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The Effects of Goal Setting and Goal Setting with Social Support on
Walking for Older African Americans with Type 2 Diabetes

BY

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Abstract

Two studies evaluated the effect of goal setting and social support to increase walking of older African American adults with Type 2 diabetes. The first study used a multiple baseline design across 3 participants and a participatory goal setting intervention. The second study used an A-B design with one participant, adding social support to increase walking as part of the intervention. A changing criterion design was embedded in the intervention of both studies. Results showed that although the goals for walking were not consistently met, the participants increased their overall steps above baseline.

DESCRIPTORS: goal setting, social support, physical activity, pedometers, Type 2 diabetes.

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The Effect of Goal Setting and Goal Setting with Social Support on the Walking for Older African Americans with Type 2 Diabetes

A chronic disease with no cure, diabetes is a hormone disorder that affects the way the body uses food for energy. In the United States, approximately 20.8 million people are diagnosed with the disease, with another estimated 6.2 million people remaining undiagnosed (American Diabetes Association, 2007). Globally, diabetes is found in approximately 194 million people (International Diabetes Federation, 2004; Wild, Roglic, Green, Sicree & King, 2004) with its highest prevalence found in India with 31.7 million people or 3% of the population, in China with 24 million people or 1.8% of the population, and in North America with 20.8 million or 7% of the population. In North America it is the fifth leading cause of death (International Disease Federation, 2005). The present research describes two interventions to increase walking in older African Americans with diabetes. I begin with a review of the relevant literatures.

Diabetes: Biology and Symptomology

Most food that humans consume is converted into glucose for the body to use for energy. After glucose has entered the bloodstream and accumulates to a certain level, the pancreas releases the hormone, insulin. Insulin moves glucose from the bloodstream into the cells where it is used to fuel the body. People with diabetes either do not produce sufficient insulin to move the glucose from the bloodstream or else their muscle cells do not utilize the insulin and they are insulin resistant. Uncontrolled glucose levels can result in medical complications such as blindness,

kidney failure, heart disease, and nerve damage, the last of which can lead to limb amputation (American Diabetes Association, 2006; Rajaram & Vinson, 1998).

According to the American Diabetes Association (ADA), people are diagnosed with diabetes if they have a fasting plasma glucose level of 126 mg/dL or more, a plasma glucose level equal to or above 200 mg/dL, or a plasma glucose equal to or above 200 mg/dL during an oral glucose test. A number of factors can affect the results, so retesting is recommended to confirm the diagnosis.

The vast majority of diabetes falls within two groups known as Type 1 and Type 2 diabetes. Type 1 diabetes, previously known as insulin dependent or juvenile onset diabetes, accounts for approximately 5%-10% of North Americans with diabetes (ADA, 2006). It occurs when the body does not produce insulin. Sufferers typically develop the condition as children or young adults. Symptoms appear suddenly and include frequent urination, extreme hunger, thirst, and weight loss; nausea and vomiting; weakness and tiredness; and irritability and mood swings. Daily insulin injections are necessary or death is inevitable.

Type 2 diabetes, previously known as non-insulin dependent or adult onset diabetes, accounts for 90%-95% of North Americans with diabetes (ADA, 2007; Sprick, Akinbola, Hagan & Brownson, 1993; Squires, 2001). It is the focus of the present research. Although its incidence is increasing in children, patients are typically over the age of 45 and do not make enough insulin or are unable to use it properly. Symptoms appear slowly and include increased thirst and increased need

to urinate; weight loss and simultaneous increase in appetite; repeated or hard to heal infections of the gum, vagina, or bladder; blurred vision; tingling or loss of feeling in the hands or feet; and dry, itchy skin (Hendricks & Hendricks, 1994; Rajaram & Vinson, 1998; Ward). In addition to people with Type 2 diabetes, another 41 million fall into a category known as pre-diabetes, a condition in which the glucose levels are higher than normal, but not high enough for a diagnosis (ADA, 2007).

The cause of Type 2 diabetes is unknown. Obesity, however, is a primary risk factor, particularly if the fat is concentrated in the abdominal region (ADA, 2007; American Obesity Association, 2007; Elbein, Hoffman, Teng, Leppert, & Hasstedt, 1999). Additional risk factors include being over age 45, having a family history of diabetes, not exercising regularly, having low HDL cholesterol or high triglycerides, belonging to certain racial and ethnic groups (e.g., African Americans, Hispanic Whites, Native Americans), being a woman who has had gestational diabetes or a baby weighing nine pounds or more at birth, and having low education or low income (ADA, 2006; Harwell et al., 2001; Sprick et al., 1993).

The goals for preventing and treating of Type 2 diabetes are the same regardless of a person's age and ethnicity, although the approach may have to be modified to accommodate age-related changes such as diminished vision and changes in hunger, thirst, and taste (Rosenstock, 2000). Prevention goals include better food choices, exercise, and weight loss. Treatment goals are the same, but with the addition that physician-recommended fasting and nonfasting glucose levels be maintained. Maintaining these levels through exercise, diet, weight loss, and/or

medications has been shown to reduce, delay, and prevent the greatest number of chronic complications (Drucker, 2006).

A global measure of how well these levels are being maintained over a 2 to 3 month period is a glycated hemoglobin test, also known as HbA1c or A1c test. According to the recommendations of the ADA, a person's A1c level should be less than 7%. The ADA further recommends a fasting glucose range of 80–120 mg/dL and a nonfasting glucose of <180 mg/dL. The American College of Endocrinologists (ACE) and the International Diabetes Federation (IDF) have more stringent recommendations. The ACE recommends an A1C target of <6.5%, with a fasting glucose range of <110 mg/dL and a nonfasting range of <140 mg/dL. The International Diabetes Federation (IDF) recommends an A1C target of <6.5%, with a fasting glucose level <100 mg/dL and a nonfasting glucose level of <145 mg/dL. All three organizations agree that glucose levels should not fall below 70 mg/dL or exceed 250 mg/dL.

Diabetes and African Americans

People of African ancestry living in Western countries show a greater predisposition and incidence of Type 2 diabetes than non-Hispanic Whites (International Diabetes Federation, 2004; Sobngwi, Mauvis-Jarvis, Vexiau, Mbanya, & Gautier, 2001). According to the ADA (2007), approximately 3.2 million or 13.3% of all African Americans age 20 and older have Type 2 diabetes. They are thus 1.8 times more likely to have diabetes than non-Hispanic Whites. In addition, they experience higher rates of complications related to diabetes, such as kidney

failure nerve damage, amputation, heart disease, and blindness (ADA, 2007).

Finally, the death rate in African Americans with diabetes is 27% higher than for non-Hispanic Whites (Joslin Diabetes Center, 2006).

The higher incidence of Type 2 diabetes in African Americans, as compared to non-Hispanic Whites, is correlated with differences in their higher fasting insulin secretion and lower insulin sensitivity (Ku et al., 2000); lower levels of physical activity (Airhihenbuwa, Kumanyika, Argurs, & Lowe, 1995); higher levels of obesity (Kumanyika, 1997); a greater waist to hip ratio; cultural norms that support higher body weight for women; family history; socioeconomic status; and system barriers (e.g., poor access to medical care; see Rajaram & Vinson, 1998); and disproportionate levels of depression in African American women (Groot & Lustman, 2001), which can lead to an increase in appetite and a decrease in exercise (Diagnostic and Statistical Manual of Mental Disorders IV, 2000).

Physical Activity, Diabetes, and Older African Americans

Although medication may be required, diet and exercise are the cornerstones of health management for people with diabetes (ADA, 2007; Bauman & Smith, 2000; Evans, 1998; Ligtenberg, Hoekstra, Bol, Zonderland, & Erkelens, 1997). The ADA supports the US Surgeon General's recommendation that all adults should engage in at least 30 minutes of physical activity most days of the week. In particular, the ADA recommends that people with Type 2 diabetes should have at least 150 minutes of moderate intensity exercise per week (50-70% of the maximum heart rate) and/or 90 minutes per week of aerobic exercise (90% of maximum heart rate). Physical activity

helps manage therapeutic glucose levels by burning glucose for energy and helps cells become more receptive to insulin. The benefits of physical activity for all older adults are commonly correlated with a decrease in mortality and morbidity and an increase in muscle strength (Heath & Stuart, 2002; Nied & Franklin, 2002). Studies using measures of self-reported health by older African Americans list the following benefits: improved physical health (e.g., decreasing joint stiffness), improved social interactions, and feeling better (Jones & Nies, 1996; Wilcox et al., 2005); improved mental health and weight loss (McQuigg & Prohaska, 2001); and improved social support associated with culturally tailored programs (Fitzgibbon et al., 2005).

Although half the people with Type 2 diabetes are concerned with their weight (Diabetes Attitudes Wishes and Needs, 2001), a considerable proportion of them do not engage in physical activity to reduce it (Bauman & Smith, 2000; Conn, Minior, Burks, Rantz, & Pomery, 2003; Prohaska, Peters & Warrant, 2000; Tudor-Locke et al., 2004; Wood, 2002). Common barriers for older people are inadequate time or schedule conflicts, socioeconomic barriers such as lack of transportation or unsafe or structural neighborhood limitations, physical discomfort or limitations, lack of social support, and experiences with injury or pain (Airhihenbuwa et al., 1995; Fitzgerald et al., 1994; Clark, 1999; Heath & Stuart, 2002; James et al., 2003; Lewis et al., 1997; Nied & Franklin, 2002; Prohaska et al., 2000; Wilcox et al., 2005). Additional barriers to physical activity for African Americans are age (e.g., age related norms that older people should limit exercise activities), health status, socioeconomic and time limitations, lack of enjoyment, lack of role models, body image (e.g., acceptance

and expectation of a larger body as a standard of beauty), and directives made by non-Hispanic Whites (e.g., racism has led to African Americans developing dispositional and situational mistrust of non-Hispanic Whites; see Ferraro, 1993; Fitzgerald et al., 1994; Jones & Nies, 1996; Kumanyika et al., 2005; McQuigg & Prohaska, 2001; Roberts et al., 2006).

Some studies report that non-Hispanic African American adults are less likely than non-Hispanic white adults to participate in physical activities (Airhihenbuwa et al., 1995; Jaimes, Hudson, & Campbell, 2003; Prohaska et al., 2000), while other studies show no significant differences due to ethnicity (Boyette et al., 2002; McKay, King, Eakin, Seeley, & Glasgow, 2001; Wood, 2002). This inconsistency may be attributed to a number of factors, among them differences in how physical activity is operationalized. Physical activity is defined as energy resulting from any bodily movement produced by skeletal muscles, while exercise, a subcategory of physical activity, is any planned or structured activity done to improve physical fitness (Tudor-Locke et al., 2002). The terms are often used interchangeably in the literature, making it difficult to compare interventions and interpret results between studies. Furthermore, some African Americans define exercise as physical activity that is part of their usual workday routine, while others consider physical activity as something done in a gym, and still others consider it a leisure time activity (Airhihenbuwa et al., 1995; Wilcox et al., 2005).

Interventions

Several interventions have been used to increase physical activity in older adults. In a review of physical activity intervention research, Conn (2003) identified 17 studies published between 1960 and 2000 that focused primarily on increasing physical activity. The most common strategies were goal setting, social support, supervised center-based exercise, self-monitoring, health education, and relapse prevention education. Six of the studies focused on walking, four of which successfully increased walking using strategies such as goal setting, behavioral contracts, and health education. The two studies that failed to increase walking used strategies such as goal setting and feedback, individualized exercise plans, self-reporting, and health education. In the 11 studies that focused on activities other than walking, six successfully used strategies such as goal setting, problem solving, self-monitoring, and health education. The remaining five studies used modeling and goal setting, counseling, personalized exercise plans, and health education, but found no significant difference between experimental and control groups.

Goal setting. From a behavioral perspective, goal setting is the application of rules to influence a variety of future behaviors (e.g., walking) and outcomes (e.g., weight loss) through implied or stated, immediate or delayed consequences (e.g., reinforcers; see Martin & Pear, 1996, p. 213). It often uses a series of specific, concrete, and observable steps to achieve a goal through gradual changes (e.g., moving from 10,000 to 12,000 steps a day; see Brobst & Ward, 2002; Shilts et al., 2004; National Center on Physical Activity and Disability [NCPAD], 2005).

Successful programs involve challenging but achievable short-term goals (NCPAD, 2005).

Goal setting is among one of the most effective interventions found in the behavioral science literature (Seijts & Latham, 2000). It has been used in health education programs (e.g., *smoking cessation, weight loss*; see *Strecher et al., 1995*), sport and exercise settings (e.g., *bowling, football, community conditioning class*; see *Johnson et al., 1997; Kyllö & Landers, 1996; Locke, 1991; Poag & McAuley, 1992; Ward Carnes, 2002; Weinberg, 1992*), and industry (e.g., *task performance*; see *Weinberg & Weigand, 1993*). It has been successful when used with individuals or groups (*Johnson et al., 1997; Seijts & Latham, 2000; Ward & Carnes, 2002*), although conflicts may arise in the latter when individual goals and group goals compete with each other (*Johnson, Ostrow, Perna, & Etzel, 1997; Seijts & Latham, 2000*).

For people at risk for Type 2 diabetes, goal setting has been used to produce weight loss through physical activity by setting weekly physical activity goals (e.g., *minutes of activity*; see *Diabetes Prevention Program, 2002*). The following studies represent the research to date on goal setting with people with Type 2 diabetes.

Yamanouchi et al. (1995) used goal setting as part of an intervention in an 8-week study to reduce weight and improve insulin sensitivity with 14 obese, sedentary participants between the ages of 23 and 59 years of age. Participants in the diet alone group were instructed to wear a pedometer and maintain an average of 4500 steps per day, while those in the diet and exercise group were told to walk at least 10,000 steps per day. The results of the study were that body weight and insulin

sensitivity improved more in the diet and exercise group.

McKay et al. (2001) used goal setting to increase physical activity levels in a sample of 78 sedentary, non-Hispanic White men and women in an 8-week, Internet-based intervention known as the Internet Active Lives Intervention. The participants were randomly assigned to the Internet information only group or to the treatment group that selected individual goals to increase gradually the intensity and time spent engaged in a physical activity. At the conclusion of the study, both groups made moderate improvements in their overall physical activity levels, but no significant difference existed between them.

Tudor-Locke et al. (2004) used goal setting to increase the amount that people with Type 2 diabetes walked each day using pedometers as measurement and feedback tools. The 16-week study, known as the First Step Program (FSP), included 47 overweight, sedentary, Canadian adults ranging in age between 47 and 57 years old. The participants were randomly assigned to a wait list control group or the FSP. The first four weeks of the FSP intervention (adoption/baseline phase) consisted of weekly group meetings combined with goal setting, with a pedometer used for feedback, followed by a 12 week (adherence phase) that continued goal setting with pedometers but with limited telephone contact from the researcher. All participants were assessed at baseline and at the end of the 16 week period. At the conclusion of the first 16 weeks, the goal setting group was taking approximately 3000 steps per day over baseline compared to the control group. At the end of the 24 week follow up, the steps taken per day were still higher for the FSP than they were for the control

group, but with no significant differences between them.

Engel et al. (2006) used goal setting to increase walking for a sample of 57 sedentary men and women between the ages of 50 and 70 years. Participants in this 6-month study were randomly assigned to a coaching or a coaching with pedometers intervention. Coaching for both groups included the development of an action plan to increase walking, including goals selected by the participant. The pedometer group set goals for the number of steps taken per day, while the coaching only group chose goals based for the time spent walking. Both groups achieved the physical activity recommendations of >150 minutes of walking weekly, but no significant differences were found between the two groups at the conclusion of the study.

These studies inform our knowledge on how goal setting can effect walking with and without a pedometer and improve the overall health status of people with diabetes. In fact, the most important physical activity goals for older people with or without diabetes is walking, with self-determined walking identified as the most acceptable form of physical activity for and by people with Type 2 diabetes (Johnson et al., 2005). Also, when setting goals for walking, researchers have found pedometers useful in measuring progress (Crouteau, Richeson, Vines, & Jones, 2004; Johnson et al., 2006; Tudor-Locke et al., 2002; VanWormer, 2004). Setting goals for walking, measured with pedometers, was one of the two intervention strategies used in one of the present studies. The other was social support.

Social support. Social support is defined broadly as a network of assistance from family, neighbors, acquaintances, and friends who voluntarily provide resources

that have affective or emotional (e.g., prayer, friendly visits), instrumental (e.g., financial, transportation), and/or informational components (e.g. informational literature, informational feedback; see Ford, Tilley, McDonald, 1998). An appraisal component is also sometimes included in the definition of social support (e.g., feedback that assists the individual in making a decision; see Westaway et al., 2005). Where social support has been operationalized for the purposes of measurement, it has included: (a) social embeddedness: the degree or the frequency of contact a person has within his/her social network; (b) enacted support: the emotional and tangible connection to members in the social network; and (c) perceived support: measures of subjective perceptions and reports satisfaction with the support received (Barrera, 1986). The extent to which social support is provided to an individual depends on the personality, ethnicity, socioeconomic status, gender, race, and size of the social support network (Ford et al., 1998; Krause & Borawski-Clark, 1995; Schoenberg, 1998). Social support within the African American community, for example, is often provided networks that include fictive kinships (e.g., unrelated people treated as relatives and/or distant relatives treated as close relatives; see Perry & Johnson, 1994; Taylor & Chatters, 1991).

Overall, research indicates that regardless of how social support is conceptualized, social support is defined by satisfaction with the number and individuals in the person's network (Sarason, Levine, Basham, & Sarason, 1983) and may be beneficial for an individual's overall health and well-being (Barker, Morrow, & Mitteness, 1998; Krause & Borawski-Clark, 1995; Lincoln, Taylor, &

Chatters, 2003; Schoenberg, 1998). The effect of social support on health has been investigated in numerous studies, but the outcomes are mixed (Belgrave et al., 1994; Biegel, Magaziner, & Baum, 1991; Krause, 2002; Kaniasty & Norris, 2000; Lincoln et al., 2003). Differences in the cultural backgrounds of those providing and receiving social support, and inconsistencies in methodology (e.g., definitions, and measures such as questionnaires), are some of the reasons why its influence has not been fully gauged (Schoenberg, 1998). For example, social support has been defined to mean everything from the presence of family or friends in a patient's social environment to having family or friends adopt a specific health care role related to emotional, instrumental, or informational support (Barker, Morrow & Mitteneß, 1998; Ford, et al., 1998; Neal & Barowski, 1995). Social support must also be matched to the needs and situation of the individual (Belgrave et al., 1994). For example, providing financial support to a person is only useful if the person agrees that needs the assistance. Methodological concerns notwithstanding, social support is thought to effect health directly and may help people manage their diabetes (Fisher et al., 1997; Ford et al., 1998; Westaway et al., 2005) and keep older African American from being institutionalized (Luckey, 1994).

A paucity of research exists on the effect of social support on African American adults with diabetes. In a review of the literature, Ford (1998) found only six studies that targeted or included African Americans. Among the findings were that (a) 51% of the men relied on their wives as a primary source of support, while only 8% of women relied on their husbands (Murphy et al., 1994); (b) a significant

relations exists among social support, keeping medical appointments, and following prescribed regimens (Belgrave & Lewis, 1994); social support for females was related to satisfaction while social support for males was related to the number of people (i.e., males were more likely to comply with insulin adherence if large numbers of people provided support; see Uzoma & Feldman, 1989); (c) social support has a positive impact on doctor visits (Butler et al., 1994); (d) participants had a strong work ethic and had not considered who was available to them as part of a social support network (Zink et al., 1992); and (e) no significant differences exist in glucose levels (i.e., HbA1C levels) between a social support groups and a control group (Maxwell et al., 1992).

Purpose

Given the increase in human life expectancy, the disproportionate incidence of diabetes among African Americans, and projected increases in the number of diagnosed and undiagnosed cases of diabetes, interventions need to be developed that increase physical activity among older African Americans with Type 2 diabetes. The present studies in particular examined whether goal setting (e.g., Experiment 1) and goal setting with social support (e.g., Experiment 2) would increase walking in older African Americans with Type 2 diabetes.

Method

Recruitment

Four participants were recruited by word of mouth between December, 2003 and February, 2004. For this, the researcher, an African American graduate student,

contacted friends and acquaintances to aid in the recruitment efforts. She then conducted an informal screening of the participants by telephone to review the intervention and determine if they had any known physical challenges that would limit their ability to walk for sustained periods on a daily basis. The informal screening was used to determine if participants (a) had a diagnosis of Type 2 diabetes by a physician for a minimum of 1 year, (b) were not currently in an organized physical activity program, (c) were over the age of 50, (d) had a prescribed treatment regimen that included glucose monitoring, (e) had no visual impairments, (f) had a self-diagnosis of sedentary or inactive lifestyle, (g) were encouraged to exercise by a health professional, and (h) expressed interest in the study. Participants would not have been invited to join the study if they had not meet the criteria outlined by the researcher.

During the initial meeting, the researcher developed rapport, explained the research design, answered questions, and asked participants to fill out a questionnaire (Appendix A). She then explained the process of informed consent. During or immediately following that meeting, participants received two consent forms: one to be completed and signed by their physician (Appendix B), the other a university informed consent form to be signed by the participant (Appendix C). The research proposal was approved by the sponsoring university's Human Subjects Committee and complied with the requirements for human subjects research.

Participants. The participants were four African-American adults who had a diagnosis of Type 2 diabetes. Each lived in a single family home. Participant 1 was a

66-year-old male who had been diagnosed with diabetes for two years. His diabetes medication regime included Toporal 220 mg/a.m. and 11 mg/p.m., Humulin-N 40mgs/a.m., and Humulin-R 5 mgs/p.m. He owned a glucometer and had started using it regularly as the result of a previous study with the researcher. Physician-recommended fasting levels were to remain <110mg/dL and nonfasting glucose levels were to remain <160 mg/dL.

Participant 2 was a 59-year-old female who had been diagnosed with diabetes for 5 years. Her diabetes medication regimen included Actos 45mg daily, Novolin Innolet 70/30 32 units a.m., and an average of 6 units/p.m. She monitored her glucose levels an average of three to four times a day with a glucometer. In November 2003, she experienced a diabetes-related stroke and had been on medical leave from work for several months prior to her participation in the study. Her physician-recommended fasting and nonfasting glucose levels were to remain between 90mg/dL and 120 mg/dL.

Participant 3 was a 56-year-old female who had been diagnosed with diabetes for 7 years and had developed mild neuropathy in one foot. She had recently been placed on long and rapid acting insulin in order to better control her glucose levels. Her medication regimen included Lantus 19mg/p.m. and an average of 8 units of Novalin before each meal. She monitored her glucose levels, on average, three to four times a day with a glucometer. Her physician-recommended fasting and nonfasting glucose levels were to remain between 90mg/dL and 140 mg/dL.

Participant 4 was a 66-year-old male who had been diagnosed with diabetes for

13 years. His prescribed medication regimen included Avandia 8 mgs/a.m., Glucophage ER 500 mg/p.m., and Glargine 15 cc/p.m. He also used 400 mgs Chromium P daily to help control his glucose levels, which he began monitoring during an extended baseline period of the present study. His physician-recommended fasting levels were to remain within <120 mg/dL and nonfasting levels were to remain within <150 mg/dL.

Settings

The initial organizing meetings were held with one or two participants in private rooms in public libraries. They lasted an average of 50 minutes, including time needed to build rapport. The room used in Experiment 1 was designed as a study room and included four chairs, a computer, and writing desks. During the treatment phase of Experiment 1, Participants 1, 2, and 3 were scheduled to meet with the researcher and then walk together without the researcher as a group at a local mall. The participants did not meet as a group with the researcher and within two weeks of the start of treatment, they chose to walk individually in their community settings. The room used in Experiment 2 was a meeting room that included one table and several chairs. The researcher initially met with Participant 4 on the campus of a local university. During each of the 4 weeks of this treatment phase, the researcher walked with him across the campus, varying this route according to his preference.

Equipment

At the start of baseline, each participant was provided with a RYP Sports (4100) battery-operated, auto filter sensor digital pedometer. It was set in a clear plastic case

that included a hinged door with an attached clip designed to be worn on a waistband or belt. The researcher reviewed the instructions for how to wear the pedometer and demonstrated the proper placement of the pedometer on the waistband above the knee. Participants were instructed to wear it daily during waking hours and reset it to zero at the beginning of each day. Written instructions that were included by the manufacturer were sent home with each participant. The pedometer recorded a maximum of 10,000 steps. Participants had to visually monitor the steps registered on the pedometer and reset it by pressing a button. The pedometers cost approximately \$10.00. Participants used their own glucometers to record their glucose levels.

Dependent Variable

In Experiments 1 and 2, the dependent variable was the number of steps each participant reported taking daily, as measured by the pedometers. Participants in Experiment 1 reported their steps through a daily phone call initiated by the researcher according to a verbally agreed upon schedule between the researcher and the participant. The participant in Experiment 2 reported his steps to the researcher via the Internet. During baseline and treatment, participants also used the telephone or the Internet respectively to communicate information about their glucose levels, medication compliance, and whether they had monitored their foot care using a check-off sheet developed by the researcher.

Independent Variables

In Experiment 1, the independent variable was participatory goal setting. Participatory goal setting is the arrival at a consensus between the researcher and the

participant on what the goal should be. The researcher, however, assigned the first week's goal during treatment by using the average steps taken during the last 30-day period of baseline, and adding 10% for Participants 1 and 3. Because Participant 2's steps during the last 30 days were dispersed sporadically, the researcher averaged the last 48 days of the reported steps and added 10% to determine the first week's goal. The purpose of this procedure was to ensure each participant had a minimum of 21 days of reported baseline data. The initial assigned goals were verbally approved by all of the participants.

The independent variables for Experiment 2 were goal setting, as described in Experiment 1, and social support. Social support was defined as meeting with the researcher for one hour a week, with 30 minutes assigned to walking together. The additional time was spent talking about his progress and coming to a verbal agreement about his goal for the upcoming week.

Experimental Design

The effect of goal setting in Experiment 1 was evaluated using a two-leg, multiple baseline design across the three participants. A multiple baseline design is used to examine experimental control of changes in behavior, generally using at least two staggered A-B designs consisting of a no treatment baseline (A) followed by an intervention (B) that introduces the independent variable at staggered intervals to control for confounding variables (Bailey & Burch, 2002, p.166). The effect of goal setting and social support was evaluated in Experiment 2 using an A-B design. An A-B design consists of a no treatment baseline (A) followed by only one treatment

intervention (B) (Bailey & Burch, 2002, p. 148).

The intervention phase for both experiments also included a changing criterion design in which treatment was applied in weekly stages, with each stage used as a baseline for the next stage (Hartmann & Hall, 1976). The changing criterion designs was used to determine if setting weekly goals produced reliable and sustained increases in the number of steps taken.

Results

Experiment 1

Although all participants increased their steps over baseline, experimental control cannot be demonstrated using the multiple baseline design. An immediate increase in steps is demonstrated when treatment is applied to Participant 1. Treatment was applied simultaneously to Participant 2, however the first data point shows a decrease in steps. Treatment was applied to Participant 3 seven days later with the first data point revealing a decrease in steps.

Participant 1. Participant 1 reported the number of steps registered on his pedometer for 29 of the last 30 days of baseline (see Fig. 1). The baseline revealed significant variability during the first two weeks, ranging from 3821 to 7566 steps per day, but it diminished toward the end of this phase (5442 to 7325 steps). His mean number of steps per day was 6422. No trends are observed when these data are graphed on a weekly basis (see Fig. 2).

During treatment, the participant's overall mean steps per day was 10,331, a 38% increase over the last 30 days of baseline. During the first 5 weeks of treatment,

the data were somewhat variable, particularly during week 5, but this largely diminished during the last 7 weeks. As for the 4 outlying lower data points during the treatment, these were due to vacation days or special occasions (e.g., birthday party, golf game). Overall, the data show no apparent daily or weekly trends. However, the weekly trends reveals two groupings of results—a grouping during the first 5 weeks have means ranging from 7464 to 9225 steps and a grouping during the remaining 7 weeks cluster around 10,000 steps. Figure 3 presents the percentage of the goals Participant 1 achieved or exceeded each week. Overall, he reached 100% of his goals for 8 out of the 12 weeks. The reported number of steps taken shows two groupings distinguished by the first 5 weeks, which is variable, and the remaining 7 weeks which indicate 100% achievement of goals, with the exception of one week at 70%.

Figure 4 shows that Participant 1 monitored and reported his glucose levels most days during baseline and intervention. During baseline, his average glucose levels remained within his doctor's prescribed range 93% of the time with some variability during the last 30 days of baseline, ranging from 93 mg/dL to 283 mg/dL, in addition to a downward trend. During the intervention, his overall glucose levels remained within the prescribed range 95% of the time. As with the variability in his steps taken and percentage of goals achieved, Participant 1's glucose was also more variable in the first 5 weeks of treatment and less so during the last 7 weeks. As for trends in the data, Participant 1's glucose readings increased slightly during the first 5 weeks, but were generally stable during the last 7 weeks. When Participant 1's fasting and nonfasting glucose levels are separated out, we see that he

remained within the prescribed fasting range only 11% of the time during baseline and only 20% during treatment (see Fig. 5). The comparable findings for his nonfasting glucose levels were 20% during baseline and 92% during treatment (see Fig. 6). The variability and trends in his fasting glucose levels were about the same as his reported mean glucose levels, while those for his nonfasting levels could not be assessed because too few data were reported.

Participant 2. Participant 2 reported the number of steps registered on her pedometer for 21 of the last 48 days of baseline (see Fig 1). The baseline revealed a number of missed days of self reports and variability in steps. The latter ranged from 147 to 3624 steps per day, with an increase reported during the third and fourth weeks of the 15 week baseline. Her mean number of steps per day across baseline was 2431. When the data are graphed weekly, a slight upward trend during the final three weeks becomes apparent (see Fig. 2).

During the treatment period, the participant's mean steps per day was 3042, a 20% increase over baseline. During the first 7 weeks, the participant's steps showed much variability from week to week, and, as with baseline, she failed to report steps on several days. The last 3 weeks also reveal some variability and an upward trend in the reporting of steps, as well as in the number of steps. A slightly different result is noted when the data are graphed weekly. They reveal a grouping of for weeks 3 through 5 and a grouping for weeks 7 through 10. The percentage of goals Participant 2 achieved or exceeded is presented in Figure 3. Overall, she reached 100% of her goals 4 of the 10 weeks. Figure 3 shows a significant degree of

variability, although the last 4 weeks reveal a sustained high rate of goal achievement (82-100%).

Figure 4 shows that Participant 2 reported her glucose levels on most days. Her mean glucose levels were within her doctor's prescribed range 11% of the time during baseline and 16% during treatment. A high degree of variability is seen during baseline, ranging from 91 mg/dL to 218 mg/dL. A high degree of variability also occurred during treatment (103 mg/dL to 261 mg/dL), with a downward trend result noted. Her fasting glucose levels remained within the prescribed range 33% of the time during baseline and 16% during treatment (see Fig. 5). The comparable findings for the nonfasting levels fell within the prescribed range 17% of the time during baseline and 16% during treatment (see Fig. 6). A high degree of variability in fasting occurred during baseline (85 mg/dL to 201 mg/dL) and treatment (80 mg/dL to 261 mg/dL). A degree of variability was noted with the nonfasting levels during baseline (83 mg/dL to 290 mg/dL).

Participant 3. Participant 3 reported the number of steps on her pedometer for 23 of her last 30 days of baseline (see Fig. 1). Her baseline revealed significant variability with her reported steps, ranging from 2,136 to 10,026 steps per day. Her mean number of steps per day was 6059 steps. Although no trends are observed in Figure 1, when these data are graphed on a weekly basis, a downward trend is noted during the last week of baseline (see Fig. 2).

During the treatment period, the participant's overall mean steps per day was 8316, a 27% increase over baseline. A degree of variability can be seen throughout

the treatment phase, ranging from 2300 to 13,105 steps per day. The weekly means indicate some stability within two groupings of results during the first 4 weeks, followed by a lower rate during the fifth through seventh weeks. The eighth and final week reveals the highest mean, although the goal was not changed from week 4 through week 8. The percentage of goals Participant 2 achieved or exceeded each week is presented in Figure 3. Goal attainment was generally low. She reached 100% of her goals only during the final week of the study..

Figure 4 reveals that Participant 3 reported her glucose levels on most days. During baseline, her mean glucose levels remained within her doctor's prescribed range 13% of the time. A degree of variability is noted during baseline, ranging from 105 mg/dL to a peak of 326 mg/dL. During treatment, her glucose levels remained within the prescribed range 7%, ranging from 122 mg/dL to 274 mg/dL. The results for the fasting range indicate that she remained within her doctor's prescribed range 27% of the time during baseline (see Fig. 5) and 31% of the time during treatment (see Fig. 5). The comparable findings for her nonfasting levels reveal that she remained within the prescribed range none of the time during baseline and 3% of the time during treatment (see Fig. 6). The variability in her fasting glucose levels are about the same as her overall levels. The variability in her nonfasting glucose levels are also similar to the overall glucose levels.

Experiment 2

Although Participant 4 increased his steps over baseline, experimental control cannot be demonstrated using an A-B design. An immediate increase in steps is

demonstrated when treatment is applied.

Participant 4. Participant 4 reported the number of steps registered on his pedometer 19 of the last 30 days of baseline (see Fig. 7). His baseline revealed a significant amount of variability, ranging from 1585 to 12,698 steps per day, with a limited number of steps reported during the first two weeks. His overall mean number of steps per day was 6372. Although no trends are noted in Figure 7, a downward trend is noted in the weekly graph between the first and second week, with some stability noted during weeks 2 through week 4 (see Fig. 8).

During treatment, the participant's overall mean steps per day was 7186, an 11% increase over baseline. Throughout the 4 weeks of treatment, variability ranged from 1032 to 13,444 steps per day. The data show no apparent trends when they are graphed daily (see Fig. 7) or weekly (see Fig. 8). The percentage of goals Participant 4 achieved or exceeded each week is presented in Figure 9. Overall, he reached 100% of his goals during the first and last weeks of treatment. This figure shows some variability, though, with a pronounced dip noted during the second week.

Figure 10 shows that Participant 4 reported his glucose levels most days and that his average glucose levels remained within his doctor's prescribed range 96% of the time during baseline and 92% of the time during treatment. Some variability is noted during baseline, primarily during the first week (90 mg/dL to 161 mg/dL). During treatment, a degree of variability is noted (84 mg/dL to 220 mg/dL). He remained within his fasting glucose range 45% of the time during baseline and 42% of the time during treatment (see Fig. 11). The comparable findings for his nonfasting

levels were within the prescribed range 86% of the time during baseline and 73% of the time during treatment (see Fig. 12). The variability in his fasting levels is comparable to his overall glucose management. His nonfasting levels, however, show the highest degree of variability during baseline (80 mg/dL to 204 mg/dL) and treatment (63 mg/dL to 297 mg/dL).

Social Validity

One measure of social validity reported by the participants was the reduction or elimination of their diabetes medication. The insulin medication for Participant 1 was reduced; an insulin sensitizer was removed from the regimen for Participant 2 and she was accepted into clinical trials; insulin for Participant 3 was capped at 25 mgs per day; and insulin was completely removed from the medication regimen at the end of the study for Participant 4.

Discussion

Experiment 1 evaluated a participatory goal setting intervention on the reported steps taken by three older, community dwelling African Americans with a diagnosis of Type 2 diabetes. All the participants increased their mean number of steps over baseline, although the number of steps was not stable from week to week and goal attainment was variable. Self-reported data on daily glucose levels were collected as they should in any experiment with people with diabetes. Glucose levels, however, were not measured and the findings cannot be evaluated without also considering exercise levels, food intake, medication compliance as well as other variables.

Experiment 2 evaluated a participatory goal-setting intervention with social support on the self-reported steps taken by an older, community dwelling African-American man with a diagnosis of Type 2 diabetes. This participant increased his mean number of steps over baseline. He had a similar degree of variability as the participants in Experiment 1 in his steps taken, daily attainment of his goals, and the overall impact on his glucose levels.

Limitations

Methodological limitations. Despite the overall gains made in the mean number of steps, both studies had methodological, procedural, and external limitations. The three main methodological limitations concern (a) the research designs, (b) interobserver agreement, and (c) random sampling of participants. The first of these limitations was that experimental control was not fully demonstrated by the multiple baseline design used in Experiment 1 for three reasons: First, the analysis of experimental control was limited to two staggered interventions among the three participants, whereas three staggered interventions is the norm for establishing experimental control (Bailey & Burch, 2002, ch. 7). A minimum of two baselines is required to demonstrate experimental control, but the minimum should only be used under ideal conditions (e.g., stable baselines, no trends). Experiment 1 not only applied the interventions under less than ideal conditions (e.g., considerable variability prior to treatment), the intervention was applied simultaneously to two of the three participants. Second, although no prescription exists for the length of the interval between baseline and the staggered interventions in multiple baseline

designs, the interval of only eight days between Participants 1 and 2 and Participant 3 did not provide enough time to assess experimental control. Third, in Experiment 2, used an A-B design, one of the weakest designs in single-subject experimentation. It does not have any reversal phases to assure that changes following intervention are due to variables other than the treatment intervention (Bailey & Burch, 2002, chap. 7).

The second methodological limitation lies in the observational methods used in the two experiments. No interobserver agreement data were collected. The results relied solely on the self reports of each participant. Community based physical activity, such as walking, typically relies on self-reports (Tudor-Locke, 2002; Van Wormer, 2004). Applied research, however, has limited value if self-reported changes cannot be verified or observed by a researcher or an independent observer (Baer, Wolf & Risley, 1968; Watkins & Pacheco, 2000). Self reports, which typically rely on questionnaires, diaries, activity logs, and surveys are subject to recall bias (Tudor-Locke & Myers, 2001). Motion sensors, such as the pedometers used in these studies, provide objective monitoring. Pedometers, for example, have been shown to provide a record of walking when paired with activity questionnaires (Singh, Fraser, Knulsen et al., 2000) and have been validated through anthropometric measures such as the body mass index (Chan, Ryan, & Tudor-Locke, 2004) and measured decreases in blood pressure (Jensen et al., 2004). The present study might have been strengthened if the reported steps had been validated through anthropometric or additional objective measures.

A third methodological limitation concerns the sampling of the study participants. Random sampling, the equal chance of being included in an experiment, is required to avoid population bias and ensure generalization (Matheson, Bruce, & Beauchamp, 1974, p.15). Participants in these experiments were referred to the researcher by friends and acquaintances and chosen based on their availability and ability and willingness to participate. The results of these studies cannot therefore be generalized easily to other African Americans with Type 2 diabetes or to the larger population of people with Type 2 diabetes.

Procedural limitations. The studies also included at least six procedural limitations. First, the goal setting procedure may not have been flexible enough to ensure the consistent daily achievement and maintenance of the goal for each participant. That is, the goal setting in this study may have yielded better results if the procedure had allowed the participants to select goals in a more flexible and participatory manner. In particular, the length of each phase of the changing criterion treatment could have been shortened or lengthened to accommodate variables that affected goal attainment, such as inclement weather, illness, or unforeseen schedule changes. Moreover, the number of steps can be affected by work schedules, the day of the week (e.g., weekday versus weekend), and other aspects of daily life (Tudor-Locke et al., 2005). Participants 2, 3 and 4, for instance, reported a significant degree of variability in their daily steps and may have benefited from achieving and maintaining one goal before discussing if that goal should be changed for a longer or shorter period of time, or if the goal should have remained the same. Goal setting for

people with diabetes, therefore, must be individualized because the majority of diabetes care is self-monitored and self-directed (Wolpert & Anderson, 2001).

A second limitation is the one-way feedback from the researcher to the participants in these studies. Although feedback is an important aspect of goal setting (Shilts et al., 2004; Strecher et al., 1995), it typically focuses on the researcher's assessment of the participant's progress, as in the present studies. Feedback from the participants regarding the goal setting process is also important if we are to better understand adherence rates, goals, and conflicts (Sprague & Shultz, 2006). Although the researcher provided regular feedback to the participants, the feedback procedure did not give the researcher an opportunity to learn why participants did not reach their goals during a particular week. Participants may have chosen goals, for example, that were in conflict with other goals (e.g., extending work hours to earn more income) or environmental challenges (e.g., weather, neighborhood, or transportation barriers).

A third limitation concerns program integrity, which refers to whether the independent variable was applied as planned (Peterson, Homer, & Wonderlich, 1982). Although the designs of the present studies allow us to make some limited conclusions about the functional relations between the independent and dependent variables, the application of the independent variables was not observed or recorded and therefore the accuracy of its application could not be verified. The goal setting application, for example, may have taken on more of a guided tone than participatory tone that was intended during the beginning or later weeks of treatment, due to the progress each participant made, and the interaction of the researcher and the

individual participants. The application of the goal setting treatment may have also been impacted by the length of time it took to come to an agreement, followed by the participants consistent understanding and/or recall of the goal setting conversation.

A fourth limitation concerns non-specific treatment effects. These include researcher-participant alliance, researcher enthusiasm and support, and other variables that threaten internal and external validity. For example, the internal validity in the present studies may have been threatened by unique personality characteristics of the researcher, which may have influenced the behavior of the participants in ways that another researcher would not have. For example, the male participants may have made more immediate gains from baseline to treatment due in part to expectations of a female researcher during the participatory goal setting process. A male researcher might have produced different effects. This may make replication across other researchers difficult. Threats to external validity also concern unrecorded idiosyncrasies associated with the social support provided to Participant 4. For example, no specific script was used during the 30 minute walk or the 30 minute discussion, which varied from week to week following the walks.

A fifth limitation concerns how social support was operationalized. Research indicates that social support can improve the health of African Americans with diabetes (Ford et al., 1998) and increase their physical activity levels (Eyler et al., 2003). However, social support must match the needs of the individual to be beneficial (Belgrave et al., 2003). In Experiment 1, the researcher defined social support as a group activity in which all participants walked together without the

researcher for 30 minutes each week. All three participants rejected the proposal. The researcher had not consulted them about whether walking in a group would provide support or whether it created unnecessary barriers associated with a structured activity (e.g., keeping pace with other participants). Barriers may have been particularly troublesome for Participant 2, who was still recovering from a diabetes related stroke, and for Participants 1 and 3, who reported diabetes-related neuropathy in their feet. In Experiment 2, the researcher defined social support as walking with the participant for 30 minutes each week without soliciting his input, and he did not always approach the intervention enthusiastically, possibly due in part to a perceived need to walk at a certain pace out of consideration of the researcher, instead of walking at a pace that was more comfortable for him. In both studies, individualized social support may have eliminated barriers associated with achieving and adhering to stated goals more consistently.

A final procedural limitation concerns the pedometer used in these studies. Non-research grade pedometers, such as the RYP Sports Model used in the present studies, are unregulated. As a result, their accuracy in counting steps cannot be assumed or verified (Tudor-Locke, 2006); they can overestimate steps by as much as 50% (Detz, 2006). Moreover, all pedometers, but particularly cheaper, non-research grade pedometers, can underestimate high intensity activities and report errors during slower walking speeds. They are also not accurate for people who bend a lot, which causes the pedometer to move or fall away from the body, or who have a high degree of abdominal fat. People with diabetes may also walk more slowly than people

without diabetes (Johnson et al., 2005) which may also affect the steps registered on a pedometer. Still, pedometers provide an objective, if not always reliable measurement and motivational tool. Accurate counts are necessary to determine and predict the relation between an intervention and the outcomes of physical activity (Bassett, 2000).

External limitations. The results of the present experiments may also have been affected by external, diabetes-related complications due to (a) medication changes, (b) neuropathy, and (c) strokes. The effects of medication changes, particularly changes in insulin, can significantly influence the physical activity of older adults. Potential side-effects include headaches, rashes, and hypo- and hyperglycemia, which can deter participants from consistently meeting their goals. Even slight changes in the administration of insulin can be detrimental. Throughout the intervention, all four participants underwent changes to their medication regimens, including incidents of running out of medication, treating and supplementing prescribed diabetes medication with over-the-counter remedies, or forgetting to take a prescribed dose. As for diabetes-related neuropathy, approximately 50% of people with diabetes develop nerve damage at various locations throughout their bodies, but most often in their hands and feet. In the feet, neuropathy can cause a degree of pain or discomfort that makes walking difficult. In Experiment 1, Participants 1 and 2 reported tingling in their feet, which might have affected their walking. As for diabetes-related strokes, Participant 2 experienced a stroke in the months leading up to the baseline phase of the study. She had not yet returned to work and was adjusting to walking without a

cane, which could have affected the number of steps she walked each day during baseline and treatment. For instance, she could have become stronger during the treatment phase. Overall, these physical constraints and changes can adversely affect the results of goal setting for people with diabetes, producing a high degree of variability and unaccounted for trends in the number of steps taken. These must be considered when evaluating the results.

Contributions

The present studies add to our understanding of the effect of the participatory goal setting on walking with people who have Type 2 diabetes. These are the first studies to use goal-setting with a pedometer to measure reported walking with older, African American adults with Type 2 diabetes. In addition, the findings are consistent with researchers that have recommended that more personalized goals, based on each person's individual baseline, may provide more achievable outcomes. (Tudor-Locke, 2005).

Second, the results of Experiment 1 are consistent with previous research reporting that some older and middle aged adults prefer to exercise on their own, rather than join a structured exercise group (Wilcox et al., 1999). The participants in Experiment 1 did not walk together because they preferred to exercise on their own as individuals or in more presumably flexible arrangements made with family or friends.

Third, the drop-out rate for all structured exercise program participants is usually 50% within six months (Tudor-Locke & Chan, 2006), with the greatest

number of older adults dropping out within the first three months (Boyette et al., 2002). Each participant in the current studies dropped out of the study within three months. They dropped out after having their diabetes medication reduced or eliminated.

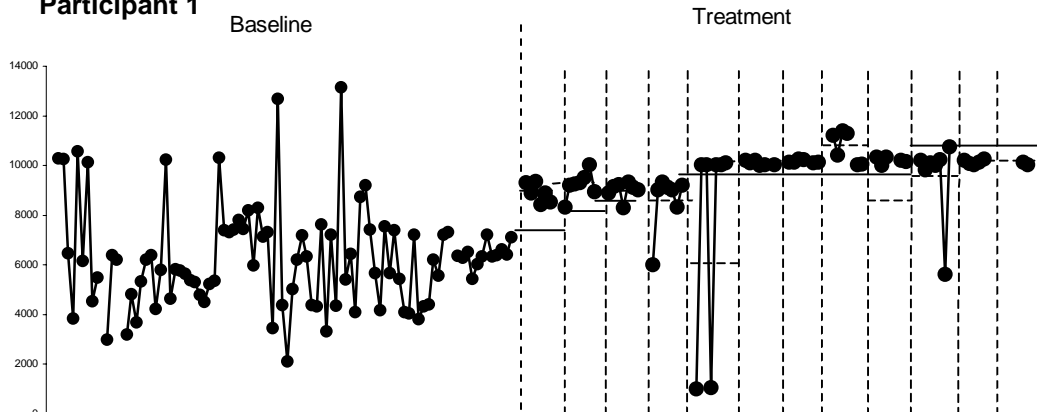
Recommendations

Given the present studies limitations, further exploration is needed to determine how participatory and other types of goal setting, social support, and goal setting with social support can influence health-related behavior changes. Further exploration is also needed to increase our understanding of the role of social support in the lives of older African Americans with or at risk for diabetes. These recommendations are particularly important today given the ongoing concerns surrounding pandemic health and health care disparities. Additionally, increased efforts should be made to train and provide more ethnic minority researchers. Ethnic minority researchers not only help to advance our understanding and knowledge of the health behaviors of ethnic minority participants, they can also help reduce the challenges of recruiting and maintaining these participants (e.g., dispositional and situational mistrust of health care and research settings). Interobserver agreement continues to pose the challenge of balancing the privacy of the individual while supporting lifestyle changes. One way to address this concern and validate self reports is to consistently include anthropometric measures such as body mass index and A1C levels. Future research should also include more innovative and community-based interventions to help overcome the common barriers to exercise

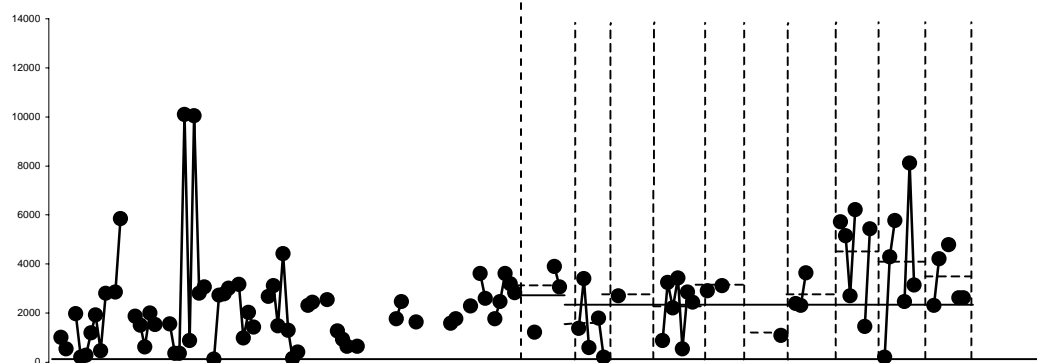
cited by older people (e.g., safety, access, time barriers). Finally, affordable, research grade pedometers should be used so that a more accurate counting of steps is possible.

Figure 1. Reported pedometer steps per day for Participants 1, 2, and 3, separated by weeks. During the intervention, the dotted horizontal lines indicate the mean steps per condition, while solid horizontal lines indicate the goal per condition.

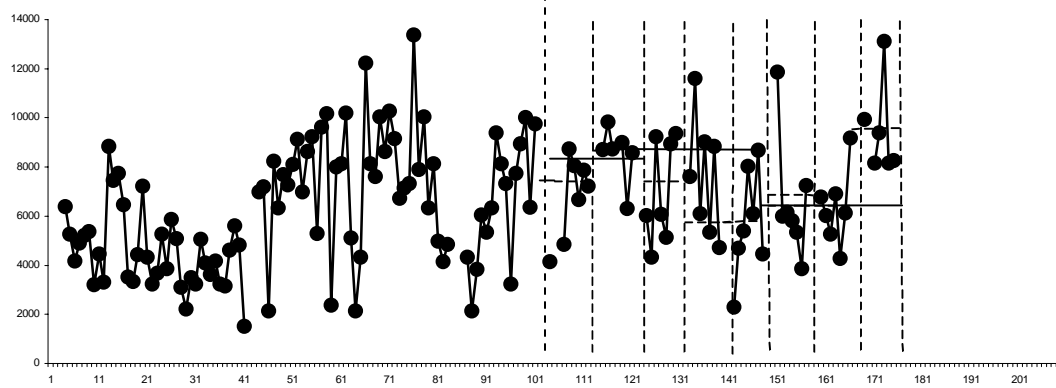
Participant 1



Participant 2



Participant 3

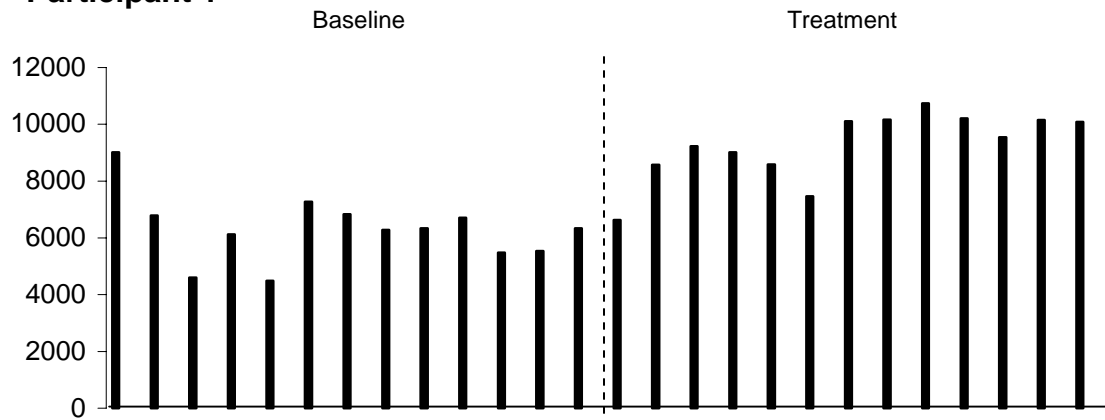


Reported Pedometer Steps

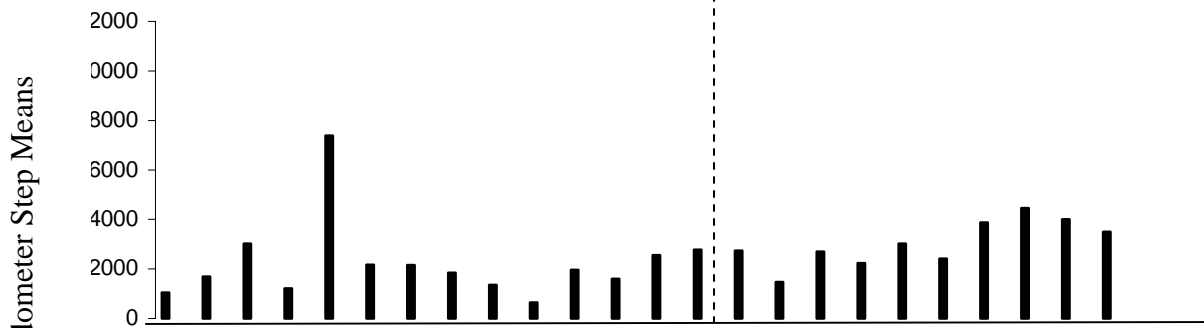
Days

Figure 2. Reported pedometer step means per week during baseline and treatment for Participants 1, 2 and 3.

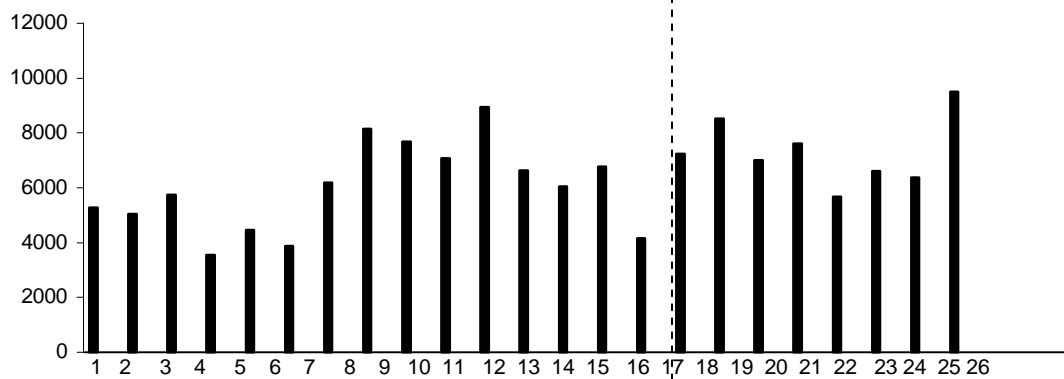
Participant 1



Participant 2



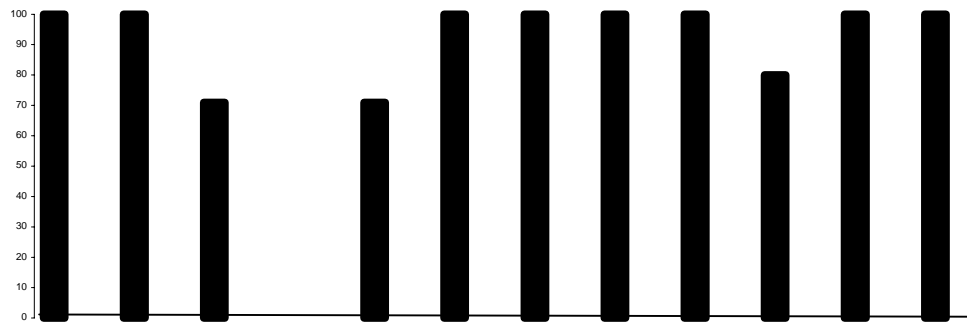
Participant 3



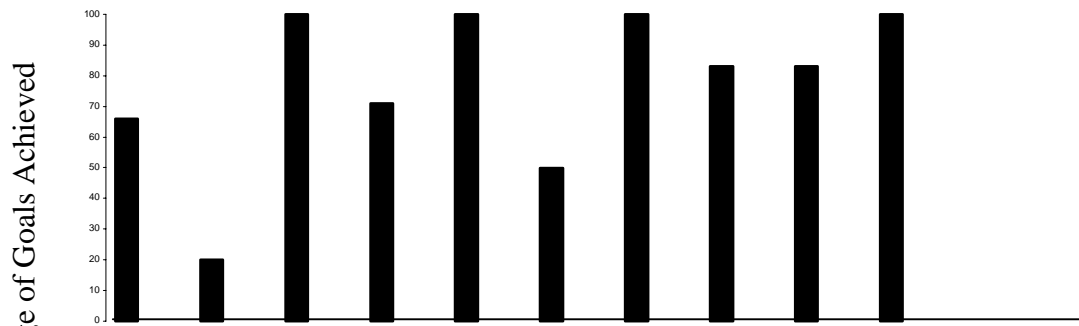
Weeks

Figure 3. Reported percentage of goals achieved per week during treatment for Participants 1, 2 and 3.

Participant 1

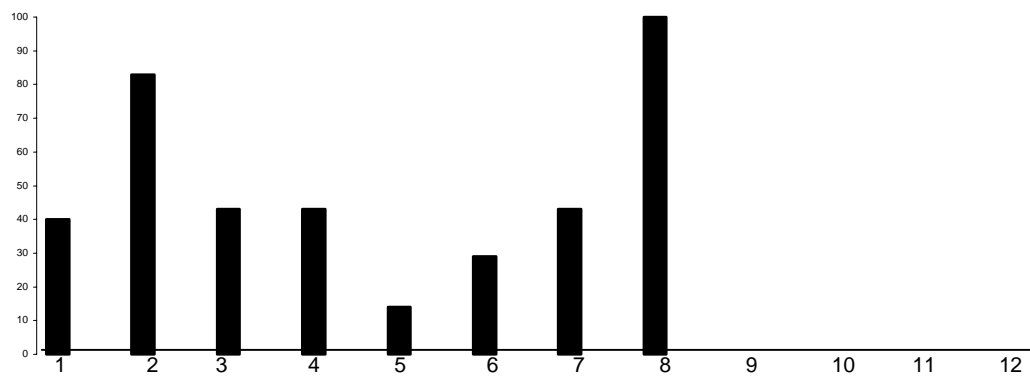


Participant 2



Percentage of Goals Achieved

Participant 3



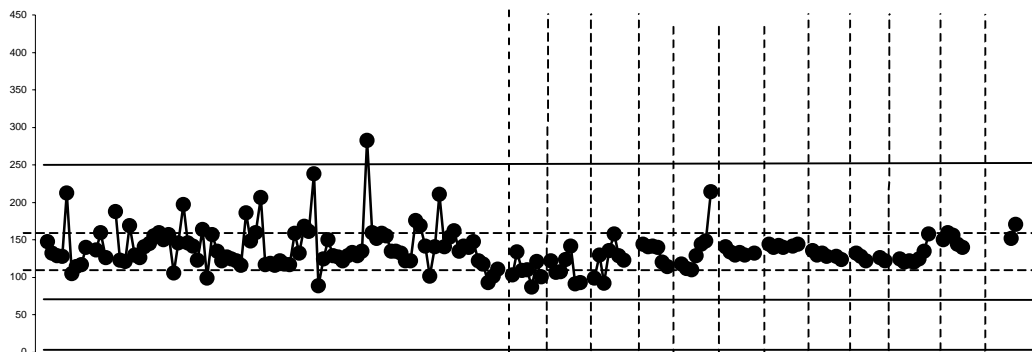
Weeks

Figure 4. Reported mean glucose levels for Participants 1, 2 and 3 per day, separated by weeks. The solid horizontal lines indicate the physician's prescribed range. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.

Participant 1

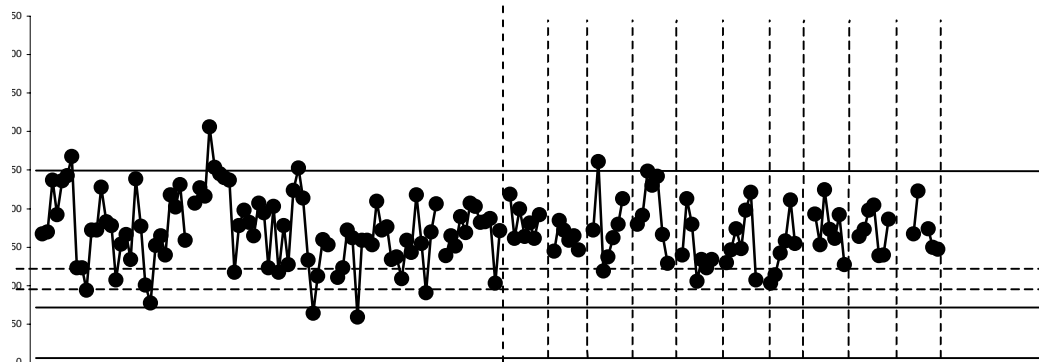
Baseline

Treatment

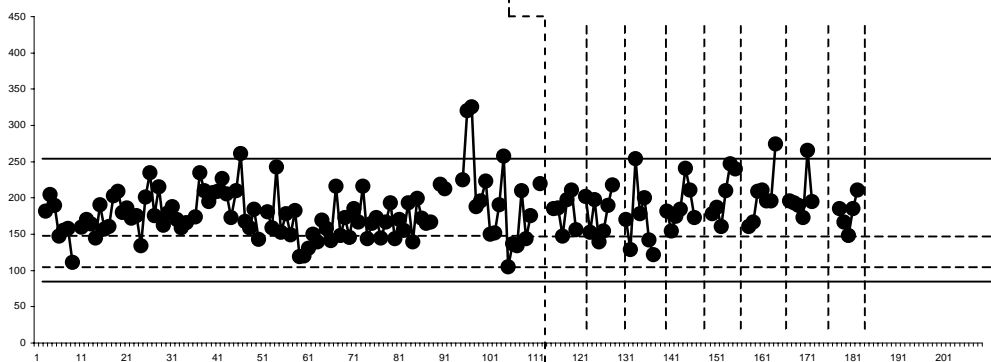


Participant 2

Mean Glucose Levels



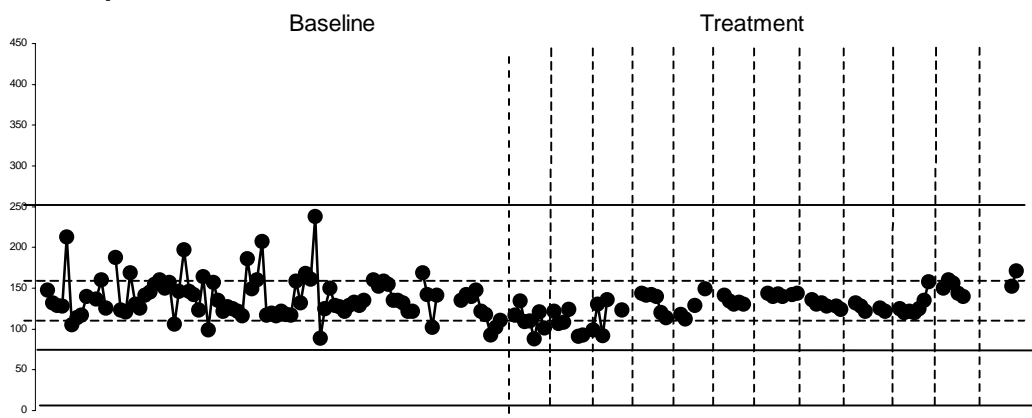
Participant 3



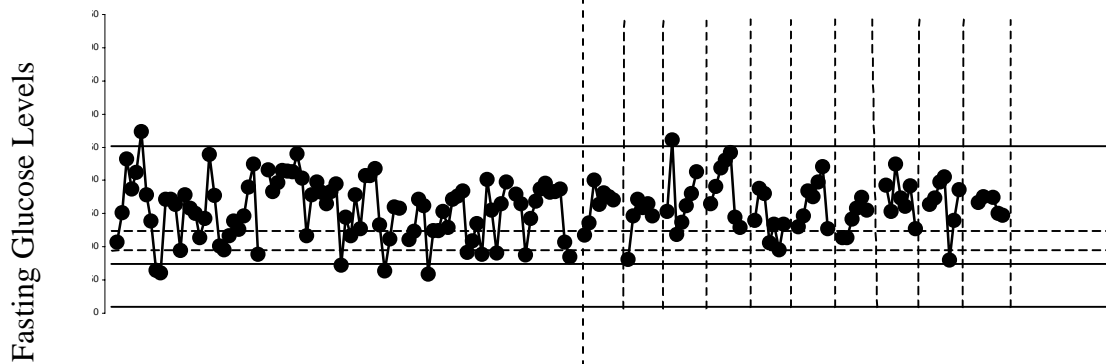
Days

Figure 5. Reported fasting glucose levels (e.g., glucose levels recorded before 8:00a.m.) for Participants 1, 2 and 3 per day, separated by weeks. The solid horizontal lines indicate the physician's prescribed range. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.

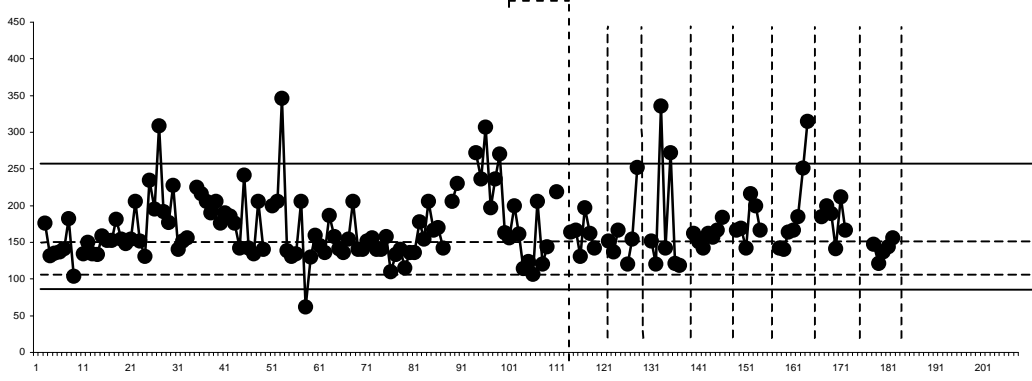
Participant 1



Participant 2



Participant 3



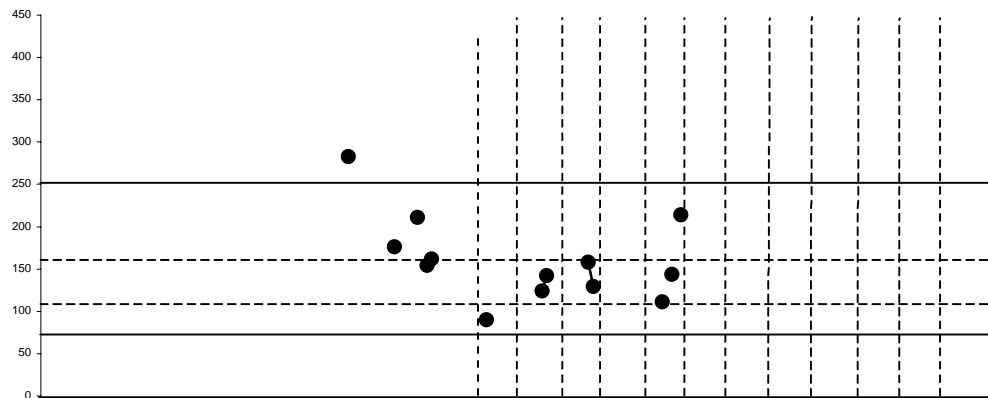
Days

Figure 6. Reported nonfasting glucose levels (e.g., glucose levels recorded after 6:00p.m.) for Participants 1, 2 and 3 per day, separated by weeks. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.

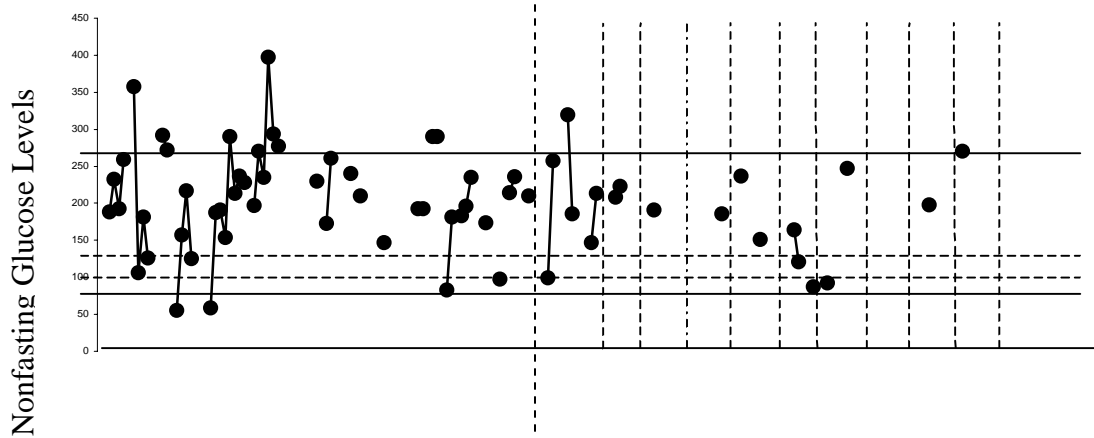
Participant 1

Baseline

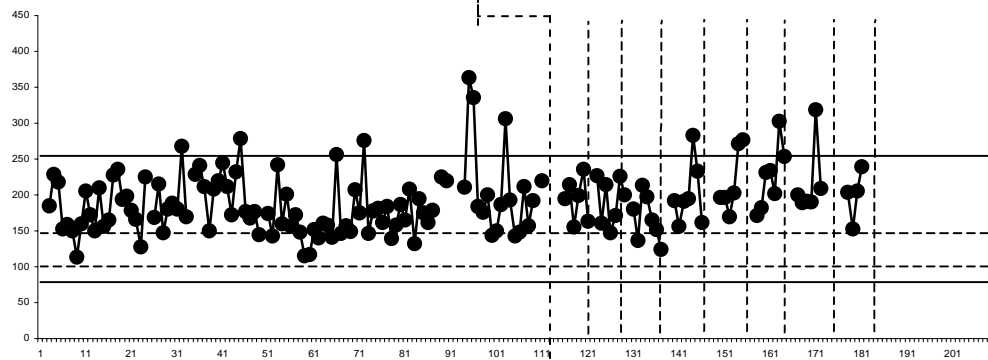
Treatment



Participant 2



Participant 3



Days

Figure 7. Reported pedometer steps for Participant 4, separated by weeks. During treatment, the dotted horizontal lines indicate the mean steps per condition while solid horizontal lines indicate the goal per condition.

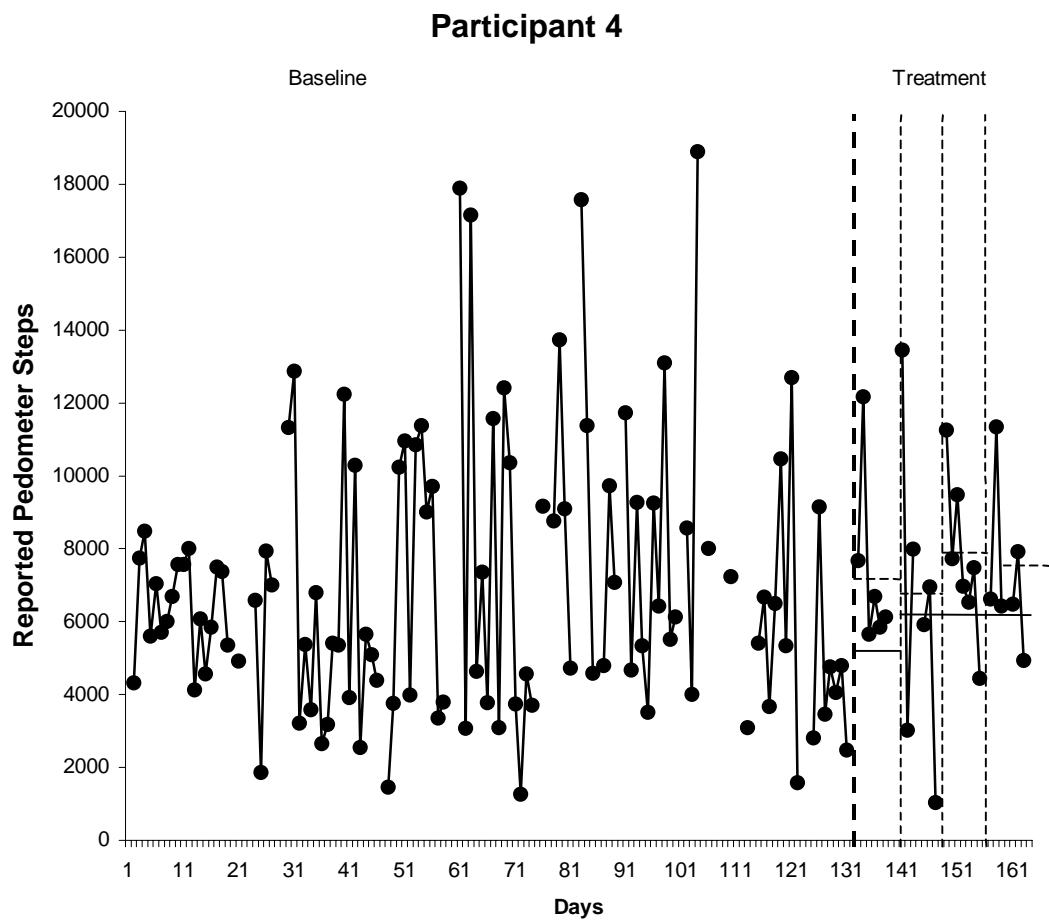


Figure 8. Reported pedometer step means per week during baseline and treatment for Participant 4.

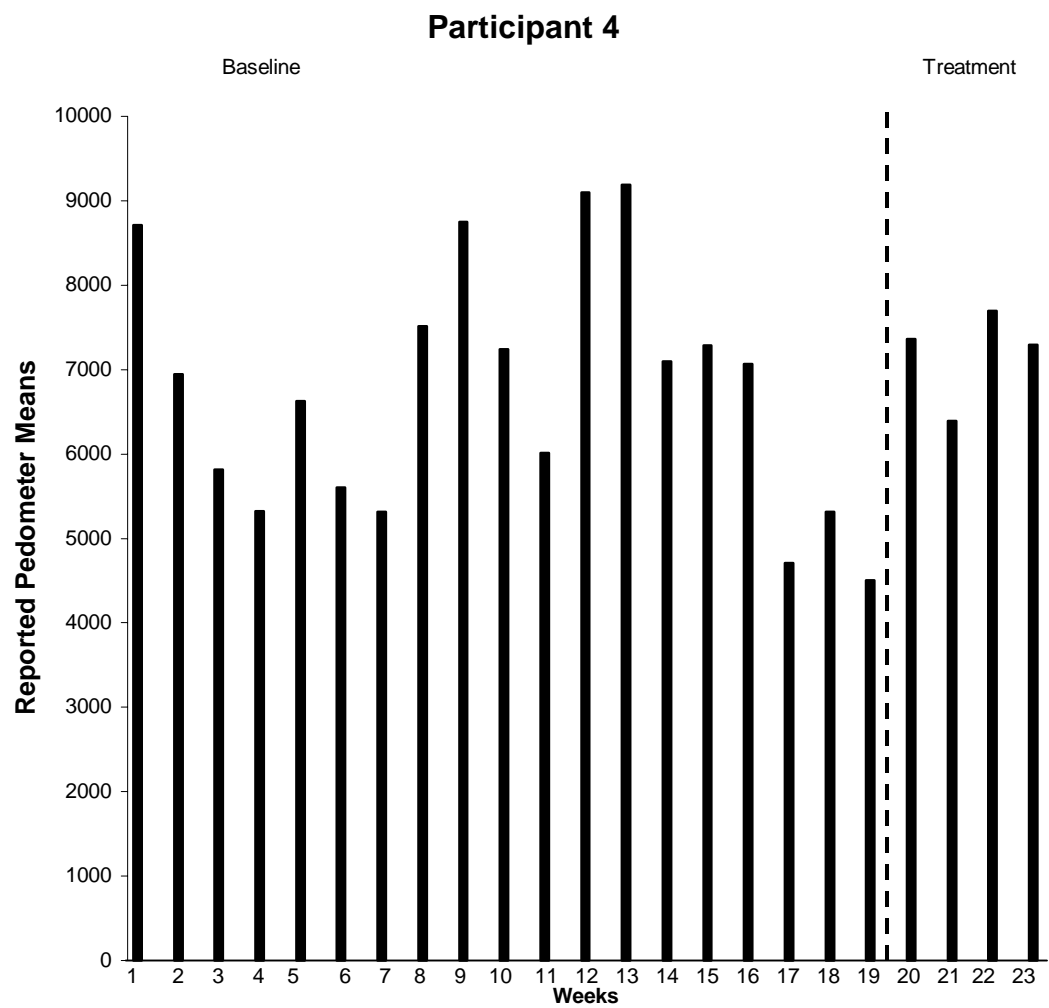


Figure 9. Reported percentage of goals achieved per week during treatment for Participant 4.

Participant 4

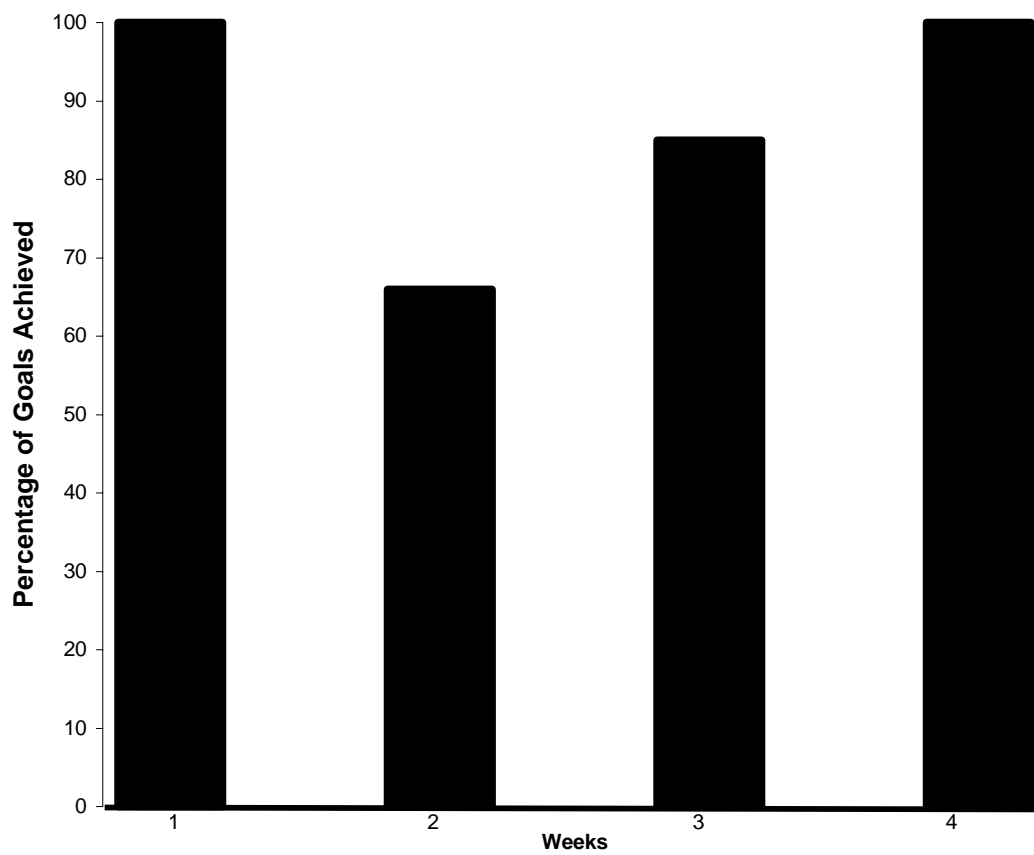


Figure 10. Reported mean glucose levels for Participant 4, separated by weeks. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.

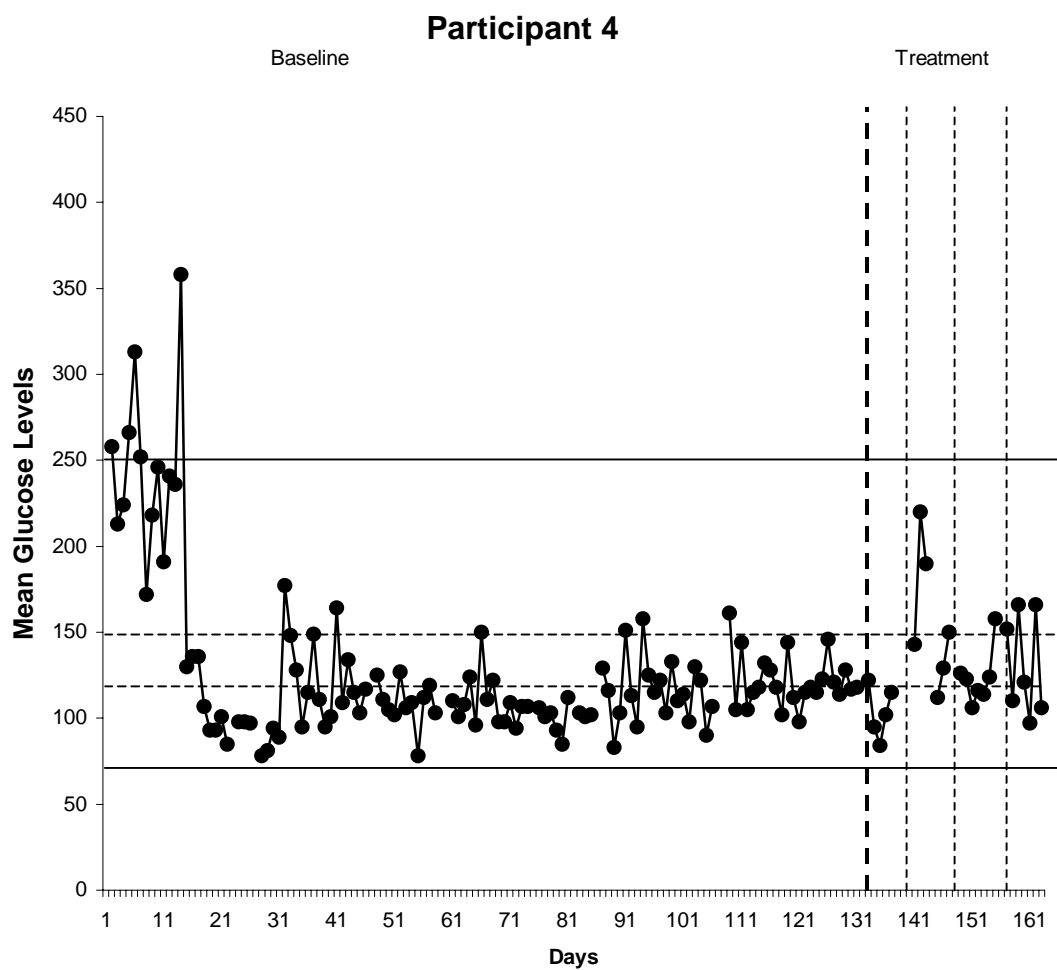


Figure 11. Reported fasting glucose levels (e.g., glucose levels recorded before 8:00a.m.) for Participant 4. The solid horizontal lines indicate the physicians prescribed range. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.

Participant 4

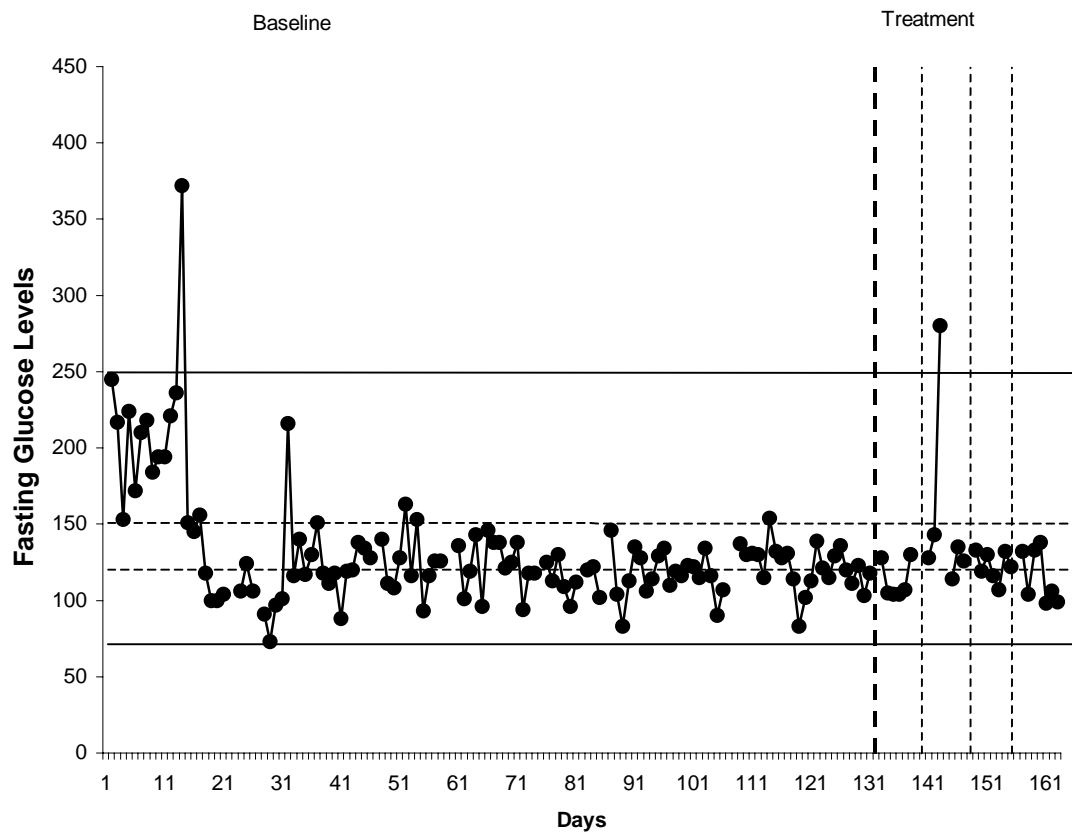
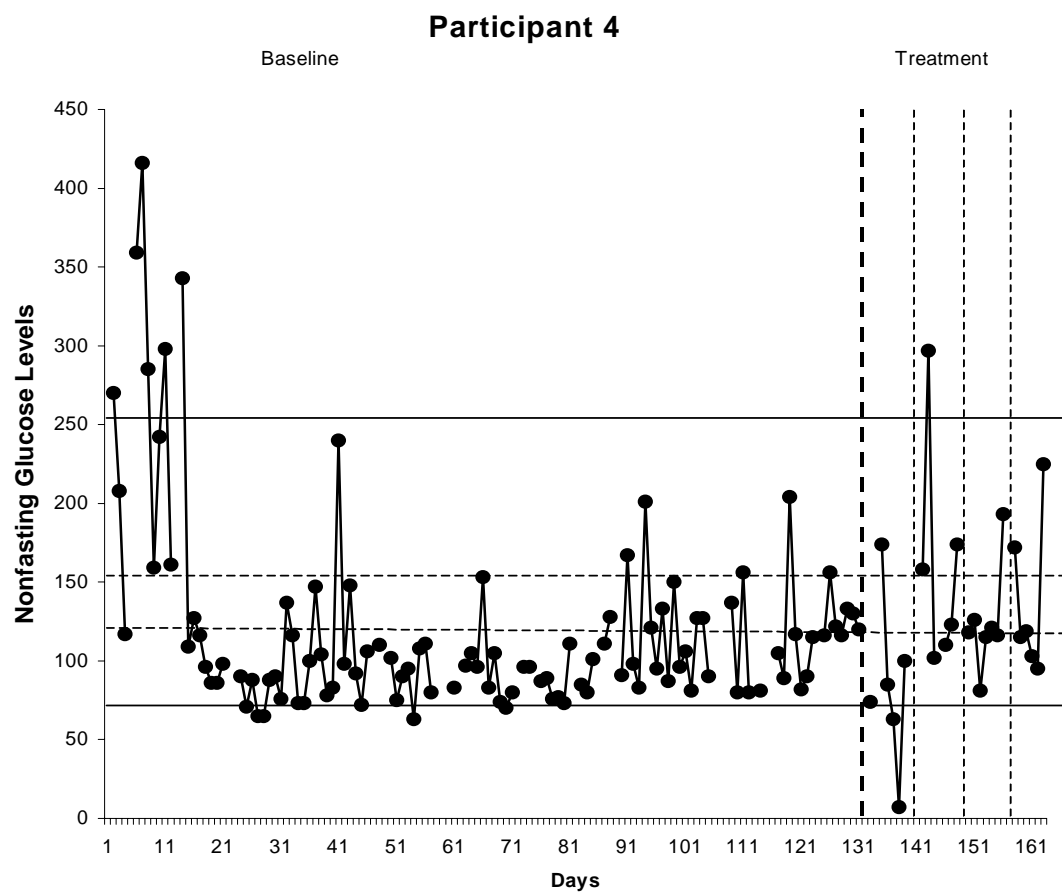


Figure 12. Reported nonfasting glucose levels (e.g., glucose levels recorded after 6:00p.m.) for Participant 4, separated by weeks. The dotted horizontal lines indicate general industry recommendations not to exceed 250 mg/dL or fall below 70 mg/dL.



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Appendix

Appendix A

Diabetes Questionnaire

Name: _____ Date _____

1. Current Age: _____ At what age were you first diagnosed with type 2 diabetes?

2. What medications do you currently use to assist in managing your diabetes?

3. What other things do you do to manage your diabetes?

4. How often have you been advised to test your level of blood sugar during the day?

5. How often do you actually perform this test? _____ If this is LESS often than recommended by your doctor, what barriers keep you from testing more often?

What types of exercise do you currently use to help manage your diabetes?

Specifically, when do you do this exercise; i.e., days of week and times?

Sunday Monday Tuesday Wednesday Thursday Friday Saturday

Time: _____

Please describe how you manage your diet to control your blood sugar.

What is currently the most difficult challenge you face in managing your diabetes?

=====

During the past week:

- | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. How successfully have you managed your diabetes? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. How much does your diabetes interfere with your lifestyle? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3a. How difficult has it been to comply with your physician's diet recommendations? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. How successfully have you complied with these recommendations? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4a. How difficult has it been to comply with your physician's exercise recommendations? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| b. How successfully have you complied with these recommendations? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 5. How satisfied are you with your current management of your diabetes? | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

Is there anything else you would like the researchers to know?

Appendix B

Physician Approval Form

Maren E. Turner
4001 Dole Building
University of Kansas
Lawrence, KS 66045

Dear Physician:

Mr./Ms. _____ is a candidate for inclusion in a research project dealing with assisting people with Type II diabetes to maintain therapeutic glucose levels. The project is being conducted through The University of Kansas. Mr./Ms. has passed our initial screening process and has indicated a willingness to participate in the project. As Mr./Ms. _____ physician, we ask that you view the accompanying list of exercises and/or assessments we will be using in this project and please indicate if you believe participation would be inappropriate for Mr./Ms. because it would put him/her at undue risk.

Although we cannot tell you at this time precisely which exercises Mr./Ms. will be asked to perform, or how often it will be performed, our intent is to have him/her perform many of the exercises numerous times weekly. Precisely which exercises he/she is asked to perform, and how often, will depend upon our assessment of his/her current abilities.

After you have examined the accompanying list of exercises, please indicate your permission for Mr./Ms. _____ to participate in our project by placing and "x" in the proper box and signing on the line provided.

Sincerely,

Maren Turner, M.S.
David Born, Ph.D.

List of Activities

- Walking 3-7 days weekly for up to 30 minutes per day
- Biking 3-5 times weekly for up to 30 minutes per day
- Swimming 3-5 times weekly for up to 30 minutes per day
- Dancing 3-5 times weekly for up to 30 minutes per day

Measurements

- Monitor glucose levels using a glucometer a minimum of twice daily
- Monitor walking activities by using a pedometer
- Monitor weight by using a calibrated bathroom scale.

Consent Form

As Mr./Ms. _____ primary physician, it is my judgment that he will not be harmed by participating.

As Mr./Ms. _____ primary physician, I certify that he/she has been diagnosed with Type II Diabetes. This patient has been made aware that his/her therapeutic glucose range should remain within the following limits:

As Mr./Ms. _____ primary physician, it is my judgment that he/she will be harmed by participating.

Physician Signature:

Date:

Appendix C

INFORMED CONSENT STATEMENT

Management of Type II Diabetes with Exercise and Diet

INTRODUCTION

The Department of Human Development and Family Life at the University of Kansas supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or the University of Kansas.

PURPOSE OF THE STUDY

Although medication may be required, diet and exercise are the cornerstones of management for individuals with Type II Diabetes. The purpose of this project is to determine how exercise and diet alters the blood sugar levels and if these changes can improve the long term quality of life for individuals diagnosed with Type II Diabetes.

PROCEDURES

You will initially be asked to gain your physician's approval for your participation in this study. Please have your physician or health care provider fill indicate his/her approval and then return the form to the researcher as soon as possible.

Once the form has been returned, you will then be asked a few questions to determine your current diet, medication and exercise routines. You will also be provided with a pedometer, a device that measure the number of steps you take each day. You will be provided with information on to use the pedometer and then you will be asked to wear it every day. You will not be asked to alter your diet, exercise or your usual number of glucometer readings in any way, however the researcher will check in with you by telephone for a two week period to ask your current weight, pedometer readings and glucometer readings for that day.

At the close of the two week period, you will be asked to meet with a small group for at least four to eight weeks, one day a week for no more than two hours a week to discuss life as a diabetic. The group meeting will begin with the researcher recording

your self reported glucose levels as indicated on your glucometer. Your weight will also be taken on a bathroom scale and recorded. Following the collection of this data, you will be asked to exercise by walking 30 minutes with the other group members that have also been diagnosed with Type II diabetes. There will be no more than 2 additional people in your group. Walking will be conducted within an enclosed area near an eating facility. Following the exercise activity, the group will have an informal discussion while eating a light snack prepared according to the recommendations by the American Diabetes Association.

Anecdotal information you discuss in the research setting will be recorded on paper informally by the researcher.

RISKS

While there are potential benefits from participation, there may also be risks. People with Type II diabetes are prone to foot ulcers that are difficult to heal. We will not ask you to engage in any type of repetitive foot trauma, which increases this risk. You should, however, wear properly fitting shoes and inspect your feet everyday for sores.

BENEFITS

The greatest conceivable benefit will impact the way we view, prevent and treat Type II Diabetes. Individual benefits include a healthier lifestyle and weigh loss that will assist you in better managing your diabetes.

PAYMENT TO PARTICIPANTS

There will be no payment for your services, however, you will be provided with a pedometer free of charge that you may keep.

INFORMATION TO BE COLLECTED

To perform this study, researchers will collect information about you. This information will be obtained from: a pre-questionnaire administered by the researcher to determine your current exercise, diet and medication routines.. Also, information will be collected from the study activities that are listed in the Procedures section of this consent form.

Your name will not be associated in any way with the information collected about you or with the research findings from this study. The researcher(s) will use a study number, initials, or a pseudonym instead of your name.

The information collected about you will be used by: Maren Turner, David Born, Ph.D. and members of the gerontology research team.

In addition, Maren Turner and Dr. Born and his team may share the information gathered in this study, including your information, with collaborating researchers who may review the information as part of Maren Turner's degree requirements. Again, your name would not be associated with the information disclosed to these individuals.

The researchers will not share information about you with anyone not specified above unless required by law or unless you give written permission.

Permission granted on this date to use and disclose your information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your information for purposes of this study at any time in the future.

INSTITUTIONAL DISCLAIMER STATEMENT

In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from the University of Kansas or to participate in any programs or events of the University of Kansas. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose information collected about you, in writing, at any time, by sending your written request to: Maren Turner, 4001 Dole Building, University of Kansas, Lawrence, KS, 66045. If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study and the use and disclosure of information about me for the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429 or write the Human Subjects Committee Lawrence Campus (HSCL), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7563, email dhann@ku.edu.

I agree to take part in this study as a research participant. I further agree to the uses and disclosures of my information as described above. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form. (Use the 18 years old disclaimer only if the study population may include participants under the age of 18).

 Type/Print Participant's Name

 Date

 Participant's Signature

[If signed by a personal representative, a description of such representative's authority to act for the individual must also be provided, e.g. parent/guardian.]
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