care provider about the types and amounts of activity appropriate for them.

**Objective measurements of PA**

**Pedometers**

Pedometers are motion sensors used to objectively measure PA (steps/day). They have been used in research as motivational tools to promote the increase of ambulatory PA. Mechanisms of action include spring loaded and piezoelectric measurements of motion. Crouter et al.\(^{35}\) studied the effectiveness between the two methods of measurement on a group of overweight and obese adult subjects. On average the piezoelectric (New Lifestyles NL-2000) pedometer recorded 1030 +/- 1414 more
steps/day than the spring loaded (Yamax Digiwalker SW-200) pedometer. It was concluded in overweight and obese individuals, a piezoelectric pedometer is more accurate than a spring-levered pedometer, especially at slower walking speeds.

The Omron HJ-720ITC is an example of a piezoelectric pedometer that has been validated through previous research. Giannakidou et al. evaluated the accuracy of the Omron HJ-720ITC (piezoelectric), HJ-113-E (piezoelectric), and Yamax Digi-Walker SW-200 (spring-levered) (YAM) at various treadmill walking speeds for the measurement of steps/day. Subjects were made up of untrained males (n=24), average age 22.7 ± 2.8 years, BMI 24.4 ± 2.2 kg/m², and females (n=18), average age 22.4 ± 2.9 years, BMI 21.7 ± 2.4 kg/m². The subjects walked at 5 different velocities (2.0, 2.5, 3.0, 3.5, and 4.0 mph) on a treadmill, in 5 minutes stages, while wearing each of the 3 pedometer models. Step counts were recorded at the end of each stage for each pedometer and compared to the value obtained by the hand counter. The YAM pedometer underestimated steps at 2.0 mph (> 1.5%), but was accurate at all other tested speeds. The Omron HJ-720ITC and HJ-113-E measurements were within ± 1.5% of actual steps, at all observed speeds (r=0.8-0.99). These data suggest that they Omron HJ-720ITC pedometers are accurate at determining step counts at a variety of different walking speeds.

Another study by Holbrook et al. evaluated the reliability of Omron HJ-720ITC pedometers during treadmill and self-paced walking. Subjects included adult males (n=24) and females (n=23) with an average age of 24 ± 4.4 years and average BMI of 25.7 ± 4.2 kg/m². Pedometers were worn in the right pocket, left waistband, and
backpack positions. Due to non-compliance only 34 of the 47 completed 3 randomized 100 meter walking trials at self-selected slow (2.7 mph), moderate (3.3 mph), and very brisk (4.1 mph) walking paces. Additionally, only 31 of the 47 participants completed a one mile self-paced walk on a standardized course. The course included flat concrete walking, stair ascent and decent, up- and down-hill grass walking, and stops at road crossings. Absolute percent error (APE) was calculated to determine the pedometer accuracy between pedometer-determined steps and actual counted steps. Actual step counts were assessed by a study investigator walking behind each participant with a hand tally counter. The HJ-720ITC had an average APE of 2.3 ± 2.8% across all walking speeds. The most accurate mounting location was the mid-back with an APE of 1.1 ± 1.1%. Additionally, the left and right hip location (APE 2.0 ± 2.7%) and left and right pocket locations (2.9 ± 3.6%) had APE values meeting the established validity criteria (<3.0%). The backpack location did not meet the validity criteria with an average APE of 3.5 ± 3.2%. The authors concluded that the Omron HJ-720ITC accurately reported steps under prescribed and self-paced walking conditions when worn in the mid-back, pocket, and waistband locations (APE <3.0% or fewer than 3 missed steps per 100). This study supports previous research that showed accuracy of the Omron HJ720-ITC pedometer as a measurement of PA when walking at selected treadmill speeds. This study also provides support for the accuracy of the pedometer as a measurement of PA during free living conditions.

Silcott, et al. 2011, conducted a clinical trial to determine the accuracy of the HJ720-ITC pedometer under free living conditions. A total of 62 adult volunteers
participated in the study. Subjects were categorized into one of 3 groups according to body mass index (BMI): normal weight (BMI<25, n = 19), overweight (BMI=25-29.9, n = 23), and obese (BMI ≥30, n = 20). Subjects wore a total of 5 pedometers for a 24 hour period. The criterion pedometer (StepWatch-3) was worn on the lateral side of the right ankle. A total of 3 Omron HJ-720ITC pedometers were worn on the belt, in the pants pocket, and on a lanyard around the neck. An additional pedometer (Yamax SW-200) was worn on the belt for comparison. Subjects were instructed go about normal activities, except water based, while wearing the pedometers at all times for a 24 hour period. The Omron HJ-720ITC, when compared with the StepWatch 3, measured most accurately in the pocket wear site, yet underestimated steps/day, recording 68%, 70%, and 65% of actual steps in the normal, overweight, and obese BMI categories, respectively. It was concluded that underestimations of steps/day by the Omron HJ-720ITC are due to its four second step filter. This feature does not count activities that are sustained for less than four seconds, leading to a possible underestimation of steps during intermittent activities. Omron accuracy was similar for lean, overweight, and obese individuals, when worn in the pocket location, as opposed to the Yamax pedometer which declined with increasing BMI categories. This study supports the findings that the Omron HJ720-ITC model pedometer is consistent across a variety of BMI categories. However, this study does not support the accuracy that was produced in previous research. The current study is limited by its use of criterion measurement (StepWatch 3) compared to previous research that utilized direct observation.

Accelerometers
Accelerometers are devices designed to detect acceleration and tilt, and like pedometers are commonly used as an objective way to quantify step counts. Unlike pedometers, accelerometers also allow for measures of PA intensity, inactivity time and energy expenditure\(^39\). Research is also being conducted to validate the use of accelerometry to assess sedentary behavior\(^40\). Trost et al.\(^41\) published a review on the use of accelerometers for PA assessment in field based research. They reported no individual make or model has provided definitive evidence to indicate that it is superior or more valid and reliable than another. Trost et al. suggests that selection of an accelerometer should be an issue of practicality, technical support, and comparability with other studies.

Freedson et al.\(^42\) conducted a study to establish accelerometer count ranges for the Computer Science and Applications inc. (CSA, Shalimar, FL) activity monitor corresponding to established MET categories. Data were obtained from 50 adults (25 males, 25 females) during treadmill exercise at three different speeds (3.0, 4.0, and 6.0 mph). The subject population had an average age of 23.8 ± 4.0 years, with an average BMI of 23.3 kg/m\(^2\). Activity counts and steady-state VO\(_2\) were highly correlated (\(r = 0.88\)), and count ranges corresponding to light, moderate, hard, and very hard intensity levels were < 1951, 1952—5724, 5725—9498, > 9499 counts/min, respectively. Light activities were defined as <3 METs, moderate intensities were equivalent to 3.0-5.9 METS, hard intensities equivalent to 6.0-8.9 METS, and very hard activities ≥ 9 METS. Subjects were instructed to walk on a treadmill at each of the prescribed intensities with a 5 minute break between each bout. The study population was limited to young adults
with a BMI <25 kg/m^2. The study also lacks a criterion measurement to compare results as it was a pilot study.

Additionally, Mathews et al. conducted research on the use of accelerometers to assess sedentary behavior. Mathews et al.\textsuperscript{43} conducted a validation study in 19 adults (female=10, male=9; mean age = 40.1 ± 10.0 years and BMI 27.2 ± 4.4 kg/m\(^2\)), utilizing the Actigraph threshold of 100-counts/minute against data from the Intelligent Device for Energy Expenditure and Activity (IDEEA) monitor. The IDEEA is a gold-standard measure of amounts of time spent sitting, reclining, and lying down. Compared with direct observation, the IDEEA monitor has been shown to correctly identify these body positions with >98% accuracy. During the 2 day observation average wear time for both devices was 13.2 ± 2.1 hours/day. It was determined that study participants spent approximately 65% of their time in sedentary behaviors. The Actigraph (<100 counts/minute) and the IDEEA recorded similar amounts of time spent in sedentary behaviors (8.63 ± 1.9 hours/day and 8.53 ± 1.9 hours/day, respectively (p = 0.82). These findings suggest that the Actigraph threshold (<100 counts/min) is an accurate measure of sedentary behaviors. The current study supports the use of accelerometers as accurate measures of sedentary behavior.

**PA Surveys and QOL of Assessment**

The International Physical Activity Questionnaire (IPAC) was developed as a way to assess PA and inactivity across a variety of populations. The questionnaire was designed specifically for adults 18-65 years old and consists of four subcategories of PA; PA at related to transportation, PA related to occupation, PA related to household and
gardening tasks, and PA during leisure time activities. In 2003, Craig et al. published reliability and validity research for the IPAQ. A total of 12 countries participated in the evaluation of the questionnaire. The IPAQ questionnaire was found to have a Spearman’s correlation of $p=0.76$ between reported and measured MET min/week. This was determined using the criterion measurement of the Computer Science and Application Inc. 7164 accelerometer. Based on the findings Craig et al. concluded that the International Physical Activity Questionnaire (IPAQ) showed a moderate correlation ($p=0.33$) between reported and observed PA when monitoring adults in diverse settings. Observations suggest the IPAQ questionnaires produce repeatable data that is comparable to other validated subjective and objective measurements and supports the IPAQ as a valid assessment tool for the subjective measurement of PA.

The Stanford 7-day activity recall (7-DR) is an instrument designed to assess work and leisure time PA in epidemiological studies. A study by Richardson et al. in 2001 evaluated the accuracy and repeatability in a population of 77 men and women between the ages of 20-59 years. Subjects completed the 7-DR twice, one month apart. Results from the 7-DR were compared with 48-hour PA records, Caltrac (Mistras co, Providence, NJ) accelerometer readings, peak oxygen uptake ($\text{VO}_2\text{peak}$), and % body fat. One month repeatability correlation values were reported as $r=0.6$ and 0.35 for men and women, respectively. A closer association was found between the 7-DR and 48-hour PA record for very hard activities ($r=0.44$) as opposed to light and moderate intensity activities ($r=0.32$). Total PA assessed by the 7-DR was significantly ($r=0.54$) associated with those recorded by the Caltrac accelerometer for men only. The criterion
used for the determination of the measured intensities was not available. Richardson et al. concluded the Stanford 7-day recall was most accurate for assessing habitual PA for activities that were vigorous compared with lower intensity activities. The observed inaccuracies at low intensity levels limit the ability of the 7-DR survey to be used in elderly and sedentary populations.

The Satisfactions With Life Scale (SWLS) was developed to be a “multi-item scale to measure life satisfaction as a cognitive-judgmental process” 47. Diener et al. 47 described the SWLS as a promising instrument in terms of measuring change in subjective well-being and intervention outcomes. In 1991, Pavot et al. 48 conducted a study including 130 (male = 84, female = 46) university students. Subjects completed the SWLS at the beginning of the study, and then on 2 more occasions at 2-week intervals. Test and re-test reliability was found to be $r = 0.84$ for the SWLS, with no significant differences between genders. A significant correlation ($P < .001$) was found between the observed life satisfaction reported by the SWLS when compared with peer and family reports of life satisfaction. The SWLS was also shown to have a significant correlation with the LSI-A and Philadelphia Geriatric Center Morale Scale. Pavot et al. concluded the SWLS had considerable evidence to support its reliability and validity.

**Barriers to PA**

Mechanization of work and domestic chores has, for the most part, eliminated obligatory PA from modern life 49. Voluntary and recreational PA has assumed central importance in filling PA needs. For these reasons it is becoming increasingly important to develop efficient and cost effective ways to promote PA. However, a variety of
different barriers have been identified during the process of developing these intervention programs.

The following is a summary of the most commonly identified barriers to increasing or sustaining PA levels and intensities. PA is viewed by many as voluntary and time consuming, and it may compete with other vocational responsibilities or leisure time interests. This is supported by recent surveys that have identified, lack of time due to caregiving responsibilities, health concerns, and lack of motivation, as the top three cited barriers to becoming more physically active\(^{49,50}\). Personal and environmental factors such as; lack of energy, self-consciousness about one’s personal appearance, lack of hills in one’s neighborhood, lack of enjoyable scenery, lack of social support, inclement weather, disruptions in routine, lack of access to facilities, dislike of vigorous activity and exercise, and infrequent observation of others being physically active have also been reported for barriers to attaining regular PA\(^{51}\). A survey of women over the age of 40 also revealed environmental factors such as safety of the surrounding neighborhood, availability of appropriate programs, and cost issues as barriers to becoming more physically active. Sixty-two percent of those surveyed rated exercising on one’s own with instruction as more appealing than undertaking exercise in an instructor-led group. Low-moderate intensity activities were more likely to be continued than high-intensity activities\(^{50}\).

**Pedometer Feedback Based PA Interventions**

Richardson et al.\(^{52}\) conducted a study utilizing pedometer feedback as a method for increasing PA and gaining additional health benefits associated with PA. The study
combined pedometer (SportBrain First Step) feedback with an existing weight loss program. A total of 12 participants (men=11, women=1) with an average age of 52 ± 12 years old were recruited for this study through 3 separate Department of Veteran’s Affairs medical centers. All subjects enrolled in the study were obese (BMI > 30) with an average BMI of 37 ± 6.5 kg/m² at baseline. The intervention included a structured nutritional counseling intervention based on the American Dietetic Association’s Medical Nutrition Therapy Weight Management Protocol. The intervention was delivered over 4 individual face-to-face sessions with the dietician, compared with the usual 6 session delivery. Upon entering into the study 10 of the 12 participants had at least one additional cardiovascular disease risk factor other than obesity (diabetes=2, hypertension=8, hypercholesterolemia=6, CAD=1). Subjects were given a SportBrain First Step enhanced pedometer (SportBrain co. Naples, FL) and followed for 18-27 days. Participants were assisted in setting step count goals by their weight loss counselors and encouraged to track their daily steps and progress towards meeting their goals. Goals were increased gradually based on average steps/day for the previous week.

Participants had an average weight loss of 4.1 pounds over the duration of the intervention. The average measured PA at baseline (6,019 steps/day) significantly increased (p=0.04) when reassessed (7,358 steps/day) post intervention. Standard deviation and standard error values were not reported for these claims. Researchers equated the 1,339 steps/day increase to approximately an additional 0.6 miles or 12 minutes of walking based on an average of 2200 steps/mile and average walking speed of
3 mph. The study reported that there were no significant changes in reported self-efficacy during the duration of the trial.

Limitations to this study include a small and isolated sample size. The sample population is limited to veterans who were already attending the Veterans Affairs Medical Centers for a weight loss program. The short duration of the study does not show sustainability of the increased steps/day. The study did not provide a control group to determine if weight loss was attributable to the increased steps per day or the weight loss program.

In 2007, Richardson et al. \textsuperscript{53} conducted a six week randomized trial utilizing an internet-based pedometer feedback program for individuals diagnosed with type II diabetes. The program utilized for the intervention was Stepping Up to Health (SUH) a web based program designed to promote walking for those with or at elevated risk for chronic disease (steppinguptohealth.org). Eligible subjects were >18 years of age, diagnosed with Type II diabetes, regular access to e-mail, internet, USB port, and self-reported <150 minutes/week of moderate-intensity PA. Subjects were also required to obtain medical clearance from a physician before participating. Subjects were excluded if they had used a pedometer in the past 30 days or were currently pregnant.

All individuals were assessed at baseline for height, weight, and BP. Following assessments subjects were provided the Omron HJ-720ITC pedometer along with written instructions on uploading their pedometer to the SUH program. During the baseline assessment the pedometers were blinded by placing a piece of tape over the screen to prevent influence by self-monitoring of PA. Subjects were also provided a written
handout on walking safely specifically tailored to those individuals with diabetes. Subjects were instructed to go about their usual activities of daily living for 7 days. During this time they were not provided individualized goals or feedback from the SUH website.

Subjects were instructed to remove the blinding tape and continue to wear pedometers during all waking hours for 6-weeks. Participants were randomized to either the lifestyle goals (LG) or structured goals (SG) groups. The LG group received goals targeting total accumulated steps, as seen in a traditional pedometer-based walking program. The SG group received goals based only on steps taken during walking bouts of at least 10 minutes, with ≥60 steps/minute. Subjects received a new personally tailored motivational message each week by way of their personalized SUH web page. Motivational messages were based on individual responses to the baseline survey and based upon the Health Belief Model and highlighted perceived benefits of exercise along with barriers and strategies to overcome barriers. Subjects were asked to download their pedometers at least once per week to the SUH page, and results were automatically transferred to a central repository.

The LG group focused on accumulating total steps/day. Daily step goals were based on an algorithm involving the previous 7 days of total step data and adding 1200 steps/day to the average from the previous week. Individual goals feedback was displayed in graph and text format on the SUH web page. The maximum allowable goal was 10,000 steps/day.
The SG group focused on bout steps, or aerobic steps as referred to on the Omron HJ-720ITC pedometer. In order to accumulate bout steps subjects had to walk for ≥10 continuous minutes in duration. Individual goals were assigned based on bout/aerobic steps from the previous 7-days of data, and adding 800 steps/day to the average. Feedback for this group was also displayed in graph and text format on their individualized SUH webpage, but only included bout step data.

A total of 30 subjects were randomized into the two groups (LG=16 vs. SG=14). Both groups significantly increased their average daily bout steps by 1921 ± 2729 steps/day. There were no significant differences in average daily bout steps between groups. Both groups also significantly increased their daily PA by an average of 1938 ± 3298 steps/day. Once again, there were no significant differences between groups. Of the subjects completing all outcome measures, 44% significantly increased average total steps/day and 37% increased average daily bout steps. Post intervention analysis showed that 40% of participants accumulated at least the minimum recommendations of 150 minutes of bout activity per day during the 6th week of the study.

This study included only participants who self-referred to a PA intervention program. It is still unknown if the SUH program would effectively increase the PA of sedentary individuals who were referred to the program by an outside source. The study also focuses only on a select group of patients with Type II diabetes. It is unknown if this approach to increasing PA would be effective in a sedentary population with other chronic diseases or no known chronic disease. It is unknown if there is greater benefit to an extended use of the SUH program beyond 6 weeks. The effects of the observed
changes in PA on cardiometabolic disease risk factors are unknown as no data was presented for changes in weight, body composition, or blood pressure. Additionally, no evaluation was provided for change in total minutes of sedentary time secondary to the observed increase in PA.

In 2011, Goodrich et al.\textsuperscript{54} conducted another study utilizing the SUH PA intervention program. This was a pilot study focused on “integrating an internet mediated walking program into family medicine clinical practice”. The clinical approach to the SUH program was designed with the assistance of a group of physicians and medical assistants. The purpose of the study was to develop a clinical interface that included provider input and allowed primary care physicians to refer patients to the SUH program and monitor their progress and safety. A secondary goal was to evaluate the feasibility of incorporating the SUH intervention into everyday clinical practice to provide objective measures of patient PA through pedometer step counts.

A group of 13 providers participated in the study. Patients were referred to the SUH program by physicians and medical assistants in the area surrounding the University of Michigan. Each physician and medical assistant pair were asked to recruit 6-8 sedentary adult patients (>18 years) with a chronic condition such as, coronary artery disease, type II diabetes, or a BMI > 25 kg/m\textsuperscript{2} and self-reported <150 minutes per week of moderate intensity PA. A total of 139 patients were referred to the program, 27% (n=37) agreed to enroll in the study. Throughout the intervention patients were required to wear the Omron HJ-720ITC pedometer during all waking hours for duration of 6-weeks. An initial baseline PA assessment was done using a blinded Omron HJ-720ITC
pedometer for 7 days before beginning the intervention. During this period subjects were instructed to download their pedometers to the SUH server. Subjects received weekly motivational messages and daily health tips that were automatically generated by the SUH program and delivered in text and graph format on the individual SUH webpage. Individually tailored motivational messages were received each week and included, links to educational content directly related to each individuals goals, updated target steps/day and graphs to help monitor individual progress towards their goals.

Subjects (n=37) were clinically obese with a mean BMI of 40.7 ± 7.6 kg/m² and average age of 45.2 ± 9.9 years. At baseline, subjects had a mean PA level equivalent to 4520 ± 309 steps/day. Post intervention a significant (p=0.003) increase in mean PA (6013 ± 443 steps/day) was observed. Significant (p=0.004) improvements were also noted for mean weekly aerobic steps from pre (406 ± 137) to post (1114 ± 218) intervention along with total minutes of aerobic walking per week from pre (27.0 ± 8.8) to post (71.7 ± 14.7).

A survey of the referring physicians and medical assistants revealed, physicians typically viewed the referrals as an additional time burden to their already busy schedules, while medical assistant viewed the program as a more feasible approach for daily clinical practice. The exact amount of time that was involved for each physician was not included in the data analysis. Physicians noted that it was often difficult to include a referral into a clinical visit as competing priorities often consumed all of their available time. However, most physician and medial assistant pairings who were able to
incorporate it into their clinical visits found the program to be a success when discussing it with patients.

One of the main limitations to the study is the brief intervention duration. The 6-week delivery format does not allow for the assessment of changes in subject risk factor profiles that may be due to a chronic increase in PA. The study also does not provide any assessment of sedentary behavior time. A longer intervention duration that incorporates measurements of risk factors, body composition, functional capacity, and sedentary time may be able to apply the increases in PA to reductions in risk factors for the prevention or maintenance of chronic disease. A control group would help support the studies claims that the changes observed were a product of the intervention and not another variable.

A 2009 study by Tudor-Locke et al. evaluated the effectiveness of the First Step Program (FSP) to promote lifestyle changes in PA. The FSP is a theory-based behavior modification program based on pedometer feedback. The program was originally developed for individuals with type II diabetes and is based primarily on the social cognitive theory, which emphasizes self-efficacy and social support, along with the trans-theoretical model.

A total of 60 individuals (33 male, 27 female) with an average age of 52.9 ± 5.0 years and BMI of 33.9 ± 5.6 kg/m² participated in the study. Subjects were randomized into either a control (n = 36) or FSP (n = 24) group. Study participants were assessed at baseline and after completion of the 16-week program. Each assessment included a pedometer assessment of PA (Yamax SW-200), resting heart rate and blood pressure, an oral glucose tolerance test, and blood samples for determination of fasting glucose and
plasma lipid profiles. During the adoption phase (initial 4 weeks), participants were asked to attend weekly group meetings. At the meetings, subjects were provided pedometers and the program manual containing goal-setting and problem-solving exercises, as well as calendars for self-monitoring PA (steps/day). During the adherence phase (subsequent 12-weeks), participants were instructed to use their pedometers and calendars for goal-setting and self-monitoring. Program compliance was reported as, 67% of those in the FSP group attended all four group sessions, with the remainder attending 3 of the 4 sessions. FSP participants increased their PA by approximately 3000 steps/day or 52% from baseline. No standard deviation or standard error values were provided for change in steps/day. This was a significant (p<0.01) increase compared to the control group who had no significant change. BMI did not change significantly in either of the groups during the intervention. Waist girth decreased 1.8 ± 0.6 cm in the FSP group compared to 0.4 cm in the control group. Change in waist circumference was significant over time; however, there was no significant difference between groups.

Limitations to the study include a small subject population. With only 9 subjects it is difficult to assume that findings will apply to the broader population. Also, subjects who participated in the study were diagnosed with diabetes. It is unknown if this intervention can also be effective in increasing the PA in other sedentary individuals who have other chronic diseases or may be at high risk for developing them.

A study conducted by Pal et al.\textsuperscript{11} in 2009, evaluated the effectiveness of a pedometer feedback approach to increasing PA in sedentary obese women. The 12-week study was conducted on Perth, Australia. Qualifying subjects self-reported <120
min/week of moderate intensity PA, and attended a group orientation meeting. All subjects in the study were provided with the National Australian Physical Activity Guidelines, which includes information on frequency, intensity, and duration of recommended PA.

The study group wore a pedometer and recorded their steps daily, while the control group was provided a blinded pedometer. Subjects in the control group were instructed to remove the seal on their pedometer each week to record their total steps. Those in the pedometer intervention group were provided a general goal 10,000 steps/day. Both groups were encouraged to set small achievable goals, such as 10-minute walks, and gradually increase to 30 min/day. Baseline and post intervention PA activity was assessed utilizing the IPAQ questionnaire. Nutritional intake was assessed utilizing pre and post intervention 3 day food diaries.

A total of 26 obese women were randomized into either a pedometer intervention group (n=13) or a control group (n=13). Subjects had an average age of 42 ± 9.2 years for the pedometer group and 44 ± 6.9 years for the control group. Average BMI for the pedometer group was 29.9 ± 0.7 kg/m² and for the control group 28.6 ± 0.7 kg/m². There were no significant differences between groups at baseline. Mean PA for the control group did not change significantly during the 12-week intervention. Observed PA at 6-weeks (8321 ± 884 steps/day) and 12-weeks (9703 ± 921 steps/day) were significantly higher than baseline (6242 ± 541 steps/day ) (p = 0.046 and p = 0.035, respectively). There were no significant changes noted between groups at 12-weeks for waist circumference, BMI, or % body fat. However, a significant (4.7%) decrease in
systolic blood pressure was noted in the intervention group. Total time spent performing moderate intensity PA was not significantly different between groups. However, a trend was observed in the study group, increasing from 161.5 ± 58.6 min/week at baseline to 214.3 ± 67.5 min/week upon completion of the intervention. There was a significant increase in total time spent walking in the pedometer intervention group; numerical data was not provided for this claim.

There current study had limitations within the control group. Participants in the control group were blinded from looking at their pedometer only by a piece of tape. This places a high reliance on subject honesty not to look at the pedometer. A true control group would not have any access to their step count and would not be instructed to record their steps every week. The goals set for participants were not individualized; a goal of 10,000 steps per day goal may be overwhelming and inappropriate for most sedentary and obese women.

A 2004 publication by Chan et al.\textsuperscript{10} outlined the potential health benefits related to a successful pedometer feedback PA intervention. The study utilized a modified version of the previously referenced First Step Program developed by Tudor-Locke. The current version was referred to as the Prince Edward Island-First Step Program (PEI-FSP) and consisted of a 4-week adoption phase and an 8-week adherence phase. During the adoption phase subjects were required to meet with a facilitator for 30-60 min/week during their lunch hour. During this interaction facilitators assisted subjects in reviewing progress from the previous week and assisted them in setting new weekly PA goals.
Subjects logged their steps/day into a personalized website designed specifically for the PEI-FSP program throughout the duration of the intervention.

Subjects (n=177) were recruited from 5 workplaces in Prince Edward Island. Subjects had an average steps per day of 7029 ± 3100 at baseline and an average BMI of 29.5 ± 5.9 kg/m². Approximately 60% (n=106) of those enrolled in the program completed the intervention. Completion of the study was defined as recording at least 8-weeks of pedometer data and completing the final health assessment. A majority of those who dropped out of the study (77.3%) did so within the first 4-weeks.

All subjects included in the study were overweight (BMI > 25). All but 9 subjects had an increased average steps/day after completing the PEI-FSP program. Two participants showed no change in their average steps from baseline, and 7 showed a significant decrease (-12.0 ± 7.6 %). Those who displayed a decrease in average steps per day had an average baseline PA of 11,389 ± 4,570 steps/day. Increases in average steps/day plateaued after a mean of 4.0 ± 3.3 weeks. During the adoption phase the average observed increase was 3451 ± 2661 steps/day, the observed change was maintained throughout the subsequent adherence phase. Reassessment at the end of the PEI-FSP program showed significant decreases in BW, BMI, WG, and HR. Access to the statistical data was not available for these measurements. No significant changes were noted for SBP or DBP. Facilitators estimated that in individual with a baseline step count of 4,600 steps/day and baseline WG of 100 cm would have to increase PA by approximately 4,300 steps/day in order to see a 2 cm reduction in WG.
Limitations to this study include lack of a control group. Changes in steps per day and cardiometabolic disease risk factors cannot be directly attributed to the PEI-FSP. It was not noted whether subjects were enrolled in any other type of wellness or health program at the time of the intervention.

The most recent research has paired pedometer feedback with motivational messaging techniques as a new approach to improve the effectiveness of PA interventions. Strath et al.\textsuperscript{56} conducted a study utilizing pedometers along with varying methods of education and motivation messages. Educational materials and motivational messages were based on the Transtheoretical model and Social Cognitive Theory, and focused on benefits of regular PA, PA barriers, and strategies to help overcome barriers. The purpose of the study was to evaluate the most effective combination for increasing the physical activity of apparently healthy adults.

Eligible subjects were inactive or insufficiently active, as determined by self-reported <30 min/day of moderate intensity PA on 5 days/week. Subjects must also have scored in the pre-contemplation, contemplation, or preparation stages of change as determined by questionnaire. Subjects who met these criteria were then given a blinded pedometer for a 7-day baseline assessment. Only those with < 7,500 steps/day qualified for participation in the study. Qualifying subjects were then randomized into one of four groups. Groups included; standard education (Group 1), pedometer plus standard education (Group 2), pedometer plus individualized education (Group 3), and pedometer plus individualized education and bi-weekly telephone contact (Group 4).
A total of 81 subjects enrolled in the study with 61 subjects (51 female, 10 male) completing all baseline and outcome measures. Subjects had a mean age of 63.8 ± 6.0 years, BMI 29.7 ± 5.7 kg/m², and baseline PA 5,235 ± 1734 steps/day. After completion of the 12-week program, group 1 did not significantly increase in steps/day compared with baseline. There were also no significant differences in steps/day between group 1 and group 2. However, group 3 showed a significant increase when compared with group 1 (2159 steps/day) and group 2 (1684 steps/day). Group 4 also showed significant increases compared with groups 1 (2488 steps/day) and 2 (2013 steps/day) at the conclusion of the study, but no significant improvement when compared with group 3 (329). Standard deviations and standard errors were not presented for step/day changes in any of the observed groups. Upon completion of the intervention 44% of group 2 attained the goal of increasing their average PA by a minimum ≥2,000 steps/day. Post 12-week intervention, 75% of the subjects randomized to group 3 had achieved their goal along with 79% of those randomized to group 4. These findings support the effectiveness of motivational messages and individually tailored feedback as a component to successful pedometer feedback based PA interventions.

The study population is limited to apparently healthy individuals who are free of any known chronic disease or risk factors. It is unknown if the same results can be translated to a diseased population. A majority of the subjects studied were female. A predominantly male sample population may not provide the same responses noted in the current study. Further research is needed to determine if the program can be implemented in a non-self-referred population.
The current study is based off of a study by Carr et al. in 2008. The Carr et al. study was designed to evaluate the effectiveness of the ALED PA intervention to increase the PA of overweight and sedentary adults and observe any reciprocal changes in cardiometabolic disease risk factor profiles. Prior to this study, there had been many trials that utilized an instructor facilitated version of the ALED program and had shown successful increases in self-reported PA and aerobic fitness. Carr et al. is the first known study to validate an internet delivery format of the ALED PA intervention program.

The subject population was predominantly from rural regions (< 12.5 people per square mile) of Wyoming and northern Colorado. Recruitment period lasted from 2005 until 2007. The paper reports results from 2 separate studies utilizing the ALED program. Subjects (n=17) in study 1 were randomized into one of 4 groups. Groups included a control group, a pedometer intervention group (TEP), and two groups that utilized the ALED program, one online (ALED-I) and the other utilizing the classroom format (ALED-C). Those randomized to the control group received a pedometer for baseline and post study measurements only, and were instructed to continue with their normal activities of daily living. Subjects in the TEP group received a pedometer and an updated exercise prescription every other week. Exercise prescriptions were based on a 10% increase over the previous week’s average steps. Those in one of the ALED groups received a pedometer along with all ALED materials and were supervised by a licensed program facilitator or administrator.
At baseline, there were no significant differences between the 4 groups, (Control, TEP, ALED-C, and ALED-I), all had similar characteristics with an average age of 35.2 ± 7.3 years of age, normotensive (SBP = 121 ± 3 mmHg; DBP = 72 ± 4 mmHg), mean BMI of 27.1 ± 0.2 kg/m², and an estimated VO₂max of 31.1 ± 2.1 ml/kg/min. Significant and similar (~25%) differences in PA were noted for all 3 intervention groups when compared with the control group and baseline values. There were no significant differences between intervention groups, with all 3 groups showing improvements between 2100 ± 696 and 2400 ± 985 steps/day.

The second study included data collection from 32 (men= 6, women = 26) obese subjects. Subjects were randomized into either the ALED-I group or control. The intervention for the ALED-I group was the same as described previously for study 1. There were no significant differences in baseline PA between groups. Average steps/day were significantly higher for the ALED-I group post intervention (7999 ± 439 steps/day) as compared with pre intervention (6614 ± 388 steps/day). Steps/day average was not significantly different pre to post intervention for the control group, nor was it significant post intervention between the ALED-I group (7999 ± 439) and control group (7678 ± 652). A significant correlation was found between steps/day at baseline and predicted change in mean step average post intervention for those subjects participating in the ALED-I intervention only. When controlling for age, waist circumferences were significantly reduced when compared with baseline measurements. No other cardiometabolic disease risk factors were significantly affected.
Limitations to this study include an isolated sample population who self-referred to the study from rural areas of Wyoming and Colorado. It is not known if the program would have the same effects on a higher population density cohort or in a physician referred population. It is the purpose of this study to evaluate these limitations and report the effects of the ALED-I intervention on the higher density population of Delaware county IN.

**Summary**
Previous research supports the use of pedometer feedback based intervention programs as an effective means for increasing PA among sedentary populations. Carr et al. has shown the ALED-I PA intervention program to significantly increase PA among rural populations in the state of Wyoming. Further research is needed to extend these findings to additional rural populations as well as higher density urban populations. Further research is also needed determine if the observed increases in PA result in significantly improved cardiometabolic disease risk factor profiles.
Chapter III

Methodology

The primary purpose of this study was to determine the effectiveness of the ALED physical activity intervention in increasing average daily step counts and decreasing total sedentary time among a physically inactive adult population; in addition to evaluating its ability to be successfully implemented through a healthcare provider in the higher density population of Delaware County, IN. The ALED intervention was designed to increase the amount of lifestyle PA performed by sedentary adult populations.

Subjects

Subjects were recruited from 4 Muncie, IN area physician offices along with the Ball State University Health Clinic. Those involved in the subject recruitment process included physicians, nurses, and the health coach from Ball State University. These individuals presented the ALED intervention to patients whom they believed were currently not meeting recommended PA guidelines and would benefit from a more active lifestyle. Patients were eligible for the study if they reported achieving <30 minutes of moderate-vigorous PA on most days of the week, or <150 minutes of moderate-vigorous PA per week, for at least 3-months as stated by the Physical Activity Guidelines for Americans 2008¹. Subjects eligible to participate in the study were between the ages of
18-79 years old, free of limitations or contraindications to ambulatory exercise, cognitive impairment, and uncontrolled cardiometabolic, respiratory, or neurological conditions. Female participants were not eligible if they were pregnant or trying to become pregnant within 20-weeks of recruitment date. The study was approved by the Institutional Review Boards Ball State University and all subjects were provided a full explanation of all study requirements and signed an informed consent document before beginning the study.

A total of 15 (2 male and 13 female) subjects volunteered for the study; however 5 female subjects dropped out or were non-compliant leaving 10 subjects included in the data analyses. Complete descriptive characteristics for all subjects, including the 5 dropouts, are provided in table 1. Reasons for discontinued participation included lack of time (n=1), injury (n=2), and failure to complete all required baseline and post intervention measurements (n=2).

**Procedures**

Subjects were required to attend 6 mandatory visits to the Ball State University Human Performance Laboratory over a 16-week period in order to be included in the data analyses. The initial visit included a full description of study requirements including the informed consent document, along with verification that no contraindications to participation were present. A 2-week baseline PA assessment was then performed utilizing accelerometers and pedometers for measures of PA intensity and average steps/day, respectively.
During the first visit to the Human Performance Laboratory (HPL) subjects were explained the details of the study and provided an informed consent, highlighting each procedure along with potential risks and benefits associated with participation in the study. Upon completion of the informed consent, subjects were provided a health history questionnaire to identify any potential medical conditions that may contraindicate further participation in the study. Additionally, subjects were asked to sign a Protected Health Information form to allow the exchange of pertinent health information between the research team and the subject’s primary care physician. Each subject was then given a series of questionnaires for assessment of the subject’s interpretation of their current PA status along with a “Quality of Life” psychosocial assessment.

Subjects were provided an Omron HJ-720 ITC (Omron Healthcare, Kyoto, Japan) pedometer and Actigraph GT3X (Actigraph Inc., Pensacola, FL) accelerometer for an assessment of current PA status over a 14-day baseline period. Subjects were instructed to wear their Omron pedometer on their left hip, midway between the front of the thigh and outside of the hip. The Actigraph accelerometers were to be worn on the right hip, midway between the front of the thigh and the outside of the hip. A 20-foot walk test was done to measure stride length, along with a 10-step walk test to check the accuracy of the pedometer.

Subjects then completed a 2-week baseline PA assessment during which time they were instructed to wear both PA monitoring devices during all waking hours, other than bathing and water based activities, and proceed with their normal activities of daily living. Subjects were provided a log sheet to record any activities that they considered to
be abnormal to their normal routine, any periods when they forgot to wear the monitoring devices, or any activities they performed that would not be detected by the monitoring devices, such as cycling.

Upon completion of the two week baseline PA assessment, subjects were asked to return to the HPL for their second visit. At this time both devices were downloaded and analyzed to determine mean daily step count. Subjects with an average daily step count of $\leq 8,000$ steps/day satisfied the inclusion criteria for the study and proceeded with their second visit. Those with an average step count of $\geq 8,000$ steps/day were excluded from participation from the study and had both their Omron pedometer and Actigraph GT3X accelerometer collected, as they were considered overly active for participation. The cut point of $\leq 8,000$ steps/day was based on previous research at the University of Wyoming who proposed those with an initial step count $\leq 8,000$ steps/day displayed the greatest improvements with the ALED program.

Those patients qualifying for further participation in the study had their 3-day food log and pedometer log sheets collected. During the second visit a baseline blood sample ($\leq 15$ mL in 2 tubes) was obtained; one tube was used for determination of lipids and glucose profile and the second tube for determination of insulin levels. If the subject had these measures taken within 4-weeks of this appointment date, the clinical data was provided to the investigative team by the personal physician’s office. Subjects were then administered a modified Stanford 7-day Physical Activity Recall questionnaire (Appendix A), oral Sedentary Criteria Screener (Appendix B), and International Physical Activity Questionnaire (IPAQ) (Appendix C) to assess recall of PA status over the 2-
week baseline assessment. Additionally, subjects completed the Satisfaction With Life Scale (Appendix D) to assess quality of life. Resting blood pressure and heart rate were then taken after subjects had been resting for five minutes. Blood pressure was measured using a calibrated ADC mobile sphygmomanometer until two consistent measurements were taken. Subjects were seated for at least 5-minutes with both feet flat on the floor prior to the measurement. Heart rate was measured by 60-second manual palpation of the radial pulse.

Additional baseline measures included a Lunar iDXA scan (GE Lunar, Madison, WI) and measurements of height, and weight, along with waist and hip circumferences. The DXA scan required participants to lie supine on the DXA platform for approximately 7-minutes while the scan was completed. Subjects were also asked to remove their shoes, any clothing containing metal, and jewelry prior to the scan. Weight was measured with a calibrated Health O Meter 349KLX electronic scale (Jarden Co. Providence, RI) and height was measured using a calibrated stadiometer. Subjects were asked to remove shoes, and excess clothing for measurements of height and weight, as well as void their bladders within 1-hour prior to the measurement. Waist and hip circumference measurements were measured following ACSM guidelines (4), using a cloth tape measure with spring-loaded handle, to reduce compression of the skin. All measurements were repeated until 2 consistent measures were recorded.

After completion of baseline measurements subjects completed a submaximal graded treadmill test. After approximately 1-minute of warm up, subjects walked at a self-selected brisk walking pace throughout the test, while grade was increased 2% every
2-minutes until subject had reached approximately 85% of their predicted maximal heart rate or a rating of perceived exertion \( \geq 17 \). RPE was determined using the Borg (6-20) Rating of Perceived Exertion scale. Predicted maximal heart rate was determined by \( 220 - \text{age of the subject} \). Heart rate and ECG were measured utilizing the GE Case 16 Marquette Stress System (GE, Milwaukee, WI). Oxygen consumption (\( \text{VO}_2 \)) was determined using the Parvo TrueOne 2400 (Sandy, Utah) metabolic system. Blood pressures were recorded during the last minute of each stage for the duration of the exercise test. Heart rate and RPE were recorded each minute. After 85% of the subjects predicted maximal heart rate was achieved, subjects performed a 3-minute active cool down followed by a 2-minute supine recovery. ECG was monitored throughout the cool down, heart rate was recorded every minute, and blood pressure was recorded once for each of the active and supine recovery periods.

After completion of the submaximal exercise test subjects were provided the ALED text book, and had a personal account created for them on the website. Detailed instructions and a walk through of the web site were provided until the subject felt that they were comfortable with the program. Subjects were encouraged to ask any questions that they had about the intervention at that time. They then had their pedometers returned to them for use during the intervention.

After completion of visit 2, subjects were instructed to begin the ALED intervention starting with chapter 1, and subsequently completing one chapter per week thereafter. Subjects were asked to return to the HPL four weeks after the completion of visit two for visit three. The primary purpose of this visit was to download their Omron
pedometers. This was necessary due to the limited 41 day storage capacity of the Omron pedometer. This was once again repeated at eight weeks after completion of visit two.

The third, 4-week pedometer download, was scheduled 12-weeks after visit two. Measurements taken during visit one, with the exception of the informed consent, PHI, and HHQ forms were retaken. In addition to the visit one protocol, subjects also completed an ALED exit survey to obtain feedback of their overall impression and interpretation of the study. At the end of this visit subjects were once again given an Actigraph GT3X accelerometer to wear along with their Omron pedometer. Subjects were instructed to wear the devices for two weeks again for a post intervention PA and sedentary behavior assessment.

After completion of the 2-week post intervention assessment, subjects returned to the lab for a repeat of visit 2. Accelerometers, PA log forms, and food logs were collected upon arrival. Blood draw, resting heart rate, blood pressure, body composition, and submaximal treadmill test measurements were repeated for comparison to those taken at baseline. Upon completion of visit two subjects were given their Omron pedometers, ALED workbooks, and retained access to the internet program for the remainder of their 12-month membership as a reward for completing the study. Subjects were encouraged to continue on with the ALED program and all lifestyle modifications that had been made over the past 12-weeks.

**Data Analysis**

The main measure of this study will be a comparison between the pre and post intervention PA levels. Physical activity will be measured by the average number of
steps per day as recorded by the Omron pedometer. The ActiGraph will be used to quantify any moderate to vigorous intensity activity minutes as well as physical inactivity minutes. In addition to these measurements, a comparison will be done to compare the objective PA measurements to the subjective PA data that was collected by surveys. A comparison will be done between pre and post nutritional intake and Satisfaction With Life survey outcomes. Additional study outcomes will include a comparison between pre and post intervention body composition, blood lipid profiles, insulin levels, and cardiorespiratory measurements during the submaximal treadmill test. All of these measures combined will be used to determine improvements that have been made in activity status and cardiovascular disease risk factor profiles.
Chapter IV

Research Manuscript

Journal Format: Medicine and Science in Sport and Exercise
Active Living Every Day Pedometer Feedback Based Physical Activity Intervention

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Abstract

Purpose: The primary purpose of this study was to demonstrate the Active Living Every Day (ALED) pedometer based physical activity (PA) intervention could be utilized by healthcare providers to successfully increase PA in Delaware County, IN (299 people/square mile). Methods: A total of 15 subjects were recruited to the study and required to attend 6 visits at the Human Performance Laboratory over a 16-week period. After completion of baseline PA and cardiometabolic disease risk factor profiles, patients were given the 12-week ALED intervention. During the intervention PA was monitored using the Omron HJ720-ITC pedometer. Reassessment of PA and cardiometabolic risk factor profiles was performed post intervention. Results: Post intervention assessment revealed no significant changes in observed PA. Further analysis was performed to compare weekend vs. weekday PA. Weekday PA levels approached significance at 4-weeks post baseline assessment. No significant changes were observed in percentage of time spent performing sedentary or lifestyle-moderate intensity PA. No significant changes or trends were observed in measurements of body composition, aerobic capacity, exercise hemodynamics or QOL. The healthcare provider delivery method was unsuccessful in recruiting a sufficient number of subjects to provide definite conclusions. However, preliminary observations suggest internet delivery of the ALED program may not be an effective method for increasing PA in the most sedentary adult populations

Key Words: Physical activity, pedometer feedback, cardiometabolic disease, risk factors
**Introduction**

Physical inactivity is has been recognized by the American Heart Association (AHA) as an independent risk factor for cardiovascular disease, the leading cause of death in the United States for men and women\(^1\). Physical inactivity is repeated failure to achieve recommended levels of physical activity (PA), defined as any bodily movement produced by skeletal muscles that result in energy expenditure\(^2\). PA increases caloric expenditure which helps to manage and prevent obesity, another independent risk factor for cardiovascular disease. PA is also known to be an effective means for the prevention and treatment of independent cardiovascular disease risk factors such as hypertension, dyslipidemia, and diabetes. Finally, PA has been shown to increase one’s quality of life and ability to perform daily activities\(^3\).

The 2008 Physical Activity Guidelines for Americans suggest all apparently healthy adults attain a minimum of 150 minutes of moderate, or 75 minutes of vigorous or an equivalent combination of the both moderate and vigorous intensity PA\(^4\).

Based on the computer assisted interviews of the National Health Interview Survey (NHIS), the Center for Disease Control (CDC)\(^5\) reported in 2007 that of the U.S. population, only 48.8% self-reported achieving the recommended amounts proposed in the 2008 PA Guidelines. Additionally, 37.7% of the U.S. population reported participation in some PA but failed to attain sufficient amounts to fulfill current recommendations. Thirteen and a half percent reported being inactive, or achieving an average of <10 minutes of moderate-vigorous activity per week. Indiana is no exception.
to these statistics and mirrors national inactivity levels with only 47.7% of the population in 2007 reporting sufficient amounts of PA, 39.7% reported achieving insufficient amounts of PA, and 12.7% determined to be inactive⁵.

The prevalence of physical inactivity is directly related to many negative health outcomes present in our society today. As currently as January 2012, the CDC has identified cardiovascular disease as the leading cause of death in the United States with approximately 1 of every 3 deaths directly related to heart disease and stroke (2,200 deaths/day)⁵. Physical inactivity is also widely recognized as a modifiable risk factor for many other chronic diseases such as; diabetes mellitus, colon and breast cancer, obesity, hypertension, osteoporosis, osteoarthritis, and depression.

Increasing an individual’s average daily PA seems to be the obvious solution to treating and preventing negative health outcomes associated with physical inactivity. Health benefits of increased and/or regular PA are well understood and include increased cardiorespiratory fitness, increased mental capacity, cardiometabolic risk factor reduction, reduced risk of cancer, weight control, improved sleep quality, and greater independence⁷. The current challenge for health professionals is to translate the established benefits of regular PA into everyday common practice in the American population.

Many Americans lead fast paced lives that including a high prevalence of sedentary activities such as long commutes and extended office hours. As a result of busy schedules many individuals feel there is a lack of time to participate in regular or recreational PA. Access to facilities that promote PA is a barrier, especially during hard
economic times, as they can be expensive and require additional travel time. Additionally, the improvement of modern conveniences has eliminated much of the obligatory PA and allows daily tasks to be performed while seated behind a desk or in the palm of your hand from the comfort of one’s own home. Another reason is the apparent lack of widespread knowledge on the deleterious health effects that physical inactivity has on an individual’s health and well-being. Recent PA interventions have tried to confront these obstacles through support groups, educational text books, self-monitoring techniques, and individualized feedback methods.

The most effective PA interventions have included both cognitive and behavioral components. The most commonly cited cognitive component of change is the social cognitive theory. The social cognitive theory suggests portions of an individual's knowledge acquisition can be directly related to observing others within the context of social interactions, experiences, and outside media influences. The behavioral component of change is most commonly based on the transtheoretical model of behavior change, which assesses an individual's readiness to act on a new healthier behavior, and provides strategies, or processes of change to guide the individual through the stages of change.

A 2006 circulation review of PA interventions concluded that studies of younger to middle-aged adults have demonstrated moderate increases in PA, although greater effectiveness has been shown for interventions that use behavior modification when compared with education alone. Interventions that utilize the healthcare setting have also shown moderate improvements in PA status after short term follow ups. Additionally,
the focus is shifting to mediated interventions that utilize print, telephone, and internet delivery formats as they require little or no face-to-face contact, and provide wide spread access along with cost-effectiveness. Preliminary research has shown these methods to be moderately effective in short and long term follow ups. However, there is a limited amount of research available to support these claims, especially with internet delivery formats. It was also noted that ongoing studies that promote lifestyle PA in addition to or instead of structured, class-based activity will likely contribute to our understanding of the options available for assisting adults with PA behavior change.

One such intervention is the Active Living Every Day (ALED) PA promotion program. The ALED program is a commercially available, internet based lifestyle PA behavior change program that is based on both the transtheoretical model and social cognitive theories of behavioral change. In 2008 Carr et. al\textsuperscript{11} reported their observed results of the ALED PA intervention program as a means for increasing PA in sedentary adult populations.

The study evaluated the ability to increase PA in a sedentary and overweight/obese population while additionally assessing the effect of the ALED program on cardiometabolic disease risk factors. The study was performed in predominantly rural regions of the State of Wyoming (12.5 people / square mile).

Multiple linear regression analyses revealed a significant correlation (p=0.03) between mean steps/day average and predicted change in steps for those in the ALED group only. This was the first known study to evaluate the ALED program using an objective measure of PA (Yamax Digiwalker SW-200 pedometer). Carr et. al, found that of those
completing all outcome measures for the study, a significant 17% increase in PA was noted. Based on observations by the research team, it was proposed that the ALED program may be most effective for those individuals who were the least active (<7,000 steps/day) at baseline.

Future research is needed to evaluate additional delivery methods, such as the proposed healthcare provider delivery format in the current study, in order to identify the most effective means for implementing the ALED program in sedentary adult populations. Future research is also needed to validate the observed effects of the ALED program on larger and more diverse population. Specifically, additional studies are needed to evaluate the effectiveness of the ALED program in higher density and urban populations in other regions of the United States. Additionally, further evaluation is needed to assess the effects of the ALED program on cardiometabolic disease risk factors.

The primary purpose of this research is to demonstrate that ALED can be successfully implemented, in the higher density population of Delaware County, IN (299 people/square mile), to increase mean steps/day and decrease sedentary time among physically inactive individuals. A healthcare provider delivery format was implemented as it was theorized by Carr et. al. to be a successful method for increasing PA. The secondary purpose of this study was to assess the effects of the ALED program on cardiometabolic risk factor profiles. Specifically, LDL and HDL cholesterol, % body fat, and waist circumference were measured as part of the analysis. Reproducing these results could provide clinicians with a feasible and powerful tool to reduce
cardiometabolic disease risk in broader segments of the population. It was hypothesized the ALED intervention program would produce a significant increase in PA (steps/day).

**Methods**

**Subjects**

Subjects were recruited from 4 Muncie, IN area physician offices along with the Ball State University Health Clinic. Those involved in the subject recruitment process included physicians, nurses, and the health coach from Ball State University. These individuals presented the ALED intervention to patients whom they believed were currently not meeting recommended PA guidelines and would benefit from a more active lifestyle. Patients were eligible for the study if they reported achieving <30 minutes of moderate-vigorous PA on most days of the week, or <150 minutes of moderate-vigorous PA per week, for at least 3 months as stated by the Physical Activity Guidelines for Americans 2008\(^4\). Subjects eligible to participate in the study were between the ages of 18-79 years old, free of limitations or contraindications to ambulatory exercise, cognitive impairment, and uncontrolled cardiovascular, metabolic, respiratory, or neurological conditions. Female participants were not eligible if they were pregnant or trying to become pregnant within 20 weeks of recruitment date. The study was approved by the Institutional Review Boards Ball State University and all subjects were provided a full explanation of all study requirements and signed an informed consent document before beginning the study.

A total of 15 (2 male and 13 female) subjects volunteered for the study; however 5 female subjects dropped-out or were non-compliant leaving 10 subjects included in the data analyses. Complete descriptive characteristics for all subjects, including the 5
dropouts, are provided in table 1. Reasons for discontinued participation included lack of time (n=1), injury (n=2), and failure to complete all required baseline and post intervention measurements (n=2).

Procedures

Subjects were required to attend 6 mandatory visits to the Ball State University Human Performance Laboratory over a 16-week period in order to be included in the data analyses. The initial visit included a full description of study requirements including the informed consent document, along with verification that no contraindications to participation were present. A 2-week baseline PA assessment was then performed utilizing accelerometers and pedometers for measures of PA intensity and average steps/day, respectively.

After completion of the 2-week baseline PA assessment, subjects meeting PA inclusion criteria (<8,000 steps/day) were assessed for resting measurements to assess traditional cardiovascular disease risk factors. A resting blood pressure measurement was performed after the subject was seated for 5 minutes with both legs flat on the ground, and arm supported at heart level. Body weight and height were measured using a standard physician scale and stadiometer. Collection and analyses of fasting blood lipids and glucose were performed by Lab Corp inc., Muncie, IN. Prior to starting the sub-maximal treadmill test, all subjects were provided a standardized oral explanation of the testing procedures and explanation of the Borg 6-20 Rating of Perceived Exertion (RPE) scale. The exercise test was performed on a motorized treadmill and controlled via the CASE ECG system (Milwaukee, WI). Oxygen consumption (VO₂) was determined
using the Parvo (Sandy, Utah) metabolic system. The test consisted of a self-selected brisk walking pace. Treadmill speed remained unchanged throughout the test and treadmill grade was increased 2% every 2 minutes. The test was terminated when the subject attained 85% of predicted maximal heart rate, as determined by (220-age) or when the subject reported a RPE > 17, whichever criteria occurred first.

After completion of baseline PA and cardiometabolic disease risk factor profile measurements, patients were provided the ALED text book and an individual account was created on the activeliving.info website. The ALED program is a 12-week PA intervention that integrates use of pedometers for self-monitoring of PA along with an interactive online component. Subjects were instructed to complete one chapter of the text book each week, including reading, activity surveys, and online components. Online components included an online step log, activity log, and individual goals tool. Before completion of the second visit, each subject demonstrated an ability to log into the online ALED website and complete all required tools listed above. Throughout the 12-week ALED intervention period, subjects returned to the Human Performance Laboratory every 4 weeks to have their pedometers downloaded. Upon completion of the intervention, subjects completed a repeat 2-week PA assessment, and were reassessed for all variables measured at baseline.

**Activity Assessment Devices**

The Omron HJ-720ITC (Omron Healthcare, Kyoto, Japan) pedometer was used for the objective measurement of PA (steps/day). The Omron HJ-720ITC pedometer was chosen to evaluate PA as it has previously been shown to accurately quantify steps/day at a
variety of different walking speeds in addition its use in overweight and obese adult subject populations\textsuperscript{12-14}. Previous research has shown both the Omron HJ720-ITC and Yamax Digiwalker SW-200 (Carr et al.\textsuperscript{11}) devices to be reliable measurements of PA across a variety of populations\textsuperscript{12}.

The Actigraph GT3X accelerometer (Actigraph Inc., Pensacola, FL) was utilized to determine the percentage of time spent performing sedentary (<100 counts/min), light (100-759 counts/min), lifestyle-moderate (760-1,952 counts/min), and moderate-vigorous (>1,953 counts/min) intensity activities.

**Data Validation Criteria**

Each subject’s Omron HJ720-ITC pedometer data was processed utilizing the Omron Health Management software. For weekly data to be included in the analysis a minimum of 480 minutes/day (8 hours) must have been recorded on at least 3 week days and 1 weekend day.

Each subject’s ActiGraph GT3X data was assessed utilizing the ActiLife5 processing software. For data to be considered valid, the device had to be worn for a minimum of 480 minutes/day (8 hours) on at least 3 week days and 1 weekend day. Data containing 60 minutes or more of continuous 0 count minutes were removed. Data was removed as this would be considered time the unit was not being worn and may provide an inaccurate representation of habitual PA.

**Statistical Analysis**

Descriptive statistics were used to compare and contrast pre and post intervention variables. The Wilcoxin non-parametric test was used for the evaluation of statistical
differences between the pre and post intervention values. Significance was defined as \( p \leq 0.05 \) and approaching significance \( \leq 0.10 \) for all comparisons.

**Results**
The primary purpose of the present study was to assess changes in PA habits over the course of the 12-week ALED intervention. Figure 4.1 represents mean observed PA (steps/day) for the 2-week baseline and post assessment periods. Mean steps/day observed during the 2-week post intervention assessment (4071 ± 1934 steps/day) were not significantly (\( p=0.386 \)) different from those values observed at baseline (3544 ± 1588 steps/day).

In addition to pre and post measurements mean steps/day were measured at 4, 8, and 12-weeks during the ALED intervention, with the proposed greatest change (+15.8%) observed at 4-weeks. The observed change at 4-weeks (\( p=0.303 \)) failed to reach statistical significance. Further analyses were performed to compare mean steps/day between weekdays and weekend days. Figure 4.2 shows an outlier in the population with average step counts of <1000 steps/day on all observed occasions.

Figure 4.3 demonstrates the percentage of total wear-time spent performing sedentary PA between baseline and post intervention assessment periods. Percentage of time spent performing sedentary activities from pre to post assessment (73.7 ± 10.6% vs. 71.9 ± 13.4 %) was not significantly (\( p=0.292 \)) changed over the course of the ALED program. Further analysis was performed to assess total minutes spent performing moderate-vigorous intensity PA. Average minutes/day spent participating in moderate-vigorous PA was compared between pre (13.6 ± 14.5 min/day) and post (14.3 ± 14.3 min/day).
intervention values. Mean time spent performing moderate-vigorous PA had an observed insignificant change between pre and post intervention periods (p=0.575).

No significant differences were noted in perceived quantities or intensities of PA as measured by the Stanford 7-day recall or IPAC questionnaires. Analysis of both surveys revealed one participant reported achieving ≥ 150 min/week of moderate intensity PA at baseline or post assessment periods. However, the Sedentary Criteria screening questionnaire revealed a significantly (p=.046) higher number of subjects reported attaining ≥ 150 minutes/week of moderate intensity PA at the post intervention (n=4) when compared with baseline (n=1) analysis.

Changes in subject body composition as a result of the ALED program were assessed post intervention. As shown in table 4.1 no significant differences were noted regarding % body fat (p=.358), waist circumference (p=.878) or BMI (p=.576) at the conclusion of the 12-week intervention.

Blood analysis as shown in figure 4.1, reveals post-intervention fasting triglyceride (TG) values (134 ± 83 mg/dl) were significantly reduced (p=0.047) on average, 8.2% from baseline. Additionally, fasting HDL cholesterol values were significantly (p=0.050) increased 6.5% after the 12-week intervention (48 ± 14 mg/dl) compared with those observed at baseline (45 ± 12 mg/dl). Baseline values for fasting glucose (102 ± 18 mg/dl), LDL cholesterol (92 ± 28 mg/dl), and total cholesterol (165 ± 38 mg/dl) were unchanged after completion of the intervention.
Finally, predicted maximal aerobic capacity was determined by an extrapolation of submaximal heart rate and VO\(_2\) values collected during each subject’s submaximal treadmill test. Predicted maximal aerobic capacity did not change significantly (p=0.593) from pre (24.2 ml/kg/min) to post (23.9 ml/kg/min) intervention. Additional fitness markers were collected during the submaximal treadmill test. Systolic blood pressure measurements were significantly reduced at both 4 (133 mmHg, p=0.036) and 6 (147 mmHg, p=0.050) minute markers and approached significance at 8 minutes (151 mmHg, p=0.078). Additionally, RPE values were significantly reduced during stage 4 (p=0.026) and approached significance at stages 2, 6, and 8 (p=.105-.205). These findings are suggestive of an increased familiarity and comfort with the treadmill testing protocol due to repeating the previously administered test.

**Discussion**
The results represent a preliminary study on the effectiveness of the ALED program to increase PA among sedentary adults in Delaware Co., IN. The proposed healthcare provider delivery format was shown to be an ineffective means for recruitment of sedentary adult subjects. Due to this finding the current sample size was not large enough to draw any definite conclusions regarding the effectiveness of the ALED program to increase PA among sedentary adults in Delaware Co., IN. The lack of effectiveness demonstrated by the healthcare providers in the recruitment process appears to be a result of limited interaction time between the physician or health coach and patient. Physicians have high patient volumes and limited time with each patient during each visit. Promotion of PA and participation in the ALED study was not a priority and is often not discussed unless prompted by the patient. This hypothesis is based on
interaction with study participants who were questioned about their recruitment process. Each participant that participated in the study reported asking their healthcare provider about the study after seeing the ALED recruitment flyer in the lobby. One subject contacted Ball State directly looking to participate in a study and was referred back to his physician by the research team. No study subject reported being approached by their physician to participate in the study.

Preliminary analysis of the small subject population revealed average steps/day measured after completion of the 12-week ALED-I intervention (4071 ± 1933 steps/day) showed an insignificant (p=0.386) 15% increase in PA (527 ± 249 steps/day) from baseline. Observed insignificant changes in steps/day were less than the significant changes observed in previous research (21-58%) evaluating pedometer feedback based PA interventions\textsuperscript{11,15-17}. The current study had many similarities to previous PA studies as well as a number of unique aspects to the study design.

The preliminary results of the current study population are not consistent with those observed previously by Carr et al\textsuperscript{11}. As shown in table 4.2, baseline values for aerobic capacity, BMI and % body fat was similar between studies. However, subjects in the Carr et al. study had a lower mean age and greater baseline PA values compared with the current subject population. Contrary to the observations made in the current study, Carr et al.\textsuperscript{11} observed a significant (p<0.05) increase in PA from pre (6614 ± 388 steps/day) to post (7999 ± 439 steps/day) ALED intervention. Comparison between study outcomes shows the preliminary PA observations in the current study are not consistent with those previously observed by Carr et al. The observed lower mean age in the Carr. et al. study
may suggest that the ALED intervention is more effective in younger adult populations who are more comfortable with interactive internet based programs. Contrary to the observation made by Carr et al. which noted the greatest improvements were made by the most sedentary subjects, lower baseline PA levels in the current study did not appear to correlate with greater improvements in PA over the course of the intervention. However, mean PA levels for both studies were below the proposed threshold of <8,000 steps/day. Subjects falling into the lowest PA categories will likely require individualized goal setting and feedback to provide further motivation to get started with a PA program and stay with it. Further research is needed to determine if there is a point in which an individual’s mean PA is too low to be significant influenced by the ALED program.

Previous research by Goodrich et al.\textsuperscript{18} evaluated the effectiveness of Stepping Up to Health (SUH) another pedometer based PA intervention aimed to increase lifestyle PA in sedentary adult populations. The study by Goodrich et al. utilized a similar healthcare provider delivery format in an urban population (Ann Arbor, MI) and use of the Omron HJ-720 ITC pedometer for objective measurement of PA. Subjects included in the Goodrich et al. study were on average younger (45.2 ± 9.9 years) than those observed in the current study and had greater mean PA (4520 ± 309 steps/day) and BMI (40.7 ± 7.6 kg/m\textsuperscript{2}) values at baseline. A significant (p=0.003) increase in PA from baseline to post 6-week intervention (6013 ± 443 steps/day) assessment was observed. A likely explanation for the discrepancy between studies is the weekly motivational messages included in the SUH intervention program. Use of weekly motivational messages in the ALED intervention may have improved adherence to the program. This is supported by
additional pedometer feedback based PA interventions in which the greatest improvements in PA were observed in programs which included intermittent individualized feedback and goal setting, such as the previously referenced study by Richardson et al., or required classroom participation throughout the course of the intervention.21,22 The current observations suggest periodic contact and individualized feedback to the subject population increases adherence and effectiveness of pedometer feedback based PA interventions.

Further analysis was performed to evaluate mean PA (step/day) levels as observed at 4-week intervals throughout the intervention as shown in figure 4.4. Average steps/day measured after completion of the 4-week ALED program increased by 16% (561 ± 261 steps/day) when compared to baseline values. This observed change in PA failed to reach statistical significance at each of the observed 4-week periods.

The ALED intervention is designed to increase moderate-vigorous intensity PA while reducing sedentary time. As shown in figure 4.3 the current subject population had no significant change in percentage of wear time spent in sedentary activities. This observation is consistent with the previously reported insignificant change in observed PA throughout the intervention period.

Furthermore no significant changes were observed in the current subject population between pre (13.5 ± 14.6 min/day) and post (14.3 ± 14.3 min/day) intervention moderate-vigorous intensity PA. Previous research utilizing pedometer feedback based interventions by Pal et al.15 observed a significant increase in mean PA along with a 33% increase in moderate-vigorous intensity PA over the course of a 12-week PA
intervention. Pal et al. is the only known author to previously publish an objective measure of PA intensity with a pedometer based PA intervention. The measurement for the determination of PA intensity was not consistent between studies. The current study assessed moderate intensity PA by accelerometer as opposed to the previous study which utilized bout steps collected by pedometers to classify intensity. Additionally, the study conducted by Pal et. al. included only obese women (BMI >30 kg/m$^2$, n=26), a different demographic than the current study which evaluated both men (n=2) and women (n=8) as well as individuals (n=4) with a BMI <30 kg/m$^2$.

The IPAQ, 7-day recall, and Sedentary Criteria Screener questionnaires were used as subjective measurements of PA pre and post intervention. All 3 questionnaires required participants to recall the PA that they had performed over the previous 7 days. No significant differences were noted between pre and post intervention assessments for the IPAC (p=.310-.889) or Stanford 7-day PA Recall (p=0.114-1.000) questionnaires. Both questionnaires identified 1 subject as reporting sufficient amounts of PA to satisfy the 2008 PA Guidelines for Americans. However, a significant increase in PA was reported for bouts ≥10 minutes of moderate intensity or greater PA (p=0.059), and number of participants reporting at least 150 minutes of moderate intensity or greater PA per week (p=0.046) were observed for the Sedentary Criteria Screener questionnaire. The Sedentary Criteria Screener also identified 1 subject at baseline as acquiring the minimum PA required by the 2008 PA Guidelines. However, post intervention this increased significantly to 4 subjects reporting sufficient PA during the final week of assessment. One possible explanation for the discrepancies noted between questionnaires
is the difference in question formatting. The IPAC and Stanford 7-day PA screening tools require participants to report the total number of hours and minutes at select intensities compared with the Sedentary Criteria Screener which simply asks 2 “yes” or “no” questions. An individual may be more likely to overestimate the total time spent performing PA when they are not required to recall exact quantities of time or specific activities.

The objective accelerometer measurement of moderate-vigorous intensity PA supports the results reported by the IPAC and 7-day PA recall questionnaires as there were no significant differences between pre and post assessment. Pre intervention accelerometer assessment revealed that 1 of the subject participants attained the recommended average of ≥150 min/week of moderate-vigorous PA. Post assessment also revealed 1 subject who attained the recommended levels of moderate-vigorous PA. These observations further support the findings of the IPAC and 7-day PA Recall Questionnaires.

Post intervention assessment revealed mean TG levels (134 ± 83 mg/dl) were significantly reduced (p=0.047) 8.2% from baseline. The previous study by Carr. et al is the only known study to have assessed blood variables associated with pedometer based PA interventions. This study also observed a significant (p=0.01) reduction in TG values from baseline (161 ± 16 mg/dl) to post (108 ± 14 mg/dl) intervention. However, the magnitude of observed change in the Carr et al. study (49%) was greater than that observed in the current study. As previously noted a significant (p<0.05) increase in PA was observed in the Carr et al. compared with the preliminary insignificant (p=0.386) change in PA observed in the current study. This is one proposed explanation for the
observed discrepancy in magnitude of change as TG levels are directly influenced by PA levels.

Fasting HDL cholesterol values were significantly (p=0.05) elevated after the 12-week intervention (48 ± 14 mg/dl) compared with those observed at baseline (45 ± 12 mg/dl). The observed change is not consistent with those found by Carr et al. who observed no significant change in HDL levels from pre (43 ± 2 mg/dl) to post intervention. A possible explanation for the difference in observed change is the lower PA levels observed in the current study at baseline (3544 ± 1588 steps/day) compared with those observed at baseline in the Carr et al. study (6614 ± 388 steps/day). Baseline values for fasting glucose (102 ± 18 mg/dl), LDL cholesterol (92 ± 28 mg/dl), and total cholesterol (165 ± 38 mg/dl) did not change significantly throughout the intervention.

No significant changes were observed for predicted aerobic capacity (pre = 24.2 ± 7.5ml/kg/min, post = 23.9 ± 7.5 ml/kg/min) (p=0.593) after completion of the ALED-I intervention. The previous study by Carr. et al. is the only known study to include a measure of aerobic capacity with a pedometer feedback PA intervention. The study by Carr. et al observed a significant change from pre (27.6 ± 2.4 ml/kg/min) to post (30.9 ± 2.3 ml/kg/min) ALED intervention. It was noted by the research team in the previous study that improvements in aerobic fitness were likely due to an increased familiarity with the submaximal walking test protocol post-intervention. Further explanation for the inconsistencies in observations can be attributed to the different methods for assessment of aerobic capacity. The previous study utilized a one-mile walk test with simultaneously monitored heart rate to predict aerobic capacity. The current study used a submaximal
treadmill test along with a direct measurement of oxygen consumption. Submaximal values were then extrapolated for a prediction of maximal aerobic capacity.

Post intervention exercise mean SBP (140.9 ± 26.8 mmHg) measurements were significantly (p=0.036) reduced at all observed points during the treadmill test when compared with pre intervention (155.5 ± 26.5 mmHg) values. Observed reductions in SBP (9%) for the current study are comparable to the observed significant 4.7% reduction in SBP observed by Pal et al. Perceived exertion, as determined by the Borg RPE scale, approached a significant (p=0.105) reduction during the post-intervention submaximal treadmill test (13.1 ± 2.8) when compared with values collected at baseline (15.8 ± 2.6). The observed change in SBP and RPE suggest an increase in comfort and familiarity with the treadmill testing protocol similar to that observed in the previous study by Carr. et al. It is the opinion of the research team that improved comfort with the treadmill test is likely responsible for the differences in observed RPE and SBP. However, a comparison cannot be performed as Carr et al. did not report measurements of SBP or RPE during the submaximal assessment of aerobic fitness.

No significant (p=0.910) change was observed in BMI from pre (32.4 ± 7.5 kg/m²) to post (32.6 ± 7.3 kg/m²) intervention. Nutrition intake was assessed by way of 3-day food logs pre and post intervention. No significant differences were noted between observation periods for total calories (p=0.790), % protein intake (p=0.625), % CHO intake (p=0.657), or % fat intake (p=0.624). Similarly, no changes were noted in either % fat (pre = 40.8 ± 7.4%, post = 40.7 ± 7.1%) or waist circumference (pre=105.6 ± 20.9 cm, post=104.7 ± 19.2 cm) during the course of the intervention. Carr et al. previously
observed post assessment BMI (31.9 ± 1.2kg/m²) (p=0.86), % body fat (45.6 ± 2.2%) (p=0.72), and lean mass (54.4 ± 2.2 kg) (p=0.72) were not significantly changed as a result of the ALED program. These results are similar to those observed by Pal et al.\textsuperscript{15} and Tudor Locke et al.\textsuperscript{19} Both studies utilized pedometer feedback as a means to increase PA. The studies were 12 and 16-weeks in duration respectively and did not include any nutritional intervention in their study designs. Neither study observed a significant change in BMI or % body fat over the course of the interventions. Pal et al. also observed no change in waist circumference, while Tudor Locke observed a significant 1.8 ± 0.8 cm reduction over the course of their 16-week intervention. The observed insignificant findings are most likely attributable to the minimal quantities and intensities of PA being performed. Mean PA in all observed studies at post intervention failed to reach the threshold of PA required for health benefits defined in the 2008 PA Guidelines.

**Study Limitations**

Study limitations include lack of a control group which would have allowed for comparison between ALED subjects and non-ALED control subjects for greater statistical power. Another limitation is lack of statistical power due to a small (n=10) sample size. The current sample size is less than that determined by power calculations for significance. Small sample size provides large standard errors and makes it difficult to prove any statistical significance. Inability to quantitatively measure the use of the ALED text book limits the ability of the research team to quantify the usage of the ALED materials in addition to online usage minutes.
Summary and Conclusions
The current study is a preliminary study on the effects of the ALED program on sedentary adult populations. Previous research by Carr. et al. proposed the utilization of healthcare for the recruitment of study subjects. The healthcare provider recruitment method proved to be ineffective and resulted in a small sample population. It was observed that limited interaction time between the healthcare provider and patient was responsible for the low referral rates. Preliminary results suggest the ALED program was not an effective means for increasing PA or reducing sedentary time among the most sedentary adult populations. Further recruitment is needed to attain a large enough subject population for statistical significance.
**Figure Legend**

*Figure 4.1:* Comparison between baseline and post ALED-I intervention PA levels.

*Figure 4.2:* Individual PA (steps/day) at each download period.

*Figure 4.3:* Percentage of total wear time spent performing sedentary activities.

*Figure 4.4:* Average PA (steps/day) observed at each download period throughout the ALED-I intervention.
<table>
<thead>
<tr>
<th>Resting Characteristics</th>
<th>Baseline (n=15)</th>
<th>Post-Intervention (n=10)</th>
<th>P value</th>
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</thead>
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<tr>
<td>Age (years)</td>
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<td>-----</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>32.4 ± 7.5</td>
<td>32.6 ± 7.3</td>
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<tr>
<td>Weight (lbs.)</td>
<td>211 ± 66</td>
<td>213 ± 65</td>
<td>0.092</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>106.7 ± 21.7</td>
<td>105.3 ± 20.2</td>
<td>0.202</td>
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<td>Body Fat (%)</td>
<td>40.8 ± 7.4</td>
<td>40.7 ± 7.1</td>
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<tr>
<td>Lean Mass (kg)</td>
<td>47.0 ± 19.1</td>
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<td>Total Cholesterol (mg/dl)</td>
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<td>168 ± 43</td>
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<tr>
<td>LDL (mg/dl)</td>
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<td>94 ± 32</td>
<td>0.959</td>
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<td>HDL (mg/dl)</td>
<td>45 ± 12</td>
<td>48 ± 14</td>
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</tr>
<tr>
<td>Triglycerides (mg/dl)</td>
<td>145 ± 79</td>
<td>134 ± 83</td>
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</tr>
<tr>
<td>Fasting glucose (mg/dl)</td>
<td>102 ± 18</td>
<td>102 ± 19</td>
<td>0.683</td>
</tr>
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</table>

Table 4.1
Figure 4.1
Figure 4.2
Figure 4.3

Percentage of Time Spent Sedentary

Percentage of Time Spent Sedentary
Table 4.2

<table>
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<tr>
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<th>Current Study</th>
<th>Carr et al.</th>
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<tr>
<td>Age (years)</td>
<td>54.0 ± 17.9</td>
<td>41.4 ± 3.7</td>
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<tr>
<td>Predicted VO$_{\text{2peak}}$ (ml/kg/min)</td>
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<td>27.6 ± 2.4</td>
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<tr>
<td>BMI (kg/m$^2$)</td>
<td>32.4 ± 7.5</td>
<td>32.3 ± 1.3</td>
</tr>
<tr>
<td>Body fat (%)</td>
<td>40.8 ± 7.4</td>
<td>45.6 ± 2.2</td>
</tr>
<tr>
<td>HDL (mg/dl)</td>
<td>45 ± 12</td>
<td>45 ± 3</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>145 ± 79</td>
<td>161 ± 16</td>
</tr>
<tr>
<td>PA (steps/day)</td>
<td>3544 ± 1587</td>
<td>6614 ± 388</td>
</tr>
</tbody>
</table>

Table 4.2
Figure 4.4
References


Chapter V

Summary and Conclusions

The current study represents a follow up analysis to a previous study at Wyoming University by Carr et al.\textsuperscript{14} showing the internet delivery of the Active Living Every Day (ALED-I) program to be an effective means for increasing the PA of apparently health sedentary adults. It was proposed that a healthcare provider delivery format may improve the effectiveness of the intervention, as clinicians and health coaches are well respected members of the medical community. The present study was designed to test the usefulness of a healthcare provider delivery model the higher density “urban” population of Delaware Co., IN.

The primary finding of the present study was the ALED-I program failed to produce a significant increase in PA among the sedentary adult population of Muncie, IN. These findings are not consistent with the Carr. et al.\textsuperscript{14} study or previous research
utilizing different delivery formats of the ALED-I program\textsuperscript{12,13}. In concert with the previously stated results on PA quantity there were no significant changes observed in measurements of sedentary, light, lifestyle-moderate, or moderate-vigorous intensities from pre to post intervention. Significant improvements were observed in fasting HDL cholesterol and triglyceride (TG) levels after completion of the 12-week ALED-I intervention. However, additional blood markers such as LDL cholesterol and fasting glucose had no observed significant change over the course of the intervention. No significant changes were observed for any of the observed measures for body composition over the course of the intervention.

The current findings suggest the healthcare provider delivery format is an ineffective means for recruitment to the ALED-I program when targeting a sedentary adult population. Additionally the findings suggest the ALED-I program is not an effective means for increasing PA in sedentary adults from an urban population. In addition to the insignificant increase in daily PA (steps/day) the ALED intervention failed to increase PA intensity from baseline to post assessment. The observed changes are consistent with the insignificant change observed in PA quantity over the course of the intervention. These findings do not support the initial hypothesis of the research team, and suggest the ALED-I program is not an effective means for increasing daily PA or PA intensity in sedentary adult populations.

Additionally, the significant improvements observed in fasting HDL cholesterol and triglyceride (TG) levels after completion of the 12-week ALED-I intervention suggest the small but insignificant improvements in PA produced by the program may be
sufficient to produce significant changes HDL and TG blood lipid levels and cardiovascular disease risk factor profiles. However, additional blood markers such as LDL cholesterol and fasting glucose had no observed significant change from pre to post intervention. These findings suggest that significant improvements in fasting TG levels are consistent with previous research, however to the authors knowledge this is the first study to show significant improvement in HDL cholesterol values using the internet based format of the ALED-I intervention program. It is suggested that the insignificant changes in PA status produced as a results of the ALED-I intervention were not enough to produce significant improvements in BMI or waist circumference over the course of the intervention.

**Recommendations for further study**

Opportunities for future research are available in assessing the effectiveness of the healthcare delivery format for PA intervention programs. Previous research has identified potential issues with physician time constraints and inability to effectively recruit study subjects. Future studies should focus on additional members of the healthcare team as a means for subject recruitment. Further study is also available to assess the internet delivery format of the ALED-I program in urban populations. Previous research subjects utilizing this delivery format have been from predominantly rural regions of the United States. Additionally, future research that included a pre and post intervention PA knowledge assessment would provide analysis that the ALED-I intervention if effectively increasing PA knowledge in the target population. Measurement of pre and post intervention PA knowledge may also provide insight into the comprehension and/or adherence related to the ALED study. In addition to a
knowledge test a measurement of participant reading level may benefit the research team in identifying appropriate subject populations. This is specifically important when utilizing the internet delivery format as research subjects do not have a readily available support group to answer questions. Weekly phone calls may provide more opportunities for study participants to ask questions, while also potentially improving adherence to the program over the course of the intervention. Finally, recruitment of a larger sample size would lend greater statistical significant to the observed findings of the current study. Possible means for recruiting a larger sample size include providing incentives for participation and the inclusion of additional healthcare team members such as nurses and physician assistants in the recruitment process.

An area of future interest with the present study cohort would be the addition of a control group. A control group would for comparison between study groups and external factors such as changes in weather status and holiday schedules. It would also provide greater statistical significance and further trend analysis among measured variables. A power calculation to determine sample size is needed to determine the number of additional subjects.
References


56. Strath SJ, Swartz AM, Parker SJ, Miller NE, Grimm EK, Cashin SE. A pilot randomized controlled trial evaluating motivationally matched pedometer


APPENDIX A

STANFORD 7-DAY PA QUESTIONNAIRE
Seven-Day Physical Activity Recall Questionnaire

Now we would like to know about your physical activity during the past 7 days to estimate the number of calories you burn. But first, let me ask you about your sleep habits.

1. On the average, how many hours did you sleep each night during the last five weekday nights (Sunday-Thursday)?

2. On the average, how many hours did you sleep each night last Friday and Saturday nights? Tell me to the nearest half hour.

Now I am going to ask you about your physical activity during the past seven days, that is, the last five weekdays and last weekend, Saturday and Sunday (GIVE DATES). Please look at this list which shows some examples of what we consider light, moderate, hard, and very hard activities. The activities are separated into those you do at your job, at home, or in sport or recreation. You may have done things this past week that are not listed here.
We consider standing driving, and walking leisurely to be light activities. Most of us spend most of the time, when we are not sleeping, doing light activities such as these. In this questionnaire, I am going to ask you about any other moderate, hard, very hard activities you do.

(PROBE IF RESPONDENT CANNOT REMEMBER PAST WEEK’S ACTIVITIES. ASSIST IN ASSIGNING ACTIVITY LEVELS.)

3. First, let’s consider moderate activities. What activities did you do and how many total hours did you spend during the last five weekdays doing these moderate activities or others like them? Please tell me to the nearest half hour. (REPEAT WEEKDAYS IF NECESSARY)

4. Last Saturday and Sunday, how many hours did you spend on moderate activities and what did you do? (PROBE: CAN YOU THINK OF ANY OTHER ACTIVITIES THAT WOULD FIT INTO THIS CATEGORY?)

5. Now, let’s look at hard activities. What activities did you do and how many total hours did you spend during the last five weekdays doing these hard activities or others like them? Please tell me to the nearest half hour. (REPEAT WEEKDAYS IF NECESSARY)

6. Last Saturday and Sunday, how many hours did you spend on hard activities and what did you do? (PROBE: CAN YOU THINK OF ANY OTHER ACTIVITIES THAT WOULD FIT INTO THIS CATEGORY?)

7. Now, let’s look at very hard activities. What activities did you do and how many total hours did you spend during the last five weekdays doing these very hard activities or others like them? Please tell me to the nearest half hour. (REPEAT WEEKDAYS IF NECESSARY)

8. Last Saturday and Sunday, how many hours did you spend on very hard activities and what did you do? (PROBE: CAN YOU THINK OF ANY OTHER ACTIVITIES THAT WOULD FIT INTO THIS CATEGORY?)

9. Were you gainfully employed, that is, did you earn money for doing work, during the last seven days?

☐ No (Go to Question 10)

☐ Yes. How many days?

☐ How many hours per day?
How many of these hours per day were spent doing moderate activities?

How many of these hours per day were spent doing hard activities?

How many of these hours per day were spent doing very hard activities?

10. Compared to your physical activity over the past three months, was last week’s physical activity more, less, or about the same?

- More
- Less
- About the same
- No answer

11. Highest level of education (K+).

APPENDIX B

SEDENTARY CRITERIA SCREENER
Sedentary Criteria:

“Over the past month, did you participate in any bouts of moderate intensity (or harder) physical activities that were at least 10 continuous minutes? What I mean by moderate intensity physical activity is any activity that feels as hard or harder than a brisk walk (3-4 mph). It gets your heart rate going and feels like you are running late for an appointment or walking fast to get out of the rain. For the activity to be counted, it needs to be for at least 10 continuous minutes without stopping. Some examples of moderate intensity physical activities could include brisk walking, jogging, aerobic dance, swimming, bicycling, and certain types of yard work, housework, or gardening.”

[ ] NO  [ ] YES

NO, continue to next question

If YES, clarify that it was at least 10 continuous minutes without stopping and was at least of moderate intensity. If yes, ask details about the average amount of time spent in these moderate intensity activities during a typical week over the past month:

<table>
<thead>
<tr>
<th>Activities</th>
<th>Times per week?</th>
<th># Minutes per bout of activity that is &gt;10 min. continuous in duration</th>
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</table>
(if total is less than 150 minutes per week = eligible)

(if total is more than 150 minutes per week = ineligible)

Based on your response above, am I correct in assuming that you do not engage in 150 minutes or more of moderate to vigorous intensity physical activity per week?

Yes  No

APPENDIX C

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE
INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think **only** about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?
Think about all the moderate activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

2. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ days per week  ➞  How much time in total did you usually spend on one of these days doing moderate physical activities?

   or

   _____ hours _____ minutes

   none

Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

3. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

   _____ days per week  ➞  How much time in total did you usually spend on one of these days doing walking on one of those days?

   or

   _____ hours _____ minutes

   none
The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

4. During the last 7 days, how much time did you spend sitting on a week day?

_____    hours _____ minutes

APPENDIX D

SATISFACTION WITH LIFE SCALE
Satisfaction With Life Scale

Below are five statements with which you may agree or disagree. Using the 1-7 scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding. The 7-point scale is as follows:

1 = strongly disagree

2 = disagree

3 = slightly disagree

4 = neither agree nor disagree

5 = slightly agree

6 = agree
7 = strongly agree

___ 1. In most ways my life is close to my ideal.

___ 2. The conditions of my life are excellent.

___ 3. I am satisfied with my life.

___ 4. So far I have gotten the important things I want in life.

___ 5. If I could live my life over, I would change almost nothing.