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Changing Physical Activity Behavior with Continuous Glucose Monitoring: A Dissertation

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CHANGING PHYSICAL ACTIVITY BEHAVIOR WITH CONTINUOUS GLUCOSE MONITORING

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CHANGING PHYSICAL ACTIVITY BEHAVIOR WITH

CONTINUOUS GLUCOSE MONITORING

A Dissertation Proposal Presented

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ABSTRACT

Up to 60% of individuals with type 2 diabetes (T2DM) do not participate in regular physical activity (PA) despite the known benefits. To encourage these individuals to increase PA behavior, this study tested the feasibility and implementation of a nurse-directed counseling intervention using continuous glucose monitoring system (CGMS). The study used a framework derived from self-efficacy theory to 1) compare changes in self-efficacy, BP and activity counts between participants receiving CGMS counseling and standard T2DM counseling, 2) examine relationships between PA self-efficacy and BP and activity counts, 3) evaluate recruitment, retention, and screening strategies, and 4) assess instrument reliability and utility.

Adults (N=52) with T2DM (non-insulin requiring, inactive) were randomized to intervention (n=27) or control groups (n=25). Both groups received 90 minutes of diabetes education with a follow-up phone call at 4 weeks. The intervention group also received feedback on their own CGMS graphs and a role model's graph depicting PA related reductions in glucose levels. PA benefits/barriers were discussed and goals were set. Outcomes were recorded at 1 and 8 weeks.

Participants were older (57±14 years), predominantly (90%) white, about half (52%) female, and had diabetes for 8±7 years. Relative to the control group, participants receiving the intervention had higher self-efficacy scores at 8 weeks, indicating more confidence in sticking to a PA program. Their light/sedentary activity minutes decreased significantly and moderate activity minutes increased significantly; systolic BP, $A1_c$ and BMI decreased significantly. Only self-efficacy for "Sticking to it" was positively associated with moderate activity. The most successful recruitment media was multiple

newspaper press releases. Most referrals came from endocrinology physicians. Of 231 study volunteers, 106 did not meet the criterion of $A1_c \geq 7.5\%$.

These data suggest that CGMS feedback is feasible for counseling individuals with T2DM to improve PA and may improve risk factors for diabetes-related complications. Newspaper press releases are effective for recruiting participants with T2DM. Less restrictive inclusion criteria in a larger study may allow more participation by sedentary individuals with T2DM but may reduce effect size. CGMS was well tolerated and its data aided diabetes-related teaching.

CHAPTER I

INTRODUCTION

Statement of the Problem

Diabetes affects 20.8 million Americans and is the fifth leading cause of death in the United States (U.S.) (American Diabetes Association [ADA], 2006). Most individuals with diabetes (90-95%) have type 2 diabetes, which has been strongly linked with decreased physical activity (ADA, 2006). The incidence of type 2 diabetes has risen as the U.S. population has become increasingly overweight and sedentary. Between 1997 and 2004, the incidence increased by 45% in people aged 18-44, 34% in people aged 45-64, and 43% in people aged 65-79 (Centers for Disease Control [CDC], 2006). Although physical activity is a cornerstone of diabetes treatment, changing physical activity behavior is difficult for individuals with type 2 diabetes (Ary, Toobert, Wilson, & Glasgow, 1986; Clark, 1997; Glasgow, Hampson, Strycker, & Ruggiero, 1997; Skelly, Marshall, Haughey, Davis, & Dunford, 1995).

Purpose of the Study

New technologies can be an important component of behavioral change programs. One type of technology used in diabetes clinical practices may serve as an important tool for nurses counseling people with diabetes about the benefits of lifestyle behavior changes, such as physical activity. The Continuous Glucose Monitoring System (CGMS; (Gross & Mastrototaro, 2000) produces a 72-hour glucose plot and allows for input of events such as meals, physical activity, and self-monitored blood glucose values (SMBG). Another type of technology, activity monitors, objectively measure walking and other ambulatory activities as activity counts over one-minute intervals (Schmidt, Freedson, & Chasan-

Taber, 2003). These technologies can be used to graphically convey interactions between physical activity and glucose levels (CGMS) and to electronically record activity over defined periods of time (activity monitors).

The purpose of this study was to test the feasibility and implementation of a nurse-directed intervention protocol using counseling and CGMS technology to change physical activity behavior in individuals with type 2 diabetes. Guided by a framework derived from self-efficacy theory, this study's specific aims were to examine the feasibility of a nurse-directed intervention by: 1) comparing changes in self-efficacy, blood pressure (BP), and activity counts between participants receiving the CGMS counseling intervention and those receiving standard type 2 diabetes education (control group), 2) examining the relationship between self-efficacy and outcomes of BP and physical activity (activity counts) in all participants with type 2 diabetes (intervention and control groups), 3) evaluating recruitment, retention, and screening strategies that maximize participant involvement in a physical activity clinical trial, and 4) assessing self-efficacy instrument reliability and utility of the CGMS and activity monitoring technology for use in physical activity studies of individuals with type 2 diabetes.

Background and Significance

History of Diabetes Nursing and Physical Activity

Early records indicate that nurses have been teaching individuals with diabetes about the importance of physical activity in managing their diabetes since 1916 (Allen, 2003). Elliot P. Joslin, one of the first diabetalogists in the U.S., outlined nursing's role in the care of patients with diabetes and using exercise as a treatment modality: "Exercise should be moderate at first, later considerable, and should always be taken after meals.

Caution patients not to get overtired, but encourage them to exercise vigorously, steadily increasing the amount of exercise to a point that would put a healthy individual into splendid physical condition. Patients must learn to know that restriction of exercise means restriction of diet"(Allen, 1913; Joslin, 1916). Dr. Fredrick Allen, who is credited with developing the undernutrition diet to treat people with diabetes (Allen, 1913), further described the exercise treatment implemented by nurses: "Many of our patients run up the eight flights of our stairs at the hospital of the institute twenty times a day. Then they walk eight or ten miles in the open air. They also skip the rope and toss medicine balls" ("Radical New Method of Treating Diabetes," 1916). Despite these early references to the use of physical activity in the care of individuals with diabetes, exercise was not discussed in one of the first articles describing the role of the diabetes educator (Langhart, 1936). To this day, there is a dearth of nursing research on physical activity in people with diabetes.

Changing Physical Activity Behavior

Behavioral theories, such as social cognitive theory (SCT) (Bandura, 1986), have improved nurses' understanding of how individuals change behaviors. Self-efficacy, or confidence in one's ability to perform a particular behavior, is a key factor in predicting several behavioral changes (Bandura, 1986, 1997), including physical activity behavior in individuals with diabetes (Plotnikoff, Brez, & Hotz, 2000). Despite the contributions of SCT to understanding physical activity behavior changes, few behavioral theory-based diabetes physical activity interventions are practical, teachable, and effective in practice. Nurse-directed counseling interventions based on established behavioral change theory are needed to increase physical activity in individuals with diabetes.

Using Technology to Change Physical Activity Behavior

New technologies can be an important component of behavioral change programs. One type of technology used in diabetes clinical practices can serve as an important tool for nurses counseling people with diabetes about the benefits of lifestyle behavior changes, such as physical activity. The CGMS produces a 72-hour glucose plot and allows for input of events such as meals, physical activity, and blood glucose values. Another type of technology, activity monitors, objectively measure walking and other ambulatory activities as activity counts over one-minute intervals. These technologies can be used to graphically convey interactions between physical activity and glucose levels (CGMS) and to electronically record activity over defined periods of time (activity monitors). The use of a nurse-directed counseling intervention based on established behavioral change theory with technology-derived graphical representation of glucose information may create a unique opportunity to test the feasibility of motivating people with type 2 diabetes to change physical activity behaviors.

Assumptions and Definitions

Assumptions

The first assumption of this study is that individuals with diabetes can be motivated to increase their physical activity levels. Other assumptions are that individuals with diabetes will consent to using technology to monitor glucose and activity levels, welcome nurse-directed counseling for motivation and information, and perceive physical activity as important in managing their diabetes.

Definition of Terms

1a. Self-efficacy: (theoretical) "Perceived self-efficacy refers to beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments" (Bandura, 1997).

1b. Self-efficacy: (operational) A participant's confidence in his/her ability to change physical activity behavior was measured by self-report on the Self-efficacy Exercise Behavior Scale (SEBS).

2a. Physical Activity: (theoretical) The term "exercise" is being replaced in the diabetes literature (ADA, 2003) with "physical activity" to emphasize programs of activity that are less structured and light to moderate in intensity.

2b. Physical Activity Level: (operational) A change in a participant's activity counts was objectively measured using Manufacturing Technologies Incorporated (MTI, Fort Walton Beach, Florida) activity monitor, which measures the amount and intensity of movement. Average counts per day represents the mean counts over all study days. Inactivity is represented by < 499 activity counts, light activity by 500-1951 counts, moderate activity by 1952-5724 counts, and vigorous activity by $\geq$ 5725 counts (Freedson, Melanson, & Sirard, 1998).

3. Blood Pressure (BP): Systolic and diastolic blood pressure measurements taken after a minimum of 5 min in a sitting position at the same time of day.

4. Standard Diabetes Mellitus Type 2 Education: (theoretical) A curriculum with criteria for successful learning outcomes using behavioral strategies of goal setting and problem solving (Mensing et al., 2004). Content areas include diabetes disease

process, nutritional management, physical activity, medications, self-monitoring of glucose (SMBG), and risk reduction.

5b. Standard Diabetes Mellitus Type 2 Education: (operational) Nurse-directed education on the topics of diabetes physiology, diet strategies, SMBG, risk reduction, foot care education, physical activity using behavioral strategies of goal setting and problem solving.

6. CGMS Utility: Participants' accurate use of CGMS as well as complications and equipment failures.

7. Activity Monitor Utility: Usable physical activity data and participant-identified activity monitor wearing issues.

Research Questions

1. What is the difference between self-efficacy, BP, and activity counts in participants receiving CGMS counseling and those receiving standard type 2 diabetes education?
2. Is self-efficacy associated with activity counts, blood pressure and demographic variables?
3. What are the most effective recruitment, retention, and screening strategies?
4. Are the monitors (CGMS and activity) and self-efficacy instrument (SEBS) reliable in this study population?

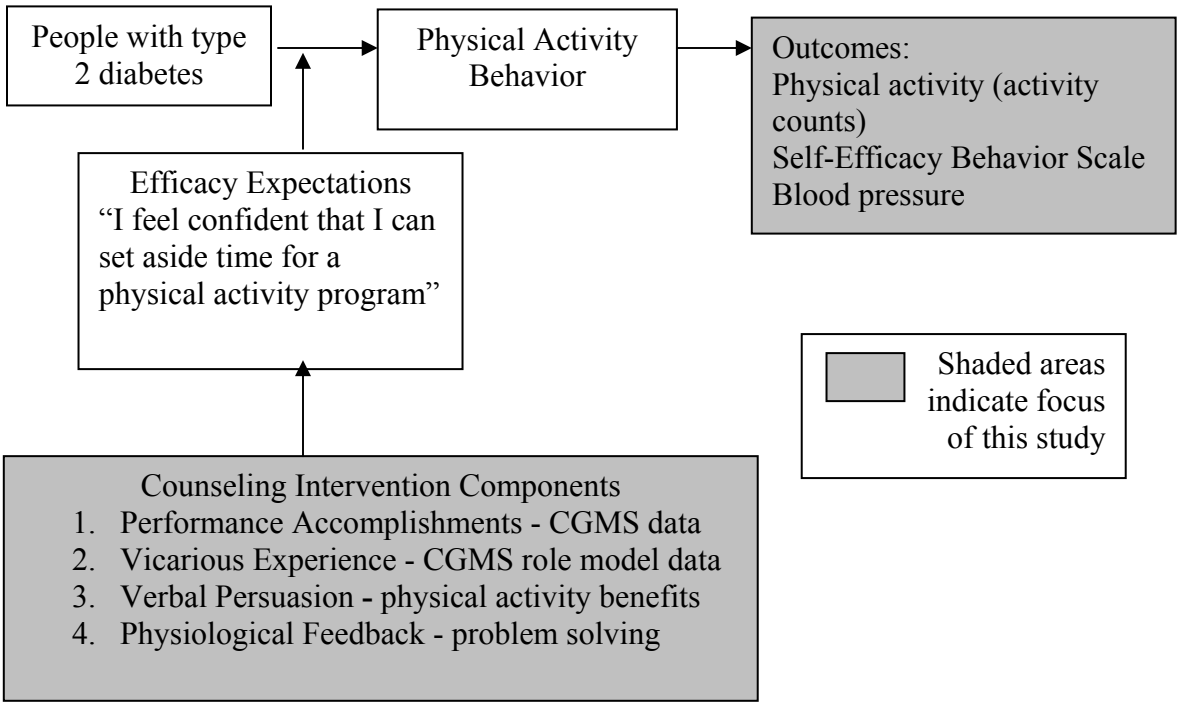
Research Hypotheses

1. Participants receiving the CGMS counseling intervention will have higher self-efficacy, lower BP, and higher activity counts than those receiving standard type 2 diabetes education.
2. Higher self-efficacy scores will be associated with higher activity counts.

Theoretical Framework

The theory of self-efficacy (Bandura, 1997), part of Bandura's larger social cognitive theory (Bandura, 1986), will be used to understand physical activity behaviors and to develop behavioral interventions to promote physical activity in people with type 2 diabetes (see Figure 1). According to social cognitive theory, the behavior of an individual, his/her internal personal characteristics such as cognition, affect, biological factors, and the environment are constantly interacting (Bandura, 1986). Two types of expectations influence the cognitive control of behavior: self-efficacy expectations and outcome expectancies. Self-efficacy expectations are an individual's beliefs in his or her capability to perform a task or course of action to achieve a desired outcome, while outcome expectancies are beliefs that a certain consequence will be produced by personal action. Therefore, physical activity behavioral changes are functions of one's expectations about one's ability to perform a certain behavior (e.g., walking) and of the outcome from performing that behavior (e.g., walking improves my diabetes).

Figure 1. Theoretical Framework: Bandura's self-efficacy theory



Self-efficacy beliefs affect human behavior through four major psychological processes: 1) selection process, 2) motivational processes, 3) cognitive processes and 4) affective processes (Bandura, 1986, 1997). These processes explain how self-efficacy affects the ways in which individuals act, motivate themselves, think, and feel.

The selection process encompasses environmental and social influences, whereas any factor that influences a particular behavior can affect the decision to engage in or avoid an activity (Bandura, 1997). People avoid activities and environments they believe exceed their capabilities, but they readily undertake activities and pick social environments they judge themselves capable of handling. For example, individuals with low physical activity self-efficacy may shy away from difficult tasks such as weight lifting in a gym, which they view as threatening. In contrast, people with diabetes and a high sense of physical activity

self-efficacy approach these tasks as challenges to be mastered rather than threats to be avoided.

Individuals motivate themselves by forming beliefs about what they can do, anticipating outcomes, setting goals for themselves, and planning a course of action (Bandura, 1997). Three types of influences affect motivational processes: satisfied and dissatisfied reactions to one's performance, confidence in one's ability to achieve a goal, and readjustment of personal goals based on one's progress. Individuals with a high sense of self-efficacy are more persistent in the face of difficulties, such as finding time to engage in physical activity when facing time constraints, than those with lower levels of self-efficacy (Bandura, 1997). Individuals with high self-efficacy may even intensify their efforts until they succeed, such as trying to find time in early in the morning or late at night to engage in physical activity. In contrast, those with low self-efficacy tend to give up when facing time constraints and other setbacks or failures.

Cognitive processes are regulated by anticipation and perceptions of valued goals that can enhance or weaken physical activity performance (Bandura, 1997). Individuals with high self-efficacy will set greater physical activity goals for themselves and have a stronger sense of commitment to their goals. Such individuals will visualize success scenarios that provide positive guides and support for engaging in physical activity behaviors. In contrast, those with low self-efficacy visualize failure scenarios and think about the things that can go wrong.

Affective processes are regulated by a person's beliefs in his or her ability to control stressors (Bandura, 1997). Individuals with high self-efficacy are less distressed by threats, such as low physical activity stamina, because they believe they can manage them.

Individuals with low self-efficacy are more likely to magnify risks such as experiencing fatigue because of low physical activity stamina. Those with high self-efficacy will manage their environment to make it less threatening to them (e.g., walk in the mall when the weather is cold outside) and cope better with disturbing or defeating thoughts. In contrast, those with low self-efficacy may not manage their environment (e.g., I can't enjoy walking when it's cold outside) and may be unable to cope with disturbing thoughts that may lead to depression.

Bandura's theory not only explains the four processes (selection, motivational, cognitive, and affective) through which self-efficacy influences physical activity behavior, but also how these processes can be developed, strengthened and/or changed. Efficacy beliefs are dynamic, task specific, and learned or developed from four primary sources: performance accomplishments, vicarious experience, verbal persuasion, and physiological information (Bandura, 1997).

Performance accomplishments are derived from mastery of certain tasks through personal experience. Experiences of success in performing physical activity enhance self-efficacy expectations, while failure decreases self-efficacy. Breaking a difficult task into parts that are easy to master can provide opportunities for success, resulting in greater self-efficacy (Baranowski, Perry, & Parcel, 1997). For example, a walking program can be designed for sedentary individuals' to start with short periods of walking and to progress incrementally over longer time intervals, thus likely leading to early success rather than failure. By achieving activity goals, self-efficacy will be strengthened. Alternatively, early physical activity failures result in lower physical activity self-efficacy. Individuals who feel certain of their capabilities (those with high self-efficacy) view failure as due to

situational factors such as poor advice or lack of education (Bandura, 1997). Individuals with low self-efficacy expectations, however, attribute failure to their own incapability. To maintain high self-efficacy in patients undergoing physical activity counseling, therefore, nurses need to convey that improved glucose levels after physical activity result from the individual's own efforts. Goal-setting directs and motivates a desired behavior (Bandura, 1986) and is a useful strategy for increasing performance accomplishments. Goals should be specific and sufficiently challenging, realistic and achievable (Bandura, 1997). Self-efficacy is enhanced through individual goal setting for specific behaviors, such as walking 10 minutes most days of the week, using personal contracts, and receiving feedback regarding achievements (Van de Laar & Van der Bijl, 2002).

Vicarious experience is achieved through seeing capable others serve as examples or models for achieving difficult goals or mastering a particular behavior, such as a engaging in a regular physical activity program. Conversely, seeing others fail despite significant effort can weaken one's self-efficacy. Using role models who are similar to the patient in experiences and characteristics is important (Gonzalez, Goeppinger, & Lorig, 1990; Schunk & Carbonari, 1984). Examples of successful strategies using vicarious experiences are role models in group education (Gonzalez et al., 1990) and in videos (Gist, Schwoerer, & Rosen, 1989; Gortner & Jenkins, 1990), self-modeling (viewing a video of yourself performing the intended behavior) (Dowrick, 1983), role playing (Grey et al., 1998), or demonstrations of desired behaviors (Oetker-Black, Teeters, Cukr, & Rininger, 1997).

Verbal persuasion from strong verbal encouragement regarding the benefits physical activity strengthens beliefs that one possesses the capabilities to achieve a

particular goal (Bandura, 1997). Instructions, suggestions, and advice are forms of verbal persuasion, as well as positive feedback regarding progress towards physical activity goals. Telling people that their ability was gained by hard work produces a lower sense of self-efficacy than telling them that their progress indicates their capability without reference to the effort they had to exert (Schunk, 1983, 1984). Conversely, devaluative feedback undermines people's belief in their abilities. Given the same level of performance, negative criticism lowers perceived efficacy and aspirations, but constructive criticism sustains aspirations and increases self-efficacy (Baron, 1988). Verbal persuasion is effective if individuals believe themselves capable of carrying out a particular task and serves to encourage perseverance (Bandura, 1997)

Physiological information or self-appraisal of an individual's bodily response to a behavior can influence one's confidence to perform physical activity (Bandura, 1997). Individuals who have experienced pain or fatigue when performing physical activity in the past will use this information to judge their own capabilities and may perceive that they have a personal deficiency. Conversely, those perceiving more energy and a sense of well-being from physical activity will attribute this to personal success. Because physical reactions to a behavior, e.g., fatigue or muscle aches, can be perceived as indicators of personal ineffectiveness (Van de Laar & Van der Bijl, 2002), it is important to change such interpretations by providing new insights. Before initiating a physical activity program, nurses can offer patients realistic expectations of physiological changes and ways to solve anticipated negative effects, thus strengthening self-efficacy (Allen, 1996). Self-efficacy can also be improved by giving feedback related to the positive physiological effects of physical activity at intervals throughout activity programs (Bandura, 1997).

These four influences on self-efficacy expectations have different predictive strengths for changing behaviors (Bandura, 1997). The most predictive is having had the experience of completing a task (performance accomplishment), such as a walking. An individual's self-efficacy will be strongly influenced by his/her past success or failure with a task. Vicarious experience (e.g., role modeling) is not as strong a predictor as actually experiencing a task, but is still an important predictor. Verbal persuasion is a weaker source of self-efficacy information and physiological information is the least predictive.

The most effective way to change patient behavior may be to use a combination of information sources (Bandura, 1997; Maddux & Lewis, 1995). Two relevant studies will be used to highlight the use of multiple information sources in related populations. In the first study, Allen (Allen, 1996) conducted a trial to evaluate the effectiveness of a nurse-directed educational program, based on social cognitive theory (Bandura, 1986), to reduce coronary artery risk factors in 138 women undergoing coronary artery bypass surgery (CABS). Table 1 describes Allen's self-efficacy enhancing intervention based on information sources theorized to strengthen self-efficacy. Beginning two weeks after discharge, the intervention group (n=59) received the behavioral program at home with regular follow-up, while the control group (n=57) received routine care. Risk factors and lifestyle changes were measured one year after surgery.

The mean percent of dietary calories from fat was significantly lowered in the intervention group compared to controls ($p= 0.008$). The prevalence of smoking decreased from 24% at baseline to 8% ($p= 0.007$) in the intervention group and 19% to 14% in the routine care group. Measures of exercise were not statistically significant between the two groups, but both groups reported improvement in exercise, with slightly higher exercise

levels in the intervention group. Since the intervention was directed at a series of diabetes-related behaviors, it is unknown how much emphasis was placed on exercise behavior during the educational program.

Table 1.

Self-Efficacy Enhancing Intervention (Allen, 1996)

Components of Self-Efficacy	Related Special Intervention Strategies
Performance accomplishments	Set small individualized goals with the patient in a series of behaviors that can be consecutively mastered so she experiences success. Rehearse desired behaviors with the nurse. Have patient keep a log of activities and diet to promote self-reinforcement.
Verbal persuasion	Provide strong verbal encouragement of relative progress. Attribute accomplishments to patient's own abilities. Utilize an experienced intervention nurse who is a highly credible source. Incorporate significant others into the intervention to increase their support and reinforcement of behaviors.
Physiological arousal	Help interpret symptoms accurately and promote relaxation training to decrease anxiety and feelings of physical inefficacy
Vicarious experience	Draw attention to relative progress of other female CABS patients of similar age through female model in videotape.
Cognitive appraisal	Provide counseling sessions to help patient process information, solve problems, and generalize self-efficacy.

In another study, Resnick (1998) used three information sources to design an intervention: role modeling (vicarious experience), verbal persuasion, and physiological feedback. She tested the effectiveness of these sources of information in an experimental pretest-posttest study of 77 older adults admitted to a rehabilitation program following an orthopedic event. The role modeling intervention consisted of videotape, which showed an

individual successfully progressing through rehabilitation. Verbal encouragement involved goal setting and reinforcement. Lastly, physiological feedback focused on techniques to help patients cope with identified problems. The treatment group had stronger efficacy beliefs related to rehabilitation participation ($p= 0.012$) and higher participation scores at discharge ($p=.010$), with lower pain ($p= 0.001$) scores than the control group. Resnick's intervention study used Bandura's hypothesized strategies to enhance self-efficacy and demonstrated that participation in a rehabilitation program promoted a commitment to continue further rehabilitation work. Resnick's study is unique in that the self-efficacy construct was pursued to its logical conclusion: Will an intervention that enhances self-efficacy contribute to an increase in self-efficacy and outcome behavior(s)? A nursing educational program that enhances physical activity self-efficacy in individuals with diabetes has not been reported.

Summary of Important Self-efficacy Concepts

Behavioral change depends on one's perceived capacity to act (e.g., start a physical activity program) to meet situational demands such as diabetes self-management. Beliefs about self-efficacy affect one's intention to change a behavior, the amount of effort expended to attain this goal, and the persistence to continue despite barriers and setbacks that may affect motivation. Individuals who believe in their abilities (high self-efficacy) to make behavioral changes are more likely to do so and feel more committed to taking action. Determinants of success in high-risk situations include beliefs in one's ability to take successful actions and in one's skills to regain control should a setback occur. Self-efficacy beliefs can be influenced through information sources such as performing physical activity, role models, verbal persuasion, and physiological self-appraisal.

Significance to Nursing

The importance of this study stems from the increasing prevalence of inactivity and diabetes in the U.S. and nursing's role in motivating individuals with diabetes to change lifestyle behaviors. Secondly, there is a critical need for nurse-directed physical activity interventions that are effective in practice and reduce metabolic and cardiovascular risks associated with diabetes. Finally, there is a need to test the effectiveness of behavioral theories to contribute to the science of nursing.

CHAPTER II

REVIEW OF LITERATURE

Introduction

The following literature review provides an overview of type 2 diabetes and explores the benefits of exercise/physical activity, uses of continuous glucose monitoring system (CGMS) technology, and issues in measuring physical activity in people with type 2 diabetes. A synopsis of the importance of self-efficacy in predicting lifestyle changes and physical activity changes will be described. Finally, a review of physical activity interventions using behavioral strategies in people with type 2 diabetes will be presented.

Overview of Type 2 Diabetes

Type 2 diabetes is a chronic health condition with high human costs in terms of quality of life (Glasgow et al., 1999) and total costs (direct and indirect) of $132 billion in the U.S. (ADA, 2006). Diabetes is most prevalent among individuals $\geq$ 40 years and disproportionately affects minorities (non-Hispanic blacks and Hispanic/Latino Americans 1.7-1.8 times more than non-Hispanic whites), but overall affects women and men similarly (ADA, 2006). Individuals with type 2 diabetes are at increased risk for heart disease and stroke, and macrovascular complications are responsible for 65% of diabetes-related deaths (ADA, 2006). Diabetes is also the leading cause of blindness, end-stage renal disease and nontraumatic lower-limb amputations (ADA, 2006). About 73% of adults with diabetes have high BP, requiring treatment with prescription medications (CDC, 2006). Not surprisingly, individuals with type 2 diabetes describe diabetes management as difficult and complex.(Ary et al., 1986; Clark, 1997; Glasgow, Hampson et al., 1997; Skelly et al., 1995). Reduction or prevention of diabetes complications requires individuals

to keep blood glucose levels as close as possible to the normal range through diet, physical activity, diabetes medications, and blood glucose monitoring (United Kingdom Prospective Diabetes Study Group [UKPDS], 1998).

Benefits of Exercise/Physical Activity for Individuals with Type 2 Diabetes

Psychological and Physiological Benefits

Exercise is an important cornerstone of diabetes therapy and has many psychological and physiological benefits. Exercise reduces anxiety and has an anti-depressive effect in patients with psychiatric disorders and individuals without a history of psychiatric illness (Tziporah Cohen & Jacobson, 2001). Moreover, participation in exercise by those with diabetes has been shown to be predictive of enhanced quality of life (Glasgow, Ruggiero, Eakin, Dryfoos, & Chobanian, 1997).

A single bout of exercise can markedly increase rates of glucose disposal (Devlin, Hirshman, Horton, & Horton, 1987; Giacca, Groenewoud, Tsui, McClean, & Zinman, 1998; Larsen, Dela, Kjaer, & Galbo, 1997; Rogers et al., 1988) and insulin sensitivity (Braun, Zimmermann, & Kretchmer, 1995; Devlin et al., 1987; Rogers et al., 1988; Tanner et al., 2002). These effects, which can last up to 16 hours (Borghouts & Keizer, 2000; Devlin et al., 1987; Goodyear & Kahn, 1998), are beneficial to BP, (Leon, Myers, & Connett, 1997; Pescatello et al., 1999; Taylor-Tolbert et al., 2000), metabolic control (Larsen et al., 1997), and maintenance of glucose homeostasis (Larsen et al., 1997). Exercise training has been shown to significantly decrease $A1_c$, independent of weight loss (Boule, Haddad, Kenny, Wells, & Sigal, 2001). Additional benefits of exercise include reduction of hyperlipidemia (Prabhakaran, Dowling, Branch, Swain, & Leutholtz, 1999; Stefanick et al., 1998) and cardiac risk factors (Dorn et al., 1999; Folsom et al., 1997;

Hakim et al., 1999; Leon et al., 1997; Manson et al., 1999; Rosengren & Wilhelmsen, 1997; Sherman, D'Agostino, Silbershatz, & Kannel, 1999).

Benefits of Moderate Intensity Physical Activity

The majority of sedentary people with type 2 diabetes can safely benefit from a moderate-intensity physical activity program defined as 40-60% of an individual's maximum oxygen uptake (Albright et al., 2000). Studies have demonstrated that moderate-intensity activities, e.g., brisk walking, are also associated with reduced risk of coronary heart disease (Hakim et al., 1999; Manson et al., 1999), stroke (Hu et al., 2000; Lee, Hennekens, Berger, Buring, & Manson, 1999; Lee & Paffenbarger, 1998), and type 2 diabetes (Diabetes Prevention Program Research Group, 2002), primarily due to beneficial effects on body weight, BP, serum cholesterol, and glucose tolerance. Modest increments in physical fitness, which can reduce the risk of overall mortality twofold (Myers et al., 2002), can be more easily incorporated into the daily routine of all individuals, regardless of income or race (Schneider & Shindler, 2001; United States Surgeon General, 1996).

Challenges of Increasing Physical Activity

A major problem in diabetes therapy is how to increase participation in physical activity. Despite the known cardiac- and diabetes-related benefits of physical activity, up to 60% of people with diabetes do not participate in regular physical activity (Nelson, Reiber, & Boyko, 2002; Plotnikoff et al., 2000; Wood, 2002). Effective interventions are needed to counsel people with type 2 diabetes on ways to integrate physical activity into their lives.

Continuous Glucose Monitoring System (CGMS) Technology

What is the Minimed CGMS?

CGMS allows clinicians to continuously monitor a patient's glucose levels for 72 hours. The Minimed CGMS (Medtronic, Minneapolis, Minnesota) uses a glucose oxidase-based sensor inserted in subcutaneous tissue to measure glucose in the extracellular fluid; tissue glucose levels are then calibrated by an external monitor against corresponding blood glucose levels (Gross et al., 2000; Mastrototaro, 2000). Signals from the subcutaneous sensor are sent every 10 seconds to a glucose monitor, where they are averaged and stored every 5 min. The monitor calibrates the sensor readings against self-monitoring of blood glucose (SMBG) by the wearer a minimum of four times per day. The CGMS software produces a color graph of glucose values marked with meals, physical activity, and other events (e.g., hypoglycemia), visually showing the interaction between the different parameters (see Preliminary Study) and a summary table of glucose excursions above and below specified ranges.

CGMS Technical Information

Glucose values obtained with the CGMS have been correlated with laboratory measurements of plasma glucose concentrations (Rebrin, 1999) and home glucose values (Gross et al., 2000). A post-marketing surveillance study from eight clinical sites compared the results of 135 patients' sensor readings to 2,477 meter readings and reported a strong correlation (0.91), with an absolute difference of 18% (Gross et al., 2000). A recent small (N=11) study reported technical problems in 18% of CGMS software data (Metzger, Leibowitz, Wainstein, Glaser, & Raz, 2002). Newer software has improved the accuracy

and reproducibility of data downloads and agreement between sensor and meter values (Shin, Dangui, Danderian, Gross, & Mastrototaro, 2002).

Among individuals wearing the CGMS sensor, 1.8% may be expected to experience mild irritation at the sensor insertion site, resolving after sensor removal (Gross et al., 2000; Mastrototaro, 2000). Infection was not identified as a risk in any of the reviewed studies (Bode, 1999; Boland et al., 2001; Buhling et al., 2004; CDC, 1999; Chico, Vidal-Rios, Subira, & Novials, 2003; Food and Drug Administration, 1999; Gross et al., 2000; Jungheim et al., 2001; Kaufman et al., 2001), but is a potential risk due to skin penetration. Only one study reported a lack of calibration between SMBG results and CGMS data, resulting in 9.1% of the data being unusable (Gross et al., 2000). In a study of 70 adults using CGMS, six sensor readings produced an "error" message, five participants reported an alarm due to a major discrepancy between SMBG and CGMS glucose values, and optimal accuracy criteria were not met on one study day in an unreported number or participants (Chico et al., 2003). The CGMS software (version 1.7a instead of 3.0b) and sensors used were outdated. The lack of current technical information about CGMS-related problems during physical activity supports a feasibility study to determine and report any of these issues.

Uses of CGMS

The CGMS has most frequently been used to adjust insulin levels in people with type 1 diabetes (Bode, 1999; Kaufman et al., 2001). Two studies examined the types of clinical recommendations based on CGMS data versus SMBG data alone in adults and children with type 1 diabetes. The majority of recommendations in both studies involved insulin adjustments and behavioral changes related to using insulin (Bode, 1999; Kaufman

et al., 2001). Although it has been suggested (Kruger & Marcus, 2000), no studies to date have examined the role of CGMS in type 2 diabetes patient counseling or psychological motivation. Empirical data are needed on the effectiveness of using CGMS in adults with type 2 diabetes and the feasibility of using it in a counseling intervention to improve behavioral and health outcomes.

Measuring Physical Activity

What is the Activity Monitor?

Self-report questionnaires, diaries and logs are typically used to quantify physical activity in diabetes research. These subjective measures are limited by recall bias (Ainsworth, Sternfeld, Slattery, Daguise, & Zahm, 1998; Sallis & Saelens, 2000); different interpretations, e.g., light, moderate, vigorous exercise (Wilcox et al., 2001); floor effects, the lowest score available is too high for some respondents, (Tudor-Locke & Myers, 2001); and may lack sensitivity to walking and other ambulatory activities (Ainsworth, Leon, Richardson, Jacobs, & Paffenbarger, 1993; Kriska et al., 1990). Objective measures of physical activity, such as activity monitors, detect movement and electronically record activity counts, a product of movement frequency and intensity, within an interval of time (e.g., over one minute). Activity monitors have been widely used in exercise/physical activity research involving adults and children (Belza et al., 2001; Matthews, Ainsworth, Thompson, & Bassett, 2002; McDermott et al., 2002; Melanson & Freedson, 1996; Schmidt, Feedson, &Chasan-Taber, 2003; Trost, 2001). In laboratory and field-based calibration studies, activity counts were significantly correlated with energy expenditure (r=0.66-0.82), oxygen consumption (r=0.77-0.89), heart rate (r=0.66-0.80), and treadmill speed (r=0.82-0.92) (Melanson & Freedson, 1995).

Uses of Activity Monitors in Diabetes Research

Using activity monitors to measure physical activity levels provides objective data (activity counts) from physical activity interventions, allowing comparison of results among studies. However, only four studies could be found using activity monitors in diabetes research (Keyserling et al., 2002; Kirk et al., 2001; Kirk, Mutrie, MacIntyre, & Fisher, 2003; Paschali, Goodrick, Kalantzi-Azizi, Papadatou, & Balasubramanyam, 2005). Kirk et al. evaluated the effectiveness of an exercise consultation to promote physical activity in people with type 2 diabetes (N=26) (Kirk et al., 2001). A significant difference in activity counts was found between participants receiving a physical activity consultation and the control group, but no significant difference in physical activity was found in a self-report measure. In a larger study (N=70), both activity counts and self-reported measure showed a significant increase in physical activity following a physical activity counseling intervention (Kirk et al., 2003). In another clinical trial, 200 African American women with type 2 diabetes wore an activity monitor for a week at baseline, six months and 12 months after three treatment conditions: clinic and community, clinic only, or minimal intervention (Keyserling et al., 2002). Significant differences in energy expenditure (calculated from activity counts) were reported between the three treatment conditions. In a small study (N=29) of individuals with type 2 diabetes, intervention group participants received accelerometer feedback and behavioral counseling while control group participants received counseling and feedback from exercise diaries (Paschali et al., 2005). The accelerometer feedback group showed an increase in activity counts from baseline to three months, but no conclusions could be drawn due to the small sample size (Paschali et

al., 2005). These studies support the use of activity monitors in measuring physical activity in individuals with type 2 diabetes.

Diabetes-Related Lifestyle Changes and Self-efficacy Theory

Changing Lifestyle Behaviors

Research has suggested that the two most difficult lifestyle changes to achieve in the majority of people with type 2 diabetes involve diet and physical activity (Ary et al., 1986; Glasgow, Hampson et al., 1997) and that education alone is ineffective at changing these behaviors (Brown, 1988, 1990; Padgett, Mumford, Hynes, & Carter, 1988). However, behavioral strategies derived from social learning theories (including SCT) have been shown to improve diabetes knowledge and self-report of behaviors such as diet, physical activity, glucose testing, and medication adherence (Brown, 1988, 1990; Padgett et al., 1988; Whittemore, 2000). Specifically, the most effective strategies, when coupled with education about diabetes, were goal setting, self-monitoring, self-reward, personal feedback, and contracting (Clement, 1995; Glasgow & Osteen, 1992; Norris et al., 2001). Based on this research, the current standard of care for diabetes education includes a combination of educational and behavioral strategies (Mensing et al., 2000). Nurse educators have a primary role in providing diabetes education, diabetes self-management training, and behavioral change support to patients (Norris et al., 2001). Nurse researchers need to develop and evaluate innovative programs that deliver these components of diabetes care.

Importance of Self-efficacy Theory for Diabetes Lifestyle Changes

In the last 17 years, evidence has amassed about the importance of self-efficacy, part of Bandura's SCT (Bandura, 1986), in explaining diabetes lifestyle changes such as

physical activity (Glasgow et al., 1989; Kavanagh, Gooley, & Wilson, 1993; Kingery & Glasgow, 1989; Ludlow & Gein, 1995; McCaul, Glasgow, & Schafer, 1987; Padgett, 1991; Plotnikoff et al., 2000; Rubin, Peyrot, & Saudek, 1989; Skelly et al., 1995), metabolic control (Kavanagh et al., 1993; Ludlow & Gein, 1995; Rubin et al., 1989), health-related quality of life (Rose, Fliege, Hildebrandt, Schirop, & Klapp, 2002), coping and problem solving (Anderson et al., 1995), self-care adherence (Kavanagh, Gooley, & Wilson, 1993; Padgett, 1991), diet (Miller, Edwards, Kissling, & Sanville, 2002), insulin management (Hurley & Shea, 1992; Wolffenbuttel, Drossaert, & Visser, 1993), and blood glucose testing (Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul, Glasgow, & Schafer, 1987; Rubin, Peyrot, & Saudek, 1989; Skelly et al., 1995).

A few important studies highlight the use of self-efficacy theory in diabetes. For example, Hurley and Shea (1992) studied insulin management self-efficacy (SE) in adults (N=142) and found a strong relationship ($r = 0.578$, $p<.001$) between self-efficacy and self-care behavior, with SE accounting for a moderate variance in self-care scores ($r^2 =33\%$). These results demonstrated a connection between self-care management and self-efficacy theory and indicate the importance of SE as a variable in diabetes behavioral research.

Subsequent work by Skelly et al. (1995) examined the predictability of self-efficacy for several self-care behaviors (home glucose testing, medication/insulin administration, diet, and exercise) in 118 inner-city African American women with type 2 diabetes. Self-efficacy beliefs predicted the greatest adherence to diet ($r = 0.215$, $p< 0.05$) and to exercise behavior ($r = 0.417$, $p< 0.05$). Of all the self-care behaviors, SE beliefs accounted for the largest and most significant reported variance in exercise ($r^2 = 53\%$).

Self-efficacy Theory and Exercise/Physical Activity

Exercise Behavior in People with Diabetes

A critical examination of the diabetes research using self-efficacy theory was conducted to determine the predictive ability of this theory in explaining exercise behavior and to identify key interventions that enhance exercise initiation and maintenance. The data were synthesized to answer two questions: 1) Are self-efficacy beliefs related to exercise adherence? and 2) Can self-efficacy theory predict exercise initiation and maintenance?

Predictive Ability of Self-efficacy Theory for Exercise Adherence

To answer the first question, the relationship between self-efficacy theory and exercise in individuals with diabetes was analyzed. Ten studies reported a significant relationship between self-efficacy and exercise. In nine studies using a predictive design, the variance explaining SE for exercise behavior ranged from 15%-53%, with one outlier of 4.4%. Two studies defined adherence as following a specific exercise regimen, and both reported that SE predicted adherence (Kavanagh et al., 1993; Padgett, 1991). Eleven studies defined adherence as self-report of self-care activities and/or exercise level (Boykin, 1996; Crabtree, 1986; Glasgow et al., 1992; Glasgow et al., 1989; Kingery & Glasgow, 1989; Ludlow & Gein, 1995; McCaul et al., 1987; Plotnikoff et al., 2000; Rubin et al., 1989; Sadur et al., 1999; Skelly et al., 1995). In seven predictive studies using the self-report definition, SE also predicted adherence (Boykin, 1996; Crabtree, 1986; Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul et al., 1987; Plotnikoff et al., 2000; Skelly et al., 1995). Five studies examined outcome expectancies with mixed results (Boykin, 1996; Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul et al., 1987;

Skelly et al., 1995). Three studies reported that outcome expectancies significantly predicted adherence (Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul et al., 1987), while the remaining two studies did not find evidence of this relationship (Boykin, 1996; Skelly et al., 1995). Of the two studies reporting an insignificant relationship between outcome expectancies and exercise, one reported a low instrument reliability (alpha = 0.50) (Skelly et al., 1995), while the other had a strong instrument reliability (alpha = 0.85) (Boykin, 1996), making it difficult to draw conclusions from this finding.

Predictive Ability of Self-efficacy for Exercise Initiation and Maintenance

The second question, does self-efficacy theory predict exercise initiation and maintenance, was addressed by examining the studies that reported self-efficacy measurements over time. Seven studies examined the predictability of SE over time. Of these, five had correlational predictive designs (Kavanagh et al., 1993; Kingery & Glasgow, 1989; McCaul et al., 1987; Plotnikoff et al., 2000; Skelly et al., 1995), and three were intervention studies (Glasgow et al., 1992; Rubin et al., 1989; Sadur et al., 1999). Of the correlational predictive studies, one examined SE at baseline and two months (Kavanagh et al., 1993), one examined SE at baseline and four months (Skelly et al., 1995), while three studies examined SE at baseline and six months (Kingery & Glasgow, 1989; McCaul et al., 1987; Plotnikoff et al., 2000). Pretest SE significantly predicted adherence to exercise at six months (R^2= 0.54) (Kavanagh et al., 1993). Of several behavioral processes examined, only SE predicted energy expenditure at baseline and six months (Plotnikoff et al., 2000). Self-efficacy significantly predicted exercise self-care practices of 118 African American women at baseline (R^2= 0.417) and four months (R^2= 0.185) (Skelly et al., 1995). The difference in predictability of SE and exercise from

baseline to four months suggests some instability of this relationship over time. Conversely, a more stable relationship was reported over time (baseline R^2 = .20; six-month R^2 =.22) in a population that was mostly Caucasian (Kingery & Glasgow, 1989). Differing from the four studies reviewed above, one study reported a lack of significant self-efficacy predictability for concurrent exercise and a comparatively smaller amount of variance accounted for at six months (R^2 = .044) (McCaul et al., 1987). Findings from the five correlational predictive studies suggest that SE is related to the initiation and maintenance of exercise, although the strength of this relationship may vary over time.

Three intervention studies examined exercise self-efficacy and exercise over time (Glasgow et al., 1992; Rubin et al., 1989; Sadur et al., 1999). In a study of exercise SE at pretest, posttest, and six months following a five-day outpatient education program, self-efficacy and amount of exercise significantly increased at all measured intervals (Rubin et al., 1989). In a second study, a 10-session, self-management training intervention did not significantly increase SE up to six months after the intervention (Glasgow et al., 1992), and the amount and frequency of exercise significantly increased in a mixed pattern. Both the control and intervention groups had exercised 3.7 and 4.4 days, respectively, prior to the intervention and reported high pre-intervention SE. Only the intervention group significantly increased its average exercise from a mean of 36.3 minutes/day (SD= 5.2) to 50.8 minutes/day (SD= 4.7) and energy expenditure (pretest M=3099.6, SD= 762.2; posttest M=4227.8, SD= 895.5). The control group, however, significantly increased the mean number of days exercised from 3.7 to 4.6. The insignificant SE findings in this study are most likely related to a ceiling effect from the high pretest scores. Finally, no significant increase in SE or minutes of exercise per week was found following a

multidisciplinary intervention in a randomized controlled trial (Sadur et al., 1999). Only one item in the SE instrument was related to exercise, and the exercise content and instruction of the intervention were unclear. The three intervention studies used strategies from self-efficacy theory, including goal setting and problem solving, but with mixed results.

Summary

This review found 13 studies that examined the relationship between self-efficacy and exercise. Of these studies, 12 examined exercise behavior as part of a self-care regimen (e.g., glucose testing, diet, medication adherence, general management) and only one study exclusively examined exercise behavior (Plotnikoff et al., 2000). All 10 correlational studies reported a significant relationship between SE and exercise behavior. Results from the eight predictive studies support the predictability of SE for exercise behavior. The results were mixed regarding the predictive ability of outcome expectancies for exercise behavior. Self-efficacy was predictive of exercise initiation (in 4/5 studies) and maintenance (in 5/5 studies) over time. The three intervention studies provided inconclusive evidence that SE and exercise behavior increased over time. Self-efficacy is task specific and is strengthened through behavioral skill-based strategies (Bandura, 1986, 1997). No studies were found demonstrating effective, behaviorally based physical activity interventions that nurses can use to increase activity levels in people with type 2 diabetes.

Physical Activity Interventions in People with Type 2 Diabetes

Structured versus Unstructured Physical Activity Programs

The majority of studies on the effects of physical activity on diabetes management have used structured exercise programs involving motivated people with diabetes (Boule et

al., 2001) and/or lack sufficient detail to guide clinical application (Walker, Piers, Putt, Jones, & O'Dea, 1999; Yamanouchi et al., 1995). Many individuals with diabetes are not interested in joining formal exercise programs (Searle & Ready, 1991) and long-term adherence for those that do is poor (Ecclestone, Myers, & Paterson, 1998; Hanefeld et al., 1991; Schneider, Khachadurian, Amorosa, Clemow, & Ruderman, 1992). Individuals with type 2 diabetes desire instructions that are individualized to their abilities and can be easily integrated into their daily lives (Tudor-Locke, 2002).

The ADA (ADA, 2006) has endorsed the U.S. Surgeon General's (U.S. Surgeon General, 1996) recommendation that all adults accumulate 30 min or more of moderate intensity physical activity on most, if not all days of the week. Physical activity counseling interventions, which have recently emerged as an alternative to structured exercise programs, have demonstrated significant long-term results.

Counseling Intervention Strategies

One pilot study (Tudor-Locke, 2002) and two larger clinical trials (Di Loreto et al., 2003; Kirk et al., 2003) used four information sources theorized to strengthen self-efficacy and specifically aimed to influence physical activity behavior. Kirk et al. (2003) based their exercise consultation on the transtheoretical model and incorporated several strategies theorized to enhance SE (performance accomplishment through goal setting, verbal persuasion using individualized counseling and physiologic information to address relapse prevention). The aim of the counseling intervention was to encourage 70 inactive people with type 2 diabetes to accumulate 30 minutes of moderate physical activity most days. Both the control and intervention groups received a diabetes exercise pamphlet and follow-up phone call one and three months later. The counseling intervention group received 30

minutes of one-on-one exercise discussion and exercise support in both follow-up calls. Activity monitors were used to objectively measure exercise. A significant between-group difference was found for the mean change in activity counts/week at baseline (95% CI 594,501 to 1,723,539) and at six months (-1786,768 to –491,490), with a 28% increase in the intervention group and a 12% decrease in the control group ($p< 0.001$). Significant between-group differences were found for the mean change in systolic BP (24.7 to –2.0 mmHg, $p< 0.05$), but not diastolic BP. These results support using behavioral counseling interventions to change physical activity behavior, the feasibility of using an activity monitor to objectively measure physical activity in individuals with type 2 diabetes, and suggest that diabetes education alone is often ineffective at changing habitual behaviors.

In an Italian study based on several social cognitive theories, a physician-directed counseling intervention promoted the adoption and maintenance of physical activity in individuals with type 2 diabetes (Di Loreto et al., 2003). The control group received standard care, including 30 minutes of general diabetes information and follow-up consultation at three-month intervals over a two-year period. The intervention group received the same standard care, 30 minutes of physical activity counseling and a follow-up phone call 30 days later. After two years, 69% of the participants (n=182) in the intervention group achieved the target exercise level (27.1 ± 2.0 METs x h/week), but only 18% of the control group (n=158) met the goal (4.1 ± 0.8 METs x h/week; $p< 0.001$). In this study, the counseling intervention was described in sufficient detail for replication and included SE-enhancing strategies of performance accomplishment (goal setting, using incremental steps to enhance success, feedback in the form of telephone calls, diaries, and quarterly physician appointments), vicarious experience (physically fit physicians, and

social support from family/friends), verbal persuasion (individualized counseling sessions), and physiological feedback (problem solving).

Role modeling was provided by a credible source, physically fit and active physicians, who explained the benefits of exercise. This form of role modeling may limit other health care professionals from achieving similar positive results. These study results are promising, but may be difficult to replicate in the U.S. health care system with most physicians limited to 10-20 min. appointments. Diabetes nurse educators have a primary role in providing diabetes education, diabetes self-management training, and behavioral change support to patients (Norris et al., 2001). The current U.S. standard of care for diabetes patients (nurse practitioner/physician visits every three months) supports the feasibility of providing ongoing support once a physical activity counseling plan has been developed by patients and nurse educators.

A pilot study tested a daily physical activity intervention using a pedometer to monitor and motivate individuals with type 2 diabetes (N=9) (Tudor-Locke, 2002). The intervention, derived from SCT, included an orientation/educational session (verbal persuasion), four facilitated group experiences over a one-month period (performance accomplishment and vicarious experience), group discussion to plan strategies (problem solving for negative and positive physiological feedback), and individual goal-setting for the upcoming week (performance accomplishment). The facilitated group experiences included individual progress reports and progressively longer group walks; 10 min the first night, 20 min the second night, and 30 min the last two sessions (performance accomplishment). Pedometers were worn daily and activity output (steps taken) was recorded in a diary. Continued individual practice was supported with minimal

professional telephone contact over a one-month follow-up period (performance accomplishment). Physical activity was assessed at baseline, one month (T1), 2 months (T2) and 4 months (T3). Results revealed a significant increase in time spent walking from baseline to T1 (Δ=34.3 min/day), to T2 (Δ= 23.6 min/day) and to T3 (Δ=22.6 min/day). Resting systolic BP decreased significantly from baseline (139.3 $\pm$ 15.7) to T3 (128.8 $\pm$ 10.3, $F=4.995$, $p<0.05$). These results provide preliminary support for using strategies theorized to strengthen SE and feedback to motivate exercise behavior.

Summary

Physical activity studies in diabetes have used several self-efficacy enhancing strategies such as: 1) performance accomplishment (e.g., goal setting (Di Loreto et al., 2003; Kirk et al., 2003; Tudor-Locke, 2002), incremental steps to enhance success (Di Loreto et al., 2003; Tudor-Locke, 2002), individual progress reports, pedometer activity counts, team-led walks (Tudor-Locke, 2002), feedback in the form of telephone calls, quarterly physician follow-up appointments, and diaries (Di Loreto et al., 2003), 2) vicarious experience (e.g., role modeling from physically fit physicians (Di Loreto et al., 2003) or team leader, (Tudor-Locke, 2002) and social support (Di Loreto et al., 2003), 3) verbal persuasion (e.g., individualized education and counseling, group counseling), and 4) physiological feedback (e.g., relapse prevention (Kirk et al., 2003) and problem solving (Di Loreto et al., 2003; Tudor-Locke, 2002). Although these three studies used SE-enhancing strategies and demonstrated significant increases in physical activity and reductions in systolic BP and $A1_c$ (Di Loreto et al., 2003; Kirk et al., 2003; Tudor-Locke, 2002), they have limitations. One study provided insufficient information to allow for replication of the intervention (Kirk et al., 2003), another did not provide a reproducible

physical activity plan, Italian health care system using a 30-min physician-directed counseling intervention (Di Loreto et al., 2003), and the third was a pilot study involving only nine subjects (Tudor-Locke, 2002). Several SE-enhancing strategies were used in each study, but self-efficacy was not measured, thus limiting further theory building.

Gaps in the Literature Relevant to This Study

Physical activity has been shown to significantly lower glucose levels and improve metabolic control in people with diabetes. Many individuals with type 2 diabetes do not engage in regular activity and have difficulty changing this behavior. Studies in this population have shown that self-efficacy is a significant predictor of exercise behavior, and SCT has been successfully used in physical activity counseling interventions to change activity behavior and improve systolic BP and metabolic control. However, no comprehensive physical activity intervention has been shown to increase physical activity-related self-efficacy in this population. Since physical activity behavior is difficult to change, counseling interventions based on self-efficacy strategies aimed at integrating physical activity into the lives of individuals with diabetes are needed to enhance this behavior. No studies have examined the effects of using performance accomplishments in the form of individualized CGMS feedback to provide a picture of the interrelatedness of diet, physical activity, and blood glucose levels (CGMS data), as well as vicarious experiences from peer role models (personal success stories from others with type 2 diabetes that have incorporated physical activity into their lives and their positive CGMS results). The individualized CGMS counseling protocol proposed in this study may provide nurses with an innovative intervention to motivate this population to change physical activity behavior.

Preliminary Study

Study Design

The researcher conducted a descriptive pilot study (4/20/03-7/10/03) 1) to gather CGMS data and open-ended data from individuals with type 2 diabetes, engaged in regular physical activity and not using insulin, and 2) to develop and test instrument-related protocols. Of these nine subjects who wore CGMS and activity monitors, seven participated in a focus group interview to explore the experience of wearing monitors, perceptions of CGMS feedback, and to gather suggestions for using CGMS data to motivate non-active individuals with type 2 diabetes. After institutional IRB approval, participants were recruited from a cardiac rehabilitation program and diabetes clinic. Two eligible patients declined participation due to family illness and discontinuation of cardiac rehabilitation.

Sample

The majority of participants were male (77.8%), white (100%), obese (BMI 32.5±4.2 Kg/m^2) with a mean age of 56 years, and a 4 year history of diabetes (Table 2). The majority of participants (55.4%) had either a college degree or a graduate degree. Few participants had self-reported diabetes related co-morbidities, but the majority had a history of hypertension (100%) and cardiac surgery (55.6%) (Table 3). All participants were non-smokers and only a minority reported a history of smoking (44.4%) (Table 4).

Table 2.

Pilot Study Sample Characteristics (*N=9*)

Demographic	Number (median)	Percent	Mean ± SD
Gender			
Male	7	77.8	
Female	2	22.2	
Race			
White	9	100	
Ethnicity			
Not Hispanic or Latino	9	100	
Marital status			
Married	7	77.8	
Single	2	22.2	
Education			
Graduate Degree	4	44.4	
Partial College Education	4	44.4	
College Degree	1	11.1	
Age (years)	38-67 (58)		56.0 ± 8.5
Diabetes duration (years)	0.5-12 (2)		3.7 ± 3.7
BMI (kg/m^2)	26.2-38.1 (32.8)		32.5 ± 4.2
$A1_c$ (%)	5.4-7.4 (6.4)		6.4 ± .70

Table 3

Self-reported Co-morbidity History (*N*=9)

Co-morbidity	Number	Percent
Diabetes:		
Neuropathy	1	11.1
Autonomic Neuropathy	1	11.1
Nephropathy	1	11.1
Retinopathy	0	0
Cardiovascular:		
Hypertension	9	100
Chest Pain	5	55.6
Cardiac Surgery	5	55.6
Cardiac Procedure (e.g. Stent)	3	37.5
Myocardial Infarction	2	22
Family History of Cardiovascular Disease:		
Family History of Premature Heart Disease (father ≤ 55 yrs, mother ≤ 65 yrs)	2	22.2

Table 4

Smoking Behavior (*N*=9)

Behavior	Number	Percent
Smoking History	4	44.4
Currently Smoking	0	0
Total Time Smoked (years)		
4-44	4	44.4

All participants were engaged in a regular physical activity regimen (Table 5). The most frequently reported types of physical activity were walking (100%) lifting weights (66.7%) and bicycling (66.7%) at a moderate intensity level (100%). Participants engaged in physical activity 2-7 days per week ranging from 30-90 minutes. These baseline assessment data on physical activity supported the walking plan used in the larger study.

Table 5

Participants' Current Physical Activity ($N = 9$)

Current Physical Activity	Number	Percent
Type of Activity		
Treadmill/Walking	9	100
Bicycling	6	66.7
Weights/Universal	6	66.7
Swimming	1	11.1
Aerobics	1	11.1
Rowing	1	11.1
Activity Frequency		
Two days per week	1	11.1
Three days per week	4	44.1
Four days per week	1	11.1
Five days per week	2	22.2
Seven days per week	1	11.1
Activity Duration per Session		
30 min	2	22.2
45 min	1	11.1
60 min	4	44.4
90 min	2	22.2
Activity Intensity		
Moderate	9	100

Medications that could affect glucose levels and CGMS interpretation were assessed (Table 6). All participants were taking long-acting diabetes medications. Therefore, significant glucose level reductions on CGMS graphs following exercise were more likely to result from exercise and not medications. However, 4 participants were taking a sulfonylurea which stimulates the release of insulin from pancreatic beta cells and may decrease glucose levels following physical activity.

Table 6

Diabetes Medications (*N*= 9)

Medication	Number	Percent
Diabetes:		
Metformin	5	55.6
Sulfonylurea	4	44.4
Glitazone	4	44.4

Pilot Study Results

Activity Monitor Results

Activity monitors recorded the magnitude of accelerations during body movement, at a rate of 10 samples per second. These data were summed to produce activity counts at one-minute intervals over a three-day period. Average total activity counts per day were 307,601 (SD= 108,791). Over an average day, categories of measured activity included inactivity (701 cts./day ± 58), light (129 cts./day ± 53), moderate (32 cts./day ± 14), and vigorous activity (3 cts./day ± 7). Issues with activity monitors are presented in Table 7.

Table 7.

Activity Monitor Pilot Study Data

PROBLEM	SOLUTION
Data lost ▪ Incorrect downloading of data (n=1) ▪ Unclear wearing instructions (n=1) ▪ Monitor failure (n=1)	 Two backup computer disks to store data Place arrow on activity monitor indicating correct position Test monitors before study initiation
Pinched skin when bending (n=1)	Patient education
Sweaty and irritating to skin (n=4)	Apply IV 3000 dressing beneath monitor
Instructions were not clear (n=1)	Bold wearing directions and emphasize

CGMS Results

CGMS technology produced usable data for all participants. No sensors or monitors failed. One CGMS graph was missing data (due to missing glucose meter entry in a 12-hr period). This datum was retrieved after entering participant's logged data. Other issues and solutions identified with the CGMS are presented in Table 8.

Table 8.

CGMS Pilot Study Data

PROBLEM	SOLUTION
Wearing proper clothing to attach monitor at night (n=4)	Inform participants of nighttime clothing requirements
Forgetting to enter meals and events (n=3)	Use manual log to provide backup for meals and events
Losing directions (n=1)	Laminate, bind, and attach directions to monitors
Length of monitor cord "too long" (n=2) or "too short" (n=5)	Place sensor more posterior and lateral to optimize cord length
7.6% of data did not meet optimal accuracy criteria due to insufficient SMBG values entered first or last days	Emphasize the minimum requirement of 4 SMBG entries on first and last days

A total of 7,831 CGMS sensor readings yielded an average blood sugar of 133 (±23; range = 40-338) and 122 SMBG entries yielded average blood sugar of 134 (±22; range = 69-274). Overall, participants averaged 8 episodes of hyperglycemia (7 mg/dL above a threshold of 140 mg/dL) lasting an average of 17 min, with an insignificant amount of hypoglycemia recorded (see Table 5). Pilot study design did not allow determination of temporal association between downward trend in glucose levels and prior physical activity (Figure 2). Several variables (meals, specific medications, etc.) were not controlled and may have affected glucose values following physical activity.

Table 9.

CGMS Glucose Data

CGMS Data	Number of High Excur-sions	Number of Low Excur-sions	Duration (min) > 140 mg/dl	Duration (min) 70-140 mg/dL	Duration (min) < 70 mg/dL	Glucose Area>140 (mg/dL* Day)	Glucose Area<70 (mg/dL* Day)
Mean	8	2	17	53	2	7	0.22
Range	2-18	0-8	00:00-49.45	20.15-84.15	00:00-4:25	0-21	0-1
SD	7	3	17	18	2	8	0.44

Focus Group Results

The focus group interview was audio taped, transcribed verbatim, coded and analyzed. The central metaphor that emerged was "a picture is worth a thousand words." In other words, the visual depiction of glucose levels in relation to meals and activity found on the CGMS graphs (Figure 2) was more meaningful than a discussion of these topics. Four themes were identified. First, CGMS feedback makes the need for behavior change real. A 51-year old male with a history of several myocardial infarctions and a body mass index (BMI) of 38 stated,

> "Most people with diabetes don't feel bad and that's the problem with diabetes when [doctors and nurses] tell you [that] you have to change your diet and you have to do all this stuff. And we don't do it. If I had been given this graph a year ago, I would have changed my diet and my exercise."

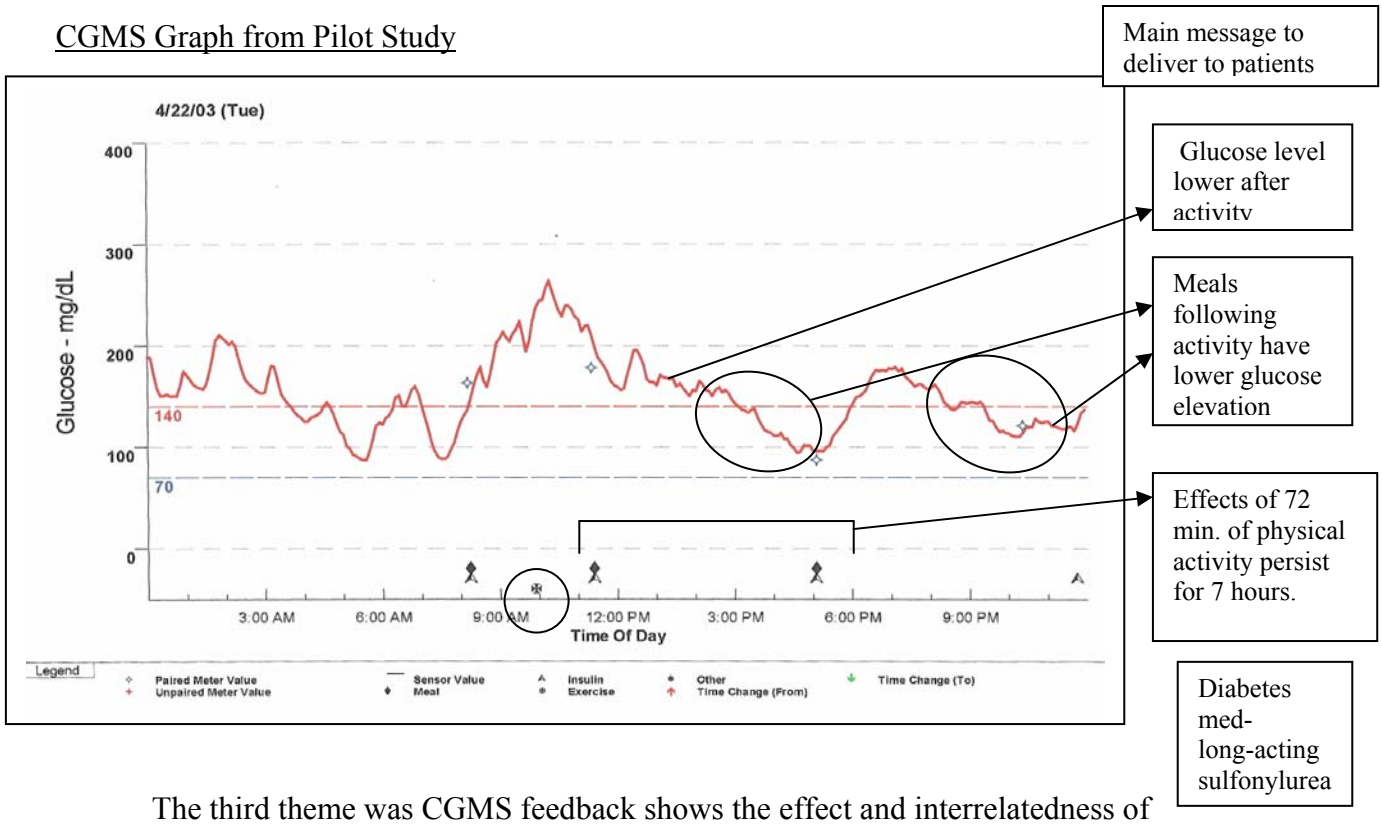
Another identified theme was that CGMS feedback reinforces diet and exercise programs. A 59 year-old male stated,

"after seeing the output [CGMS], I noticed that it [glucose level] went up and it went right back down because that happened to be the day I exercised. So that to me shows that exercise is really effective in maintaining sugars."

Another 51 year-old male stated that "for me it proved that I should continue doing what I'm doing and I can't lay off whether it's the golf or the treadmill or whatever, but continue doing the exercise."

Figure 2.

CGMS Graph from Pilot Study



The third theme was CGMS feedback shows the effect and interrelatedness of exercise, diet, and stress on glucose levels. A 53 year-old female stated, "When you get the numbers back you really see, ok, I gotta cut down on breakfast because too many carbs, but the exercise brought it down! It was really amazing! You got feedback." Lastly, individualized feedback is valuable for behavioral change. A newly diagnosed 57 year-old male stated, "It changed my thoughts because I could actually see it on the graphs how I

was reacting [to diet and exercise] and what was changing inside of me and the benefits [of diet and exercise on blood sugar levels]. I could actually see it on the graphs!" Focus group participants suggested motivating non-active individuals with diabetes by: 1) using CGMS on all newly diagnosed patients 2) having them wear CGMS a second time to see effect of changes, 3) using phone calls to monitor progress, 4) communicate the seriousness of diabetes and the need for exercise, 5) telling patients to "get moving," and, 6) "think seven days of exercise, not five."

Summary

The CGMS and activity monitor technology provided useful data for measuring glucose and physical activity levels. Several technology-related problems and solutions were identified. A central metaphor that emerged from the focus group sessions was "a picture is worth a thousand words. Also, four themes were identified: 1) CGMS feedback makes the need for behavior change real, 2) CGMS feedback reinforces diet and exercise programs, 3) CGMS feedback shows the effect and interrelatedness of exercise, diet, and stress on glucose levels, and 4) individualized feedback is valuable for behavioral change. The pilot study results provided the data necessary for proceeding to a larger, feasibility study.

CHAPTER III

METHODOLOGY

Research Design

This feasibility study employed a randomized clinical trial designed to evaluate the effectiveness of the counseling intervention and the relationship of self-efficacy to study variables. Participants were randomly assigned (1:1) to either an experimental group (CGMS counseling intervention) or a control group (standard diabetes education). The researcher used a study protocol to administer CGMS counseling (see Appendix A), thus ensuring that the same information was provided to all subjects in the intervention group. Based on ADA standards and guidelines (ADA, 2003), the time spent counseling individuals was the same for both groups (90 min), but the control group was not exposed to the CGMS counseling (see Data Collection Procedures, Table 1). Participants were asked to begin a moderate-level physical activity program (i.e., walking 30 min most days of the week (see Appendix A) (Marrero, 2001). The researcher collected data at baseline and eight weeks post-intervention, providing participants the necessary time to safely increase activity levels and frequency (Albright et al., 2000; Ruderman, 2001).

Sample

Because feasibility studies are used to develop and refine a research protocol (Burns & Grove, 2001), the sample size was intentionally small. The convenience sample for this study consisted of 52 adults referred through Baystate and Berkshire Health System providers. Participants were randomly assigned (Hjelm-Karlsson, 1991) to a CGMS counseling (intervention) group (n=27) or to a standard education (control) group (n=25) using a 4 block randomization schedule developed a priori. Most CGMS studies

have not reported participant attrition rates (Boland et al., 2001; Gross & Mastrototaro, 2000; Gross & Ter Veer, 2000; Kaufman et al., 2001), but in Bode's pilot study (N=10) one participant (10% attrition rate) did not return for a second CGMS insertion (Bode, 1999). When subjects declined participation in any phase of the study, the researcher documented comparative demographic information and stated reason for discontinuing study involvement.

Inclusion Criteria

Participants were eligible for participation in this study if they met the following inclusion criteria: (1) males and females over age 18, (2) a medical diagnosis of type 2 diabetes, (3) $A1_c$ >7.5 in previous 6 months, (4) not receiving insulin to manage diabetes, (5) not engaged in a physical activity program more than two days per week, and (6) able to read and speak English. Based on the ADA's clinical recommendations (2003), all participants had a screening history and physical examination (H&P) (see Appendix B) with a resting electrocardiogram (ECG) before initiation of physical activity (ADA, 2003; Schneider & Shindler, 2001).

Exclusion Criteria

Since physical activity variables were assessed, participants reporting an inability to walk 0.25 miles in 10 min were excluded (Diabetes Prevention Program Research Group, 2002). Participants taking glucocorticoids, which could interfere with evaluation of blood glucose levels, were also excluded (Zoorob & Cender, 1998). The researcher documented the number of referred participants excluded, based on screening H&P and inclusion/exclusion criteria.

Setting

The primary setting for the study was Baystate Medical Center in Springfield, Massachusetts. Baystate Medical Center is the largest primary- and tertiary-care organization in western Massachusetts and the third largest acute care hospital in New England. Three outpatient community health centers owned by Baystate serve inner-city residents of Springfield and provide care to patients with a broad spectrum of cultural and economic backgrounds.

The Baystate Diabetes Education team, consisted of five nurses, two dieticians, two behavioral health counselors, and six endocrinologists. This team cared for 1,159 patients in 2001, of which 572 had non-insulin requiring type 2 diabetes (J. Foss, personal communication, October 21, 2002). Patients treated at the Baystate Diabetes Education Center (59% non-Hispanic white, 25% Hispanic, 14% African American, 41% male and 59% female (J. Foss, personal communication, October 21, 2002) reflect more ethnic diversity than the Springfield area population (84% non-Hispanic white, 13% Hispanic, 7% African American, 48% male and 52% female)(United States Census Bureau, 2000).

The Berkshire Health System served as a secondary research site after May 2005. The health system consists of two hospitals, Berkshire Medical Center Pittsfield, Massachusetts and Fairview Hospital, Great Barrington, Massachusetts, a primary care clinic, Hillcrest Family Health Center, several long-term care facilities, and Berkshire Visiting Nurse Association. The Berkshire Diabetes Education team consisted of two nurses and one dietician until January 2005 when an Endocrinologist joined the program. The education team saw 710 individuals with diabetes from October 2004 to September 2005 of which 660 had type 2 diabetes (Candice Luce, personal communication September

7, 2006). Patients treated at Berkshire Diabetes Education Center were mostly Caucasian (98%), with very few Indian, Hispanic, African-American, or Asian patients (<5%) (Candice Luce, personal communication September 7, 2006). These statistics are similar to the Pittsfield, Massachusetts population (Caucasian 92.6%; African-American 3.7%; Asian, Pacific Islander, American Indian < 0.5%) (US Census Bureau, 2000).

Data Collection Procedures

Ethical Considerations and Recruitment

Institutional Review Board (IRB) approval was obtained from the University of Massachusetts, Baystate Medical Center, and Berkshire Medical System before the study was initiated. Participants were recruited from the Baystate and Berkshire Health Systems. Posters were strategically placed in outpatient clinics caring for patients with diabetes. Clinicians and receptionists were given fact sheets for interested patients. A monthly total of referrals were kept and when recruitment numbers fell below five-per month, other recruitment strategies were initiated such as advertisement in churches, public service announcements in newspapers and radio. As the study progressed, the researcher discussed bi-monthly recruitment numbers and expressions of gratitude with staff at research meetings. Participants were asked how they learned about the study and the stated reason was documented (see Appendix C). The researcher discussed the study with prospective participants in person or via telephone. At the initial appointment, subjects agreeing to participate were asked by the researcher to sign an IRB-approved informed consent form (see Appendix D). A document describing the study and participants' involvement was reviewed and given to each prospective subject. Data were collected as outlined in Table 6.

Retention Strategies

Retention strategies included: (1) requesting the names and telephone numbers of each participant, (2) making pre-appointment reminder phone calls, (3) drinks and refreshments at appointments and (3) offering $25 for each participant's time/travel. At the conclusion of the study, each participant was asked to rate the effectiveness of each retention strategy (see Appendix C).

Study Sequence

Table 10.

Study Sequence

Week #	Control Group	Intervention Group
Week 1	Consent, demographics; H&P screening, Self-efficacy Behavior Scale; BP; activity monitor placed	Consent, demographics; H&P screening, Self-Efficacy Behavior Scale; BP; activity monitor & CGMS placed
Week 2	Activity monitor removed ADA curriculum for standard education includes: ❑ Content: diabetes physiology, diet strategies, SMBG, risk reduction, foot care education, physical activity (walking hand out) ❑ Education and behavioral strategies: goal setting, problem solving, log books (total 90 min)	Activity monitor & CGMS removed ❑ ADA curriculum for standard education (see control group) ❑ Nurse-directed CGMS counseling intervention. See Table 4 (total 90 min)
Week 4	Phone call to reinforce counseling	Phone call to reinforce counseling
Week 7	Activity monitor placed	Activity monitor placed
Week 8	Activity monitor removed; BP; Self-efficacy Behavior Scale	Activity monitor removed; BP; Self-efficacy Behavior Scale

Study Variables and Instruments

Nurse-Directed Counseling Intervention Strategy

Using CGMS data, the researcher gave participants individualized information about the effects of physical activity on their blood glucose levels. The CGMS data was only used for the counseling intervention and not as an outcome measure due to low statistical power of this feasibility study. Self-Efficacy Theory (Bandura, 1986, 1997) interventions effective in previous physical activity studies (Di Loreto et al., 2003; Kirk et al., 2003; Tudor-Locke, 2002) and the researcher's preliminary study supported the content of the counseling intervention (see Table 11).

Table 11.

Nurse-Directed Counseling Intervention using CGMS

1. Review CGMS graphs (performance accomplishment and vicarious experience)
   - Use daily visual feedback of glucose values to discuss their relationship to marked events: meals, physical activity, and medications. Together identify periods of low (< 70 mg/dL), normal (70-140 mg/dL) or elevated (>140 mg/dL) glucose levels (performance accomplishment).
   - Identify periods of physical activity (using marked or logged events) and their relationship to glucose values (expect to see lower glucose values immediately following physical activity and subsequent meal) to provide positive feedback (performance accomplishment).
   - Use CGMS graph and story of a successful exerciser with type 2 diabetes similar to participant (e.g., women's stories matched with women participants). After physical activity events, identify lower glucose values, lower baseline glucose levels contrasting to pre-physical activity levels and lower post-prandial glucose levels with faster return to baseline glucose values (vicarious experience).
2. Describe the effect of increased activity on blood glucose values (verbal persuasion)
   - Independent of weight loss, physical activity improves body's use of glucose and sensitivity to insulin, resulting in lower $A1_c$; reduces high BP, high cholesterol, and cardiac risk factors; and can reduce anxiety and depression. People who increase their physical activity often report improved quality of life.
3. Ask participants to rate, on a 1–10 scale (with 10 as the highest), their confidence about increasing their physical activity. Ask why a higher score was not chosen and what it would take to score 9 or 10 (assessment of self-efficacy). Summarize participants' responses.
   - Identify previous types of physical activities and experiences (performance accomplishment).
   - If barriers are presented, ask participant for solutions (physiological feedback/problem solving).
   - Discuss solutions that have worked for others similar to themselves (vicarious experience).
4. Present walking program based on the ADA's recommendations (ADA, 2003) and individualize program with participant (performance accomplishment/goal setting).
   - Discuss ways to increase physical activity throughout day (e.g., stairs vs. elevators). Write physical activity prescription with participant.
5. Discuss normal responses to starting a physical activity program (e.g., initial fatigue, muscle aches) and problem-solve anticipated physical activity-related concerns (physiological feedback). Discuss proper footwear.

The intervention protocol used had five steps: 1) Review CGMS graphs with each participant (performance accomplishment), use examples of CGMS graphs and stories

from role models to show activity-related glucose reductions (vicarious experience) and use participants' CGMS graph to indicate expected areas of activity-related glucose reduction; 2) outline cardiac-, diabetes-, and health-related benefits of physical activity (verbal persuasion) (Ruderman, 2001); 3) assess confidence to change physical activity; 4) review ADA recommendations for physical activity, discuss physical activity goals, write physical activity prescription targeting a moderate-level physical activity program (i.e., walking 30 min, most days of the week (Marrero, 2001) (performance accomplishment); and 5) discuss normal responses to starting physical activity program (physiological feedback).

Intervention Fidelity

Intervention fidelity is defined as the adherent and competent delivery of an intervention by the interventionist as set forth in the research plan (Santacroce, Maccarelli, & Grey, 2004). A research manual was developed and used to control for intervention fidelity. First, a study check list included the order and steps to follow from the first contact with each participant for study screening and at each appointment. This check list included materials, supplies, and objectives needed at each appointment. The next check list included contents for each study packet (intervention or control) and counseling materials for each appointment. Third, the counseling intervention was broken into 14 steps. Next to each intervention step was a line design for placing a check mark at the completion of each step and several places for recording comments (see Appendix A). Lastly, master copies of all materials were kept in the research manual and included IRB approved consent forms, Health Insurance Portability and Accountability Act (HIPPA) authorization for release of information form, H & P form, SEBS, CGMS logs, activity

monitor logs, screening and study recruitment assessment tool, activity monitor and CGMS assessment tool, and session 8 measures form. All educational handouts were kept in the study manual including, International Diabetes Center (IDC) dietary teaching handout, IDC dietary logs, NIH physical activity brochures, and IDC diabetes success plan handouts.

The only interventionist for this study was the researcher. Every attempt was made to consciously follow the outlined intervention counseling procedure. However, a method was not developed for an outside expert to rate the researcher's content, processes, and timing used during participant counseling.

Continuous Glucose Monitor System (CGMS)

The utility of the CGMS technology was assessed (see Appendix E) by determining: 1) the accuracy of participants' CGMS input (meal markers were compared with glucose level elevations, physical activity markers were compared with changes in activity counts, verified required number of SMBG entries on graphs, recorded optimal accuracy criteria as met or not met), 2) complications at sensor insertion site (i.e., skin irritation, infection, pain, discomfort) or sensor failures (i.e., signal value <10 or >200; ISIG values varied randomly), 3) monitor equipment failures (e.g., alarms), and 4) data download failures (e.g., lost data, gaps in graphs). Sensors failing to meet performance criteria, malfunctioning or that became dislodged/disconnected during the study were replaced.

Self-Efficacy Behavior Scale (SEBS)

Self-efficacy in the proposed study was operationally defined as a participant's confidence in his/her ability to change physical activity behavior. The SEBS (see

Appendix F) is a 12-item instrument that was used to measure the participant's confidence in his/her ability to change physical activity behaviors (Sallis, Pinski, Grossman, Patterson, & et al., 1988). The scale consists of two subscales: "Resisting relapse" (five items; e.g., stick to your exercise program when your family is demanding more time from you) and "Making time" for exercise (seven items; e.g., get up earlier to exercise). SEBS is a self-report measure using a Likert-type scale ranging from 1 ("I know I cannot do it") to 5 ("I know I can do it"), with higher scores indicating greater self-efficacy. Internal consistency reliability ranged from 0.83 and 0.85 in a college age population (Sallis et al., 1988), but has been reported to be higher for the total scale (0.91) in a more recent study of middle-aged women engaged in moderate or higher intensity physical activity (Speck & Looney, 2001). Factor test-retest reliabilities were 0.68. Criterion-related validity has been assessed by correlating a self-efficacy factor score with reported physical activity habits; both subscales were significantly correlated with reported participation in vigorous activity ($r=0.32$, $p<0.001$; $r=.40$, $p<0.001$) (Sallis et al., 1988).

Activity Monitor

Physical activity level, defined as a change in a participant's activity counts, was objectively measured using Manufacturing Technologies Incorporated's (MTI) original activity monitor, which measured the amount and intensity of movement. The activity monitor is a small (5.1 x 3.8 x 1.5 cm), unobtrusive monitor that was secured by a strap at the participant's right waist. These activity monitors were programmed to collect activity counts at one-minute intervals for a seven-day period at weeks one and seven, allowing measurement of activity levels before and after the intervention. Information from the activity monitor were downloaded to a computer and imported into an ActiGraph software

program (DOS RIU256K.EXE, software 2.27) for analysis. To limit confounding results, participants were blinded to information from the activity monitor. The utility of the activity monitor was assessed by evaluating: 1) wearing issues (i.e., problems with sweaty skin, pinched skin, irritation to skin, monitor movement), 2) correct usage (i.e., start and end times on paper logs match with activity graphs, presence of inverted data indicating incorrect positioning), 3) data download issues (lost data), and 4) monitor failures (no data produced) (see Appendix E).

Blood Pressure

The researcher followed the American Heart Association guidelines (Perloff et al., 1993) to measure BP. BP at baseline was taken in a lying position after a minimum of 5 minutes as part of orthostatic assessment. BP post intervention was taken after a minimum of 5 min in a sitting position at the approximately the same time of day. The researcher determined BP cuff size using the following criteria: 1) width of the bladder is 40% of the arm circumference and 2) length of the bladder is long enough to encircle at least 80% of the arm (Perloff et al., 1993). Systolic blood pressure was recorded upon hearing the first Korotkoff sound and diastolic pressure was recorded at the last audible Korotkoff sound (Perloff et al., 1993).

Demographic Measures

Age, gender, race, marital status, occupation, spouse's occupation, and number of years diagnosed with diabetes was recorded at the beginning of the study. A widely tested instrument, the Hollingshead Two-Factor Index (Miller et al., 2002), was used to determine socioeconomic status (see Appendix G).

Body mass index (BMI) was obtained by direct measurement to assess and categorize overweight and obesity as recommended by NIH treatment guidelines (NIH, 1998). Weight in kilogram (kg) to the nearest 0.1 kg was measured using the same designated standing scale in each clinic. Participants were asked to wear light indoor clothing and to remove their shoes prior to measurement. Height was measured to the nearest 0.5 cm. BMI was calculated as weight (in kg) divided by height (in m^2).

For descriptive and screening purposes, a history of each participant's co-morbidities, recent $A1_c$ and current medications was obtained (see Appendix B). The demographic data collection form include a modified NIH risk-status assessment (NIH, 1998) with questions regarding cardiovascular risk, smoking history, retinopathy, neuropathy, nephropathy, and current medications (Gordon, 2001).

Data Management

Each participant was assigned a unique study number for identification throughout the study. A record of participants and their identification numbers was maintained separately in a logbook until completion of data collection. Participant identification numbers were written on all data collection forms. The researcher conducted an ongoing accounting of data forms. All data were kept in a locked cabinet at the researcher's offices. The researcher obtained informed consent, demographic data, BP measurements, activity monitor data, and SEBS questionnaires from all participants as outlined in Table 1. After reviewing data for completeness and accuracy, the researcher coded and entered the data into Statistical Package for the Social Sciences (SPSS) System (version 11.0). Data entry was verified by hard copy.

Data Analysis

Statistical analyses were performed using SPSS. Frequencies were obtained on all continuous interval data to check for inaccurate codes, out-of-range data, and extreme values. Frequencies were calculated on a variable-by-variable basis to identify missing data.

Demographic and outcome variables (self-efficacy, BP, activity counts) were described using frequency distributions and appropriate summary statistics for central tendency and variability. The experimental and control groups were compared on all variables using t-test or chi-square to determine group differences.

Question 1: What is the difference between self-efficacy, BP, and activity counts in participants receiving CGMS counseling and those receiving standard type 2 diabetes education?

Changes in self-efficacy, BP, and activity counts between participants in the experimental and control groups were analyzed using t-tests. Participants exposed to the CGMS counseling intervention were expected to have higher self-efficacy, lower BP, and higher activity counts than the control group.

Question 2: Is self-efficacy associated with activity counts, blood pressure and demographic variables?

The relationship between self-efficacy and outcomes of BP and physical activity (activity counts) in all participants with type 2 diabetes was explored using correlation statistics. Change score was calculated by subtracting participant's outcome scores at time 1 from outcome scores at time 2 on continuous variables. The change score for each variable was used in calculating the correlation coefficient. Correlations were used to

explore if: 1) change in self-efficacy was associated with higher activity counts, 2) change in activity counts was associated with decreased BP, and 3) change in self-efficacy was associated with decreased BP. Because of the feasibility nature of this study to identify significant trends, a p value < 0.05 was used to determine the significance of any hypothesized association. It was hypothesized that improvement in self-efficacy would be associated with higher activity counts. An exploratory analysis using *t*-tests was conducted to examine the effects, if any, of gender, age, race and ethnicity, BMI, and marital status.

Question 3: What are the most effective recruitment, retention, and screening strategies?

Recruitment, retention, and screening efforts were addressed by descriptive statistics to analyze data tracking records (see Appendix C). Screening records were analyzed to determine referral patterns from providers (e.g., nurse practitioners, physicians, registered nurses, diabetes educators, medical assistants, receptionist), type of referral (e.g., poster, fact sheet, radio, newspaper, church, word of mouth), and clinic type (e.g., specialty, general practice) as well as clinic location. Retention records were analyzed with descriptive statistics to determine rated efficacy of retention strategies (reminder phone calls, refreshments, reimbursement for time/travel, family/friend support strategies).

Question 4: Are the monitors (CGMS and activity) and self-efficacy instrument (SEBS) reliable in this study population?

The self-efficacy instrument reliability was addressed by calculating the internal consistency (Cronbach's alpha coefficient) of the two SEBS scales. Descriptive statistics were used to analyze activity monitor utility. Parameters addressed included 1) wearing issues (i.e., problems with sweaty skin, pinched skin, irritation to skin, monitor movement), 2) correct usage (i.e., records of start and end times match activity graphs,

presence of inverted data indicating incorrect positioning), 3) data download issues (lost data), and 4) monitor failures (no data produced) (see Appendix E).

Descriptive statistics were used to analyze CGMS monitor issues. Parameters addressed included 1) accuracy of participant's CGMS input (meal markers were compared with glucose level elevations, physical activity event markers were compared with changes in activity counts, required number of SMBG entries on graphs were counted and verified, optimal accuracy criteria documented as met or not met), 2) complications at sensor insertion site (i.e., skin irritation, infection, pain, discomfort) or sensor failures (i.e., signal value <10 or >200; initialization signal values vary randomly, sensor temperature dot clear, not black), 3) monitor equipment failure (e.g., alarms) and, 4) data download failures (e.g., lost data, gaps in graphs) (see Appendix E).

CHAPTER IV

RESULTS

Introduction

This chapter provides an analysis of the study data. The sample data were analyzed to describe participant characteristics and co-morbidities, and to verify the effectiveness of randomization. For each hypothesis appropriate statistical analyses were conducted to evaluate the major study outcomes and to explore theory building. Finally, study findings are presented to confirm effective recruitment, retention and screening strategies and to examine the feasibility of study instruments and procedures.

Sample

Of the 52 subjects who participated in the study, 46 completed the protocol (Figure 3). The majority of participants were white (90.4%) and obese (BMI 35.2 $\pm$ 5.8 Kg/m^2), with a mean age of 57 years, an 8-year history of diabetes (±6.2), and mean $A1_c$ of 8.63% ($\pm$ 5.8). (Table 12). Subjects were classified by the Hollingshead Two-Factor Index of Social Position (Miller et al., 2002) into socioeconomic groups, according to occupation and education. The range of scores in each of five social classes is 11-77 with higher scores indicating higher socioeconomic status. The majority of participants had a high school education and occupation within the Hollingshead category of administrative personnel, owners of small business, and minor professionals (Table 12). After weighting the occupational and educational scores , the majority of participants ranked in the third category (scored 32-37) of socioeconomic class on a scale of I-V (Table 12).

Figure 3

Flow of Participants through the Trial

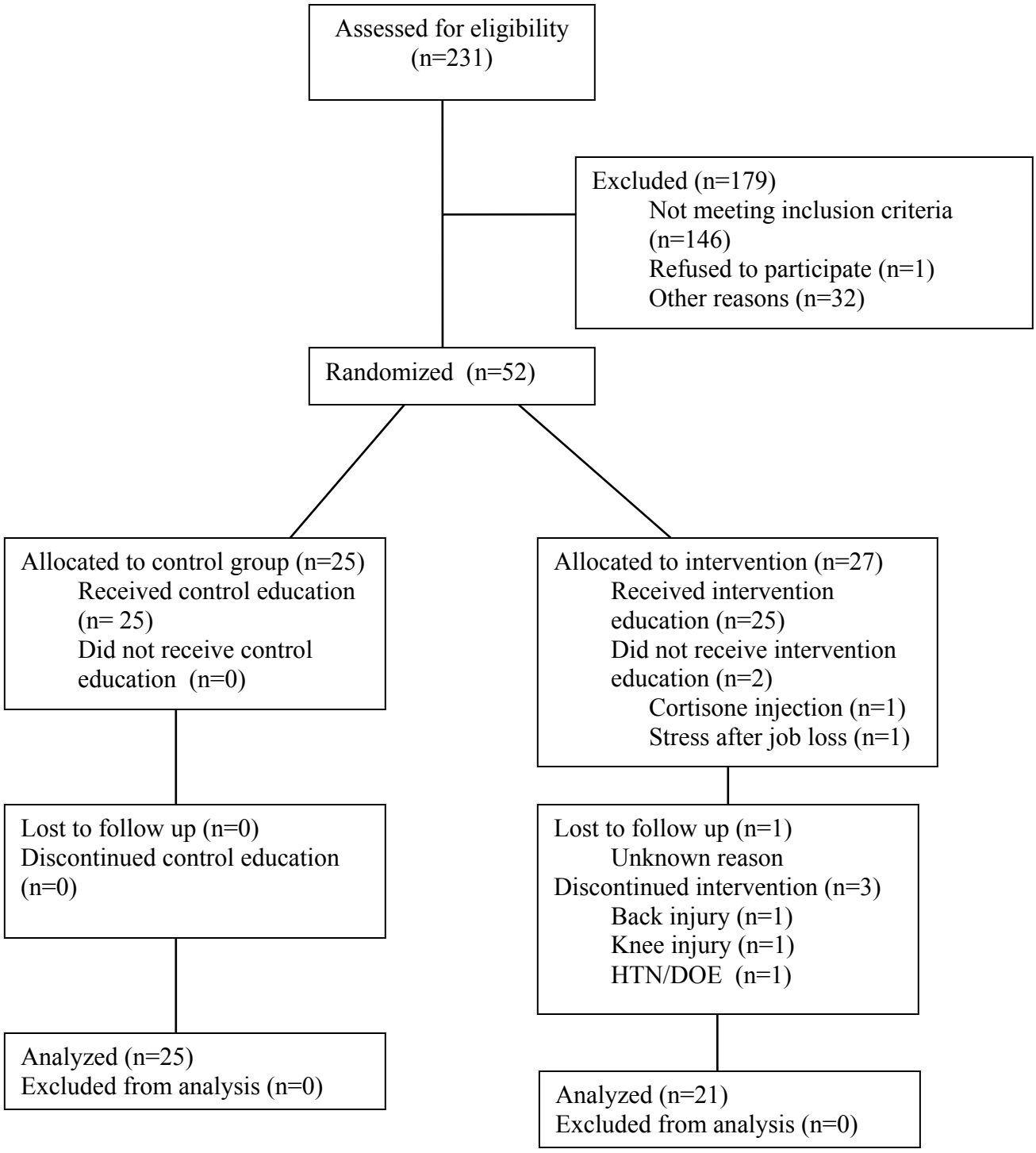


Table 12

Baseline Sample Characteristics ($N = 52$)

Demographic	Number (median)	Percent	Mean ± SD
Gender			
Female	27	51.9	
Male	25	48.1	
Race			
White	47	90.4	
African American	5	9.6	
Ethnicity			
Not Hispanic or Latino	48	7.7	
Hispanic or Latino	4	92.3	
Marital status			
Single	13	25.0	
Married	29	55.8	
Divorced	6	11.5	
Widowed	4	7.7	
SES			
Class I (11-17)	6	11.5	
Class II (18-31)	10	19.2	
Class III (32-47)	18	34.6	
Class IV (48-63)	14	26.9	
Class V (64-77)	4	7.7	
Age (years)	19-81 (60)		57.0 ± 13.5
Diabetes duration (years)	0.5-29 (8)		8.4 ± 6.2
BMI (kg/m^2)	25.1-52.9 (34.3)		35.0 ± 5.9
$A1_c$ (%)	7.6-12.6 (8.4)		8.6 ± 1.2

Although participants in this study reported many co-morbidities (Table 13) and smoking behaviors (Table 14), these conditions did not deter their willingness to volunteer for a physical activity study, but did require consideration when providing physical activity counseling. In particular, many participants had several self-reported cardiovascular risk factors, including a strong family history of heart (71.2%) and cerebral vascular disease (46.2%), hypertension (59.6%) and a history of previous tobacco use (55.8%). Twenty three percent of participants had already suffered a myocardial infarction, with 2

individuals requiring cardiac stent placement. Furthermore, many individuals reported a history of arthritis (52%) and neuropathy (34.6%).

Table 13

Self-reported Co-morbidity History (*N*=52)

Co-morbidity*	Number	Percent
Diabetes:		
Neuropathy	18	34.6
Autonomic Neuropathy	12	23.1
Retinopathy	6	11.5
Nephropathy	5	9.6
Cardiovascular:		
Hypertension	31	59.6
Myocardial Infarction	12	23
Chest Pain	12	23
Arrhythmias	6	11.5
Tachycardia	5	9.6
Intermittent Claudication	4	7.7
Cardiac Stent	2	3.8
Cerebral Vascular Accident	1	1.9
Deep Vein Thrombosis	1	1.9
Transient Ischemic Attack	0	
Family History of Cardiovascular Disease		
Family History of Myocardial Infarction (Siblings, Parents, Aunts, Uncles)	37	71.2
Family History of Cerebral Vascular Accident	24	46.2
Family History of Premature Heart Disease (father ≤ 55 yrs, mother ≤ 65 yrs)	6	11.5
Pulmonary		
Bronchitis	9	17.3
Asthma	4	7.7
Emphysema	2	3.8
Pulmonary Emboli	1	1.9
Musculoskeletal		
Arthritis	27	51.9
Other		
Anemia	8	15.4

* See appendix B

Table 14

Smoking Behavior (*N=52*)

Behavior	Number	Percent
Smoking History	29	55.8
Currently Smoking	5	9.6
Total Time Smoked (years)		
1-45	29	100

Participants were therefore queried specifically about past problems with physical activity (Table 15). A number of participants reported difficulty with their back (23%), hip (15%), knee (29%), and feet (23%) when engaging in physical activity. In contrast, very few participants reported past problems with low (14%) or high (6%) glucose levels with physical activity.

Table 15

Self-reported Past Problems with Physical Activity

Problem	Number	Percent
Diabetes:		
Low Blood Glucose	7	13.5
High Blood Glucose	3	5.8
Pulmonary:		
Shortness of Breath	7	13.5
Cardiac:		
Tachycardia	3	5.8
Arrhythmias	0	
Musculoskeletal:		
Knee Problems	15	28.8
Foot Problems	12	23.1
Back Problems	12	23.1
Hip Problems	8	15.4

Participants' current physical activity was assessed at baseline and used when providing physical activity counseling (Table 16). The majority of participants (n=34)

were not engaged in any type of regular physical activity. Of those participating in physical activity (n=18), walking was the most frequently reported (31%) type of physical activity at light (12%) to moderate (23%) intensity levels. Participants engaging in physical activity were active 1 to 2 days per week ranging from 11 minutes to 2 hours. These baseline assessment data on physical activity supported the gradual walking plan used in this study.

Table 16

Participants' Current Physical Activity ($N = 52$)

Current Physical Activity	Number	Percent
Type of Activity		
None	34	63.5
Treadmill/Walking	16	30.8
Bicycling	4	7.7
Weights/Universal	2	3.8
Swimming	2	3.8
Aerobics	1	1.9
Basketball	1	1.9
Car Racing	1	1.9
Kayaking	1	1.9
Manual Labor	1	1.9
Activity Frequency		
None	34	65.4
Two days per week	12	23.1
One day per week	6	11.5
Activity Duration		
None	34	65.4
5-10 min	0	
11-20 min	2	3.8
21-30 min	2	13.5
31-60 min	7	13.5
1.5 hours	1	1.9
2 hours	1	1.9
Activity Intensity		
None	34	65.4
Moderate	12	23.1
Light	6	11.5

Medications that could affect glucose levels and blood pressure during physical activity were also assessed at baseline (Table 17). A majority of participants were taking sulfonylurea medications (69.2%) known to predispose individuals to hypoglycemic reactions. Participants reported taking several categories of anti-hypertensive medications. Since physical activity is known to lower blood pressure, all of these anti-hypertensive

agents had the potential to cause symptoms with the prescribed physical activity in this study.

Table 17

Diabetes and Anti-Hypertensive Medications (*N*= 52)

Medication	Number	Percent
Diabetes:		
Sulfonylurea	36	69.2
Metformin	36	69.2
Glitazone	12	23.1
Blood Pressure:		
ACE Inhibitor	23	45.1
Diuretic	13	25.5
Beta Blocker	11	21.6
Calcium Channel Blocker	9	17.6
Angiotensin Receptor Blocker	1	2.0

Of the 52 participants recruited for this study, 25 were randomized to the control group and 27 to the intervention group. Six participants did not complete the study for the following reasons: 1) back injury after moving furniture, 2) dyspnea on exertion and hypertension, 3) emotional distress following job loss, 4) knee injury, 5) cortisone injection for shoulder injury, and 6) lost to follow up. Dropouts did not differ from the larger sample population on demographic or outcome measures (Table 18 and 19).

Table 18

Demographics of Dropouts (*N=6*) and Individuals that Completed the Study (*N=46*)

Demographics	Completers	Dropouts	Chi *P*
Gender			
Female	24	3	0.92
Male	22	3	
Race			
White	41	6	0.34
African-American	5	0	
Ethnicity			
Not Hispanic or Latino	43	5	0.38
Hispanic or Latino	3	1	
Marital Status			
Married	26	3	0.63
Single	11	2	
Divorced	6	0	
Widowed	3	0	

Table 19

Comparison of Dropouts (*N=6*) to Individuals that Completed the Study (*N=46*)

Outcome variable	Completers Mean (± SD)	Dropouts Mean (± SD)	t-test *p*
Age (year)	56 (13)	10 (18)	0.53
SES (I-V)	2.98 (1.1)	3.17 (0.9)	0.70
BMI (kg/m^2)	35.55 (5.74)	32.33 (5.62)	0.20
$A1_c$ (%)	8.6 (1.11)	8.7 (1.59)	0.90
Systolic BP	132 (17)	132 (20)	0.95
Diastolic BP	77 (10)	77 (6)	0.88
Self-efficacy Sticking to it	3.55 (0.87)	3.62 (1.46)	0.09
Self-efficacy "Making time"	3.82 (1.42)	3.58 (1.42)	0.55

Participants in the control and intervention groups did not differ on demographic or outcome variables (see Tables 20 and 21). Participants in the control group had a higher baseline mean daily activity count, but this difference was not significant.

Table 20

Control vs. Intervention Group Demographics

Demographic	Control (n=25)	Intervention (n=27)	Chi *p*
Gender			0.78
Female	15	12	
Male	12	13	
Race			0.58
Caucasian	25	22	
African American	2	3	
Ethnicity			0.94
Not Hispanic or Latino	25	23	
Hispanic or Latino	2	2	

Table 21

Control vs. Intervention Group Outcome Variables

Outcome variable	Control (n=25)	Intervention (n=27)	*p* *t* (df)
	Mean ± SD	Mean ± SD	
Age (years)	57.04 (12.47)	57.04 (14.56)	0.93 -0.83 (50)
SES (I-V)	3.12 (1.13)	2.89 (1.12)	0.47 -0.74 (50)
Diabetes Duration (years)	8.46 (6.23)	8.31 (6.31)	-0.08 0.93 (50)
Self-efficacy "Sticking to it" (1-5)	3.70 (0.85)	3.41 (1.01)	0.28 -1.10 (49)
Self-efficacy "Making time" (1-5)	3.84 (0.69)	3.74 (1.03)	0.68 0.41 (49)
Activity Counts- baseline (counts per day)	259,717 (124,559)	216,025 (90,150)	0.17 -1.38 (46)
Moderate Activity- baseline (min/day)	21 (22.46)	16 (13.90)	0.33 -0.99 (45)
Systolic BP (mm/Hg)	131 (15)	133 (19)	0.71 3.69 (50)
Diastolic BP (mm/Hg)	79 (11)	76 (9)	0.33 0.99 (50)
$A1_c$ (%)	8.4 (1.06)	8.3 (1.23)	0.23 1.22 (50)
BMI (kg/m^2)	33.81 (4.86)	36.05 (6.67)	0.18 1.37 (50)

Missing Data

Missing data were evaluated for all major and secondary variables. Full scale missing data occurred on one self-efficacy instrument pre- and post-intervention. These data were omitted from analysis. Of the 51 pre- and 45 post-intervention self-efficacy scales, no individual items had missing data. Data loss was minimized by reviewing all self-efficacy instruments for completeness immediately following completion. If items were not completed, participants were asked to complete the missing items. Data from four

activity monitors were discarded following each participants' discontinuation from the study. One participant was excluded from the analysis of moderate activity due to the lack of moderate activity minutes. All other major and secondary variables had complete data sets.

Research Hypotheses

Prior to statistical analysis, descriptive statistics for outcome variables were analyzed (Table 22). Although some distributions were slightly skewed, non-parametric equivalent test (Wilcoxon for within group change; Mann-Whitney for between group change) results yielded the same significance as parametric tests (t-test) in this data set. The robustness of t-tests even with slightly skewed data is the reason for this concordance. Therefore, t-tests were used to compare all outcome variables within and between the intervention and control groups.

Changes in self-efficacy, BP and activity counts from pre- to post-intervention were analyzed using t-tests to determine within-group changes (Table 23) and between-group changes (Table 24). Secondary outcomes, i.e., changes in BMI and $A1_{c,}$ were analyzed similarly. Outcome variables were measured at baseline (pre-intervention) and at completion of the study protocol 8 weeks later (post-intervention). Significance was determined at $p<0.05$.

Table 22

Pre-intervention Data Distribution (*N=52*)

	Control (n=25)		Intervention (n=27)	
Outcome	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Self-efficacy "Making time"	3.8 (±0.69)	4.0 (3.4-4.3)	3.7 (±1.0)	3.9 (3.2-4.5)
Self-efficacy "Stick to it"	3.7 (±0.9)	4.0 (3.0-4.3)	3.4 (±1.0)	3.6 (2.5-4.2)
Systolic BP (mm/Hg)	131 (±15)	128 (123-140)	133 (±19)	128 (120-144)
Diastolic BP (mm/Hg)	79 (±11)	80 (71-87)	76 (±9)	76 (72-82)
Activity Counts (counts per day)	259,717 (±124,559)	262,927 (175,164-299,976)	216,025 (±90,150)	193,132 (156,421-281,944)
Light/sedentary activity (min/day)	1,419 (±22.7)	1,422 (1,412-1,432)	1,424 (±14.5)	1,431 (1,412-1,435)
Moderate activity (min/day)	21 (±22.5)	18 (7.8-28.1)	16 (±14.0)	10 (6.0-25.7)
$A1_c$ (%)	8.4 (±1.1)	8.2 (7.7-8.9)	8.8 (±1.2)	8.4 (7.7-9.8)
BMI (kg/m^2)	33.8 (±4.9)	32.9 (30.9-36.3)	36.1 (±6.7)	36.1 (32.4-39.1)

Table 23

Within-Group Change from Pre- to Post-intervention

Outcome	Control Group (n=25) (Mean ± SD)		Intervention Group (n=21) (Mean ± SD)		*p* (Paired t test, df)	
	Pre	Post	Pre	Post	Control	Intervention
Self-efficacy Sticking to it	3.70 (0.85)	3.59 (0.67)	3.35 (0.88)	3.87 (0.82)	0.42 (0.83, 24)	0.02* (-2.63, 19)
Self-efficacy "Making time"	3.84 (0.69)	3.45 (0.82)	3.78 (0.93)	3.92 (0.76)	0.01* (2.87, 24)	0.58 (-0.56, 19)
Activity counts (counts/day)	259,716 (124,558)	250,435 (97,564)	199,100 (73,187)	230,244 (80,100)	0.67 (0.43, 24)	0.04* (-2.24, 20)
Sedentary and light activity (min/day)	1,419 (22.71)	1,419 (22.16)	1427 (12.11)	1422 (10.97)	0.39 (-0.88, 24)	0.00* (4.59, 20)
Moderate activity (min/day)	21 (22.46)	20 (21.25)	13 (11.12)	18 (10.61)	0.30 (1.068, 24)	0.00* (-8.21, 19)
Systolic BP (mm Hg)	131 (15)	134 (16)	133 (19)	126 (12)	0.26 (-1.16, 24)	0.05 (2.05, 20)
Diastolic BP (mm Hg)	79 (11)	77 (11)	76 (10)	73 (8)	0.44 (0.79, 24)	0.25 (1.19, 20)
$A1_c$ (%)	8.4 (1.06)	8.1 (0.87)	8.9 (1.15)	7.7 (1.23)	0.13 (1.55, 24)	0.00* (5.13, 20)
BMI (kg/m^2)	33.81 (4.86)	33.93 (5.34)	37.11 (6.68)	36.58 (6.61)	0.53 (0.65, 24)	0.00* (3.22, 20)

*$p<0.05$

Table 24

Between-Group Mean Changes from Pre- to Post-intervention

Outcome	Control Group (n=25)	Intervention Group (n=21)	t	df	*p*
	Mean ± SD	Mean ± SD			
Self-efficacy (Sticking to it)	-0.11 ± 0.68	0.52 ± 0.89	-2.71	43	0.01*
Self-efficacy ("Making time")	-0.39± 0.68	0.14 ± 1.09	-1.98	43	0.05
Activity counts (counts/day)	-9,282 ± 108,033	31,144 ± 63,627	-1.51	44	0.14
Sedentary and light activity (min/day)	0.60 ± 2.85	-2.65 ± 4.83	1.25	44	0.04*
Moderate activity (min/day)	-0.66 ± 3.07	5.48 ± 2.98	6.74	43	0.00*
Systolic BP (mm Hg)	3 ± 15	-7 ± 16	2.33	44	0.02*
Diastolic BP(mm Hg)	-2 ± 9	-3 ± 11	0.42	44	0.68
$A1_c$ (%)	-0.32 ± 1.02	-1.16 ± 1.04	2.78	44	0.01*
BMI (kg/m^2)	-0.12 ± 2.35	-0.53 ± 0.75	2.53	44	0.02*

*$p<0.05$

Hypothesis 1: Participants in the intervention group will have higher self-efficacy scores, lower BP, and higher activity counts than those in the control group.

Self-efficacy for Physical Activity

Compared to the control group, participants receiving the nurse counseling intervention had a significantly higher mean score (pre 3.35, post 3.87, $p<0.05$) on the "Stick to it" subscale indicating more confidence in their ability to engage in regular physical activity post-intervention. Although participants in the intervention group

reported a non-significant increase in mean score on the "Making time" for exercise subscale (3.78 to 3.92, p=0.58), participants in the control group showed a significant decrease in their scores (3.84 to 3.45, $p<0.05$), indicating less self-efficacy for control group participants on this subscale.

Significant differences were found in the mean self-efficacy change scores between the control and intervention groups from pre- to post-intervention (Table 24). At the end of the study, participants in the intervention group were significantly more confident in their ability to "Stick to" a regular physical activity regimen ($p< 0.05$) than those in the control group. In contrast, control group participants trended towards less confidence in their ability to "Make time" for exercise ($p= 0.05$) than those in the intervention group.

Amount and Intensity of Physical Activity

Activity monitors were worn at baseline and at week 8 to obtain objective data regarding the amount and intensity of physical activity. Only the activity of participants within the intervention group increased significantly from baseline to week 8 (216,025 to 230,244 counts per day, $p<0.05$). The amount of sedentary and light daily activity minutes decreased significantly within the intervention group from pre- to post-intervention (1,427 to 1,422 min/day, $p <0.05$). However, the amount of moderate intensity activity minutes within the intervention group significantly increased from baseline to week 8 (13 to 18 min/day, $p<0.05$). Neither group on average reached the recommended 30 minutes of moderate level activity per day as measured by the activity monitor. However, 5 (23.8%) individuals in the intervention group and 7 (28%) in the control group had 20-29 minutes of moderate minutes of activity post intervention. Only 3 (14.3%) individuals in the intervention and 4 (16%) in the control group reached >29 minutes of moderate activity

post-intervention. Intervention group subjects set goals for participating in one or more types of physical activity on the activity prescription (Appendix A). The majority set walking goals (90.5%) and bicycling goals (42.9%). Few intervention group participants set weight lifting goals (19%) or swimming goals (4.8%). In contrast, control group participants set general goals of being more physically active (76%) documented on IDC Diabetes Success Plan goal records. Of those that set specific goals, 21.7% were for walking, and 8.7% for each bicycling and swimming.

The mean differences for certain indicators of activity between the control group and intervention group from pre- to post-intervention were significant. Overall, activity counts between the intervention and control group were not significantly different ($p=0.14$). As opposed to the activity count numbers, minutes of sedentary and light activity were significantly less in the intervention group than the control group ($p< 0.05$) and moderate activity minutes were significantly greater in the intervention group than the control group ($p< 0.001$). It is important to note that the amount of sedentary and light activity changed for less than one-half of all participants (n=24), but the amount of moderate activity changed for most individuals (n=43). Of the 43 individuals who had a change in moderate activity minutes, 19 (90.5%) intervention group participants increased their moderate activity minutes while only 9 (36%) participants in the control group had a similar increase.

Blood Pressure

Baseline blood pressure readings were measured as part of the screening history and physical exam. As part of this exam, participants were screened for the presence of orthostasis. Blood pressure (BP) was measured in the lying and standing position at

baseline. Blood pressure was measured in the sitting position post intervention. Systolic BP trended toward a significant decrease within the intervention group (133 to 126 mmHg, $p= 0.05$) pre- to post-intervention (Table 23). However, the difference in systolic blood pressure pre- to post-intervention changed significantly between the intervention and control groups ($p<0.05$). In contrast, diastolic blood pressure did not change within or between either group from pre- to post-intervention. The intervention group had a non-significant ($p= 0.10$) increase in blood pressure medication dosages pre- to post-intervention (19%) compared with the control group (4%).

Blood Glucose Control

Blood glucose control, as reflected by $A1_c$ levels, improved in both groups from pre- to post-intervention. However, only the intervention group participants' $A1_c$ was significantly lower ($p< 0.05$) pre- to post intervention (8.85% to 7.69%). Additionally, the t-test analysis results were consistent with Wilcoxin non-parametric analysis. The between-group differences were significant ($p< 0.05$) providing support for the impact of the counseling intervention. The control group had a non-significant ($p= 0.61$) increase in diabetes medication dosages (20%) compared with the intervention group (14.3%).

Body Mass Index (BMI)

Body mass index decreased from pre- to post intervention within both groups. Both groups had lower BMI's pre to post-intervention. However, only the BMI of participants in the intervention group was significantly lower (37.11 to 36.58 kg/m^2) pre- to post-intervention ($p<0.05$). Differences between the two groups for the BMI change scores were not significantly different pre- to post-intervention. Lastly, the t-test analysis results were consistent with Wilcoxin non-parametric analysis.

Summary

The first hypothesis was partially supported by the study data. Thus, participants receiving the physical activity counseling intervention had higher "Sticking to it" self-efficacy and higher physical activity levels than individuals in the control group. Additionally, $A1_c$ and BMI improved significantly from pre- to post-intervention in the intervention group only. The between-group differences were significant for self-efficacy, systolic blood pressure, light and sedentary activity minutes, moderate activity minutes, and $A1_c$, supporting the efficacy of the counseling intervention.

Hypothesis 2: Self-efficacy will be associated with change in activity counts, BP, and demographic variables.

Correlations were explored among the pre- to post-intervention change scores for self-efficacy, activity counts, and BP (Table 26). Change score was calculated by subtracting participant's outcome scores at time 2 from outcome scores at time 1 on continuous variables. The change score for each variable was used in calculating the correlation coefficient. Although some distributions were slightly skewed, non-pararmetric equivalent test (Spearman's rho) results yielded the same significance as parametric tests (Pearson). The only correlation found was between moderate activity minutes and the "Sticking To It" self-efficacy subscale ($r = 0.33$, $p<0.01$). Regression analysis was not conducted because only one variable was correlated with self-efficacy.

Table 25

Control vs. Intervention Group Change Score Data Distribution

	Control (n=25)		Intervention (n=27)	
Outcome	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Self-efficacy "Making time"	0.39 (±0.68)	0.25 (0.0-0.8)	-0.14 (±1.1)	.0.00 (-0.7-0.5)
Self-efficacy "Stick to it"	-0.11 (±0.68)	0.12 (0.3-0.6)	-0.52 (±0.86)	-0.42 (-1.5-0.3)
Systolic BP (mm/Hg)	-3.44 (±14.78)	-6.0 (-10.0-5.0)	7.19 (±16.1)	6.0 (-2.5-13.0)
Diastolic BP (mm/Hg)	1.48 (±9.43)	2.00 (-5.0-7.0)	2.71 (±10.48)	-2.0 (-5.0-10.0)
Activity Counts (counts per day)	-28,897 (±92,604)	-33,110 (-71,904-3,545)	1,384 (±101,356)	-17,993 (-56,668-20,241)
Light/sedentary activity (min/day)	-0.48 (±2.74)	-0.69 (-2.7-0.8)	4.62 (±4.61)	6.08 (1.2-7.0)
Moderate activity (min/day)	0.66 (±25.08)	0.14 (-6.2-11.1)	-0.66 (±11.52)	-1.29 (-6.8-4.1)

Table 26

Correlations Among Outcome Variables Using Change Scores from Pre- to Post-Intervention (*N=46*)

Outcome	Diastolic BP	Systolic BP	Moderate Activity	Light Activity	Self-efficacy ("Make time")	Self-efficacy ("Stick to it")
Diastolic BP (mm/Hg)	1.00	-0.21	0.26	0.04	0.04	0.08
Systolic BP (mm/Hg)		1.00	-0.13	-0.10	0.03	0.22
Moderate Activity (min/day)			1.00	0.81**	0.14	0.33*
Light Activity (min/day)				1.00	0.13	0.27
Self-efficacy ("Make time")					1.00	0.71**
Self-efficacy ("Stick to it")						1.00

** Correlation is significant at the 0.01 level (2 tailed)
* Correlation is significant at the 0.05 level (2 tailed)

An exploratory analysis of variables that may have affected the change in self-efficacy among all participants was conducted. Differences in change in self-efficacy scores by gender, race, ethnicity, and marital status were explored using t-tests (Table 27). Similarly, correlations of age, SES, ΔBMI, $\Delta A1_c$, Δ moderate activity minutes and diabetes duration with change in self-efficacy were examined (Table 28). Change in self-efficacy "Stick to it" score was significantly different by race. African Americans had a smaller mean change difference pre- to post-intervention than Caucasians. Because there were only five African Americans in this study, this relationship was not statistically explored but may be a consideration in future studies. None of the relationships among population

characteristics with change in self-efficacy scores from pre- to post-intervention were significant (Table 28). However, change in moderate activity minutes did correlate with change in $A1_c$ ($r = -0.32$, $p<0.05$).

Table 27

Exploratory Analysis of Population Characteristics and Change in Self-efficacy Scores Pre- to Post- intervention

Variable	Number	Mean (±SD)	t	df	*p*
Δ Self-efficacy- "Stick to it"					
Gender					
Male	22	-0.05 (0.71)	0.96	43	0.34
Female	23	-0.29 (0.94)			
Race					
White	40	-0.07 (0.79)	2.27	43	0.03
African-American	5	-0.93 (0.93)			
Ethnicity					
Not Hispanic	42	-0.12 (0.82)	-1.20	43	0.18
Hispanic	3	0.94 (0.94)			
Marriage					
Married	25	-0.11 (0.87)	-0.50	43	0.62
Not married	20	-0.24 (0.81)			
Δ Self-efficacy- "Make time"					
Gender					
Male	22	0.31 (0.55)	1.15	31.7	0.26
Female	23	0.01 (1.16)			
Race					
White	40	0.21 (0.94)	1.01	43	0.32
African-American	5	-0.23 (0.63)			
Ethnicity					
Not Hispanic	42	0.29	0.45	43	0.64
Hispanic	3	0.94			
Marriage					
Married	25	0.14 (0.97)	0.12	43	0.90
Not married	20	0.18 (0.86)			

Table 28

Exploratory Analysis of Relationships Among Population Characteristics and Change in Self-efficacy Scores from Pre- to Post-intervention

	Δ Self-efficacy "Stick to it"	Δ Self-efficacy "Make time"	Δ BMI	Δ $A1_c$	Age	Diabetes Duration	Δ Mod-erate Activity	Δ Light Acti-vity	SES
Δ Self-efficacy "Stick to it"	1.00	0.71**	-0.16	0.22	0.08	0.03	0.33*	0.27	0.18
Δ Self-efficacy "Making time"		1.00	-0.15	-0.01	0.05	0.15	0.14	0.13	0.18
Δ BMI (kg/m^2)			1.00	0.03	0.02	0.04	-0.01	-0.22	-0.28
Δ $A1_c$ (%)				1.00	0.12	-0.15	-0.32*	-0.14	0.14
Age (years)					1.00	0.48**	-0.3	-0.09	-0.10
Diabetes Duration (years)						1.00	-0.19	-0.25	0.02
Δ Moderate Activity (min/day)							1.00	0.81**	-0.11
Δ Light Activity								1.00	-0.01
SES									1.00

** Correlation is significant at the 0.01 level (2 tailed)
* Correlation is significant at the 0.05 level (2 tailed)

Research Question 3: What are the most effective recruitment, retention, and screening strategies?

Of 231 individuals screened for participation in this study, 179 individuals were ineligible. Of these, 106 (59.2%) had $A1_c$ less than 7.5%, 17 (8.5%) exercised more than 2 days per week, and 10 (5.6%) were taking insulin. Participants were also excluded for

health-related reasons such as musculoskeletal (n=7), cardiac (n=4), and pulmonary (n=2) limitations.

A multifaceted recruitment strategy was used over a 17-month period to meet recruitment goals. Recruitment efforts were focused primarily at Baystate Health System (BHS) and towns within a 40 mile radius (Table 29). Specifically, recruitment efforts targeted three BHS primary care clinics, two BHS specialty practices, four community hospitals/clinics, and four private endocrinology practices. Recruitment numbers declined in January 2005 and several participants dropped out between December 2004 and April 2005 (Table 30). Subsequently, a secondary research site was added at Berkshire Health System 60 miles from BHS (Table 31) and new recruitment strategies were implemented.

Table 29

Primary Research Site Recruitment Strategies

Recruitment Strategy	Specific Action
Health System Public Affairs Officer	1. Regional newspapers and weekly informational and advertisement publications (3 releases) 2. Employee newspaper publications 3. Senior quarterly publications 4. Global e-mail to all employees 5. Posters in cafeteria
Health System Clinics (3)	1. Medical director meeting 2. Multilingual Diabetes Educator meeting 3. Bilingual diabetes support group meetings 4. Recruitment packets for providers 5. Waiting areas posters
Specialty Clinics (2)	1. Posters and fact sheet to clinics 2. Endocrinology nurse researcher/lab tech meetings 3. Type 2 diabetes patient research letters mailed 4. Study notice front of patient charts 5. Luncheon for NP providers (cardiology) 6. Lecture for diabetes/cardiology support group 7. Follow up e-mails
Private Practice Endocrinologists (4)	1. Endocrinology noon conference lecture and study presentation 2. Follow up reminders to community Endocrinologists 3. Posters and fact sheets to providers
Community Hospitals/Clinics (4)	4. Nurse practitioners and diabetes educator meetings 5. Community health fair diabetes and exercise lecture 6. Health fair recruitment booth 7. Posters to clinics and providers 8. Follow up e-mails
Dietician Private Practice (1)	1. Posters and fact sheets 2. Follow up e-mails/phone calls
Participant's Primary Care Provider	1. Follow up letters

Table 30

Seasonality of Recruitment

Month/Year	Season	Recruitment Numbers	Dropouts
August 2004	Summer	2	
September 2004	Fall	8	
October 2004	Fall	3	
November 2004	Fall	4	
December 2004	Winter	3	2
January 2005	Winter	2	1
February 2005	Winter	2	1
March 2005	Spring	5	1
April 2005	Spring	1	1
May 2005	Spring	3	
June 2005	Summer	2	
July 2005	Summer	6	
August 2005	Summer	1	
September 2005	Fall	7	
October 2005	Fall	3	
November 2005	Fall	0	

Table 31

Secondary Research Site Recruitment Strategies

Recruitment Strategy	Specific Action
Health Systems Public Affairs Officer	1. Regional Newspaper (2 releases) 2. Radio interview (1 hour)
Hospital Endocrinologist and Diabetes Education team (1 practice)	1. Luncheon 2. Posters 3. Fact Sheets
Primary Care Clinics (2)	1. Luncheon 2. Posters 3. Fact Sheets
Major Business (1)	1. On-site nurse practitioner meeting 2. Posters and fact sheets
Other Businesses (2 different cities)	1. Pharmacies- posters 2. Grocery stores-posters

The largest number of participant referrals came from physicians and an endocrinology nurse researcher (Table 32). Endocrinology group and private practices were the major source of clinic referrals. The most successful recruitment media was multiple newspaper press releases.

Table 32

Recruitment Data

Referral Type	Frequency	Percent
Referrals		
None of the above	22	47.8
Physician	11	23.9
Research Nurse	7	15.2
Nurse practitioner	4	8.7
Diabetes Educator	2	4.3
Clinic referral		
No clinic referral	26	44.9
Group Endocrinology Practice	12	26.1
Private Practice Endocrinology	9	19.5
Primary Care Practice	4	7.6
Registered Dietician Practice	1	1.9
Advertisement*		
Newspaper	17	37.0
None of the above	10	21.7
Fact Sheet	9	19.6
Poster	6	13.0
Word of mouth	3	4.4
Global e-mail	2	6.5

*Multiple answers possible

At post-intervention, participants were asked one open-ended and one closed-ended question on retention strategies. Overall, participants rated phone calls as more important than reimbursement or family support as a reason for completing the study (Table 33). Several participants (34.8%) selected “none of the above” for the closed-ended question preferring instead to give an open-ended response. Responses to the open-ended question

revealed several key themes (Table 34). The top reasons for completing the study were the desire for diabetes education, encouragement from the nurse researcher, and to help themselves manage their diabetes.

Table 33

Retention Data: Closed-ended Question: "Which of the following encouraged you to complete the study?"

Retention Category	Frequency	Percent
Phone calls	27	58.7
None of the above	16	34.8
Reimbursement	4	8.7
Family support	2	4.3

Multiple answers possible

Table 34

Retention Data: Open-Ended Question: "What other reasons encouraged you to complete the study?"

Retention Category	Frequency	Percent
Education	12	23.1
Nurse researcher	9	17.3
Help self	8	15.4
Saw results/better control	7	13.5
Afraid of diabetes/complications	5	9.6
To help others	3	5.8
Curiosity	2	3.8
Like participating in research	1	1.9
Interested in technology	1	1.9

Multiple answers possible

Summary

Screening, recruiting and retaining participants for a physical activity study revealed several problems and solutions. The $A1_c$ criteria of >7.5% prevented several interested individuals from participating although health-related problems excluded only a

few individuals. Recruitment lasted 16 months but the addition of a second research site proved to be beneficial for meeting targeted numbers. The most successful strategies were print ads and referrals from endocrinology practices. Phone calls were an important retention strategy but reimbursement was not. Additionally, education and support were important retention strategies. These data will be useful in designing future physical activity studies.

Research Question 4: Are the monitors (CGMS and activity) and self-efficacy instrument (SEBS) reliable in this study population?

SEBS reliability, as measured by Cronbach's α, was calculated on 52 participants at pre-intervention and 45 participants at post-intervention (Table 35). The reliabilities for the "Making time" subscale were low (α 0.64) pre-intervention and high post-intervention (α 0.85). In contrast, the "Stick to it" subscale pre- and post-intervention were both high (α 0.87 and α 0.94). Similarly, the reliabilities for the total scale pre- and post-intervention were 0.89 and 0.84, respectively. These reliabilities are similar to internal consistency scores for a college-age population ("Making time"=0.83, "Stick to it"=0.85) (Sallis et al., 1988) and for a population of middle-aged women (total scale=0.91) (Speck & Looney, 2001). Only one instrument question, "Attend a party only after exercising," had low pre-intervention corrected item total correlation (0.17). If this item were deleted, the alpha would improve to 0.76.

Table 35

Self-Efficacy for Exercise Behavior Subscale Reliability Scores

SEBS	Pre α	Post α
"Stick to it" subscale (8 items)	0.87	0.94
"Making time" subscale (4 items)	0.64	0.85
Total scale	0.89	0.83

Utility of the Activity Monitor

Activity monitors were attached with an elastic belt at the right hip next to the participants' skin. The activity monitor was most commonly worn for 6-8 days at pre-intervention (n=41, 85.5%). Other durations pre-intervention were 4-5 days (n=2, 4.2%) and 8 or more days (n=13, 10.5%). At post-intervention, the most common duration the activity monitor was worn was 6-7 days (n=37, 80.4%). Four participants (8.6%) post-intervention wore the activity monitor 4-5 days while 5 (10.8%) wore the activity monitor 8 or more days. To estimate habitual physical activity in adults, 3-5 days of monitoring are needed (Trost, McIver, & Pate, 2005). Therefore, all activity monitor data were used even though a few participants wore the monitors 4-6 days. A minimum wear time of at least 360 "yes" minutes (minutes in the day when the count value was greater than 0) was used to define one day of monitor wear time for statistical analysis. Originally the data were run with 480 "yes" minutes. However, this criterion resulted in too many days that monitors were worn being eliminated from the analysis. The older participants in this study were inactive and required the lower "yes" minutes to prevent erroneous data loss.

Activity monitor wearing issues were assessed in a seven-part questionnaire at post-intervention (see Table 36). None of the participants had difficulty understanding

activity monitor directions, but several participants reported wearing problems such as sweaty skin (n=9), irritated skin (n=14), and pinched skin (n=16). Participants reported more difficulty remembering to put the monitor on (n=18) than to take it off (n=8). Of the 18 reporting difficulty remembering to put the monitor on, the participants had an average of 10 "yes" days of the expected 14 days. Of those reporting no difficulty remembering to put the monitor on, participants had an average of 12 "yes" days.

Table 36

Problems Wearing Activity Monitor (*N*=46)

Problem	Frequency	Percent
Wearing problem:		
Pinched skin	16	34.8
Irritated skin	14	30.4
Sweaty skin	9	19.6
Difficulty securing to waist	9	19.6
Problem with directions:		
Forgetting to put monitor on	18	36.1
Forgetting to take monitor off	8	17.4
Understanding directions	0	0

Four activity monitors failed, preventing access to activity data. Participants were asked to wear the activity monitor a second time and all agreed. No data were lost from data management errors. The majority of participants accurately filled out the activity monitor log at pre-intervention (n=40, 76.9%) and at post-intervention (n=39, 84.8%). Completeness of activity logs (defined by a recorded time on and off on the activity monitor log, Appendix H) did not differ significantly between the intervention and control groups on visit pre-intervention (p=0.07) or post-intervention (p=0.52).

Utility of the Continuous Glucose Monitoring System (CGMS)

Twenty-seven participants in the intervention group wore the CGMS for approximately 72 hours over a 3- to 4-day calendar period. Participants' CGMS graphs

were reviewed for accurate use of meal, exercise, and medication event markers. A missed meal event was identified by a rise in glucose level without an event marked on the CGMS graph and was recognized by the participant as a meal either on the CGMS paper log or during the CGMS review with researcher. A missed exercise event was identified by a decrease in glucose level without an event marker that followed an increase in activity measured by the activity monitor or acknowledged by the participant during review with the researcher. A missed medication event was identified after reviewing a participant's medication list and determining medication times. CGMS graphs were then reviewed for the presence or absence of diabetes medication markers. Event entries were considered accurate if no events were missed.

Meals (42-58%), exercise (70-82%), and medications (56-68%) were most accurately entered on the first and last days of wearing the CGMS versus the middle two days (Table 37). The CGMS was worn for the shortest times on the last and first days of wearing the device compared with the middle two days. Of all the events, meals were entered with the lowest accuracy on days 2 and 3 (26-33%). In general, exercise (52-59%) and medications (46-58%) were entered with moderate accuracy on days 2 and 3. These data support those from a follow-up questionnaire on which 52% of participants reported difficulty remembering to enter CGMS events. Despite many participants using the event monitor with only moderate accuracy, most participants (81.5%) kept an accurate paper log of events.

Table 37

Events not Entered on the CGMS

Number of Missed Entries	Day Wearing the CGMS			
	1	2	3	4
	n (percent)	n (percent)	n (percent)	n(percent)
Meal marker				
0	15 (57.7)	7 (25.9)	9 (33.3)	11 (42.3)
1	6 (23.1)	6 (22.2)	5 (18.5)	8 (30.8)
≥2	5 (19.2)	14 (51.8)	13 (48.1)	7 (26.8)
Exercise				
0	22 (81.5)	16 (59.3)	14 (51.9)	18 (69.2)
1	4 (14.8)	9 (33.3)	10 (37)	8 (30.8)
2	1 (3.7)	2 (7.4)	3 (11.1)	
Medications				
0	18 (67.7)	15 (57.7)	12 (46.2)	14 (56)
1	8 (29.6)	5 (19.2)	7 (26.9)	8 (32)
≥2	1 (3.7)	6 (23)	7 (26.9)	3 (12)

Although the CGMS data were not used as an outcome measure in this study, the accuracy of data were reviewed to assess the utility of the CGMS as a monitor in the type 2 diabetes population. Optimal accuracy criteria were calculated by CGMS software from two data sources, a glucose sensor and glucose meter data, for each day the sensor was worn. Optimal accuracy of CGMS data depended on two criteria: (1) correlation between sensor and meter readings of at least 0.79, and (2) a mean absolute difference ≤ than 28% (Mastrototaro, 2000). When data from the CGMS monitor were downloaded, the software calculated a correlation coefficient between the glucose meter readings and the calculated sensor glucose values (paired data) for each day. Using the paired data, the mean absolute difference was derived from the difference between the meter glucose reading and the sensor glucose measurement, divided by the meter value, and then averaged across pairs within a day. A message ("use clinical judgment") appeared when optimal accuracy

criteria were not met or if there were fewer than 3 meter-sensor pairs (correlation coefficient can't be calculated) (Table 38).

Table 38

CGMS Optimal Accuracy Criteria

Optimal accuracy criterion	Day of Wearing the CGMS			
	1	2	3	4
	n (percent)	n (percent)	n (percent)	n (percent)
Paired meter readings				
≤2	14 (51.8)	4 (14.8)	4 (19.1)	14 (51.9)
3	9 (33.3)	6 (22.2)	10 (38.5)	6 (22.2)
≥4	4 (14.8)	17 (63)	11 (42.2)	7 (25.9)
Missing			1	
Correlation coefficient				
< 0.79	2 (50)	1 (11.1)	0	0
> 0.79	2 (50)	8 (88.9)	6 (100)	2 (100)
Missing	23	18	21	25
Mean absolute difference				
≤ 28	24 (96)	24 (96)	25 (100)	20 (100)
≥ 29	1 (4)	1 (4)		
Missing	2	2	2	7
Use clinical judgment	19 (70.4)	5 (18.5)	6 (22.2)	13 (48.1)

About half the participants (51.8%) did not enter more than 2 glucose meter readings on days 1 and 4 of the study (Table 38). This omission may be partly attributable to the shorter wear times on days 1 and 4. In contrast, most participants entered 3 or more meter entries on days 3 (85.2%) and 4 (80.7%). Of the 59 missed glucose meter readings, 83% of the missed entries were from 18 participants aged 55-77 years old and only 17% were from 9 participants aged 19-54 years old.

Only 2 participants on day 1 and one participant on day 2 failed to meet the necessary correlation coefficient of >0.79 for optimal accuracy criteria. Because glucose levels did not vary much in this sample of individuals with type 2 diabetes, the majority of

participants (n=18-25) had no calculated correlation coefficients. The mean absolute difference could not be calculated for 2 participants on days 1-3 and for 7 participants on day 4 because of insufficient paired meter and sensor readings. Several CGMS graphs had "use clinical judgment" messages on study day 1 (n=19) and 4 (n=13) because participants did not enter the necessary 3 meter readings for optimal accuracy criteria to be calculated. Overall, optimal accuracy criteria on days 1 through 4 were not met by a majority of participants because their glucose levels did not vary enough and they did not enter enough glucose meter entries on days 1 and 3.

To determine issues related to wearing the CGMS, 15 evaluation questions were completed by the 21 participants in the post-intervention group who completed the study (Table 39). Participants reported some minor difficulties: skin irritation (n=4), pain (n=1) or discomfort at sensor site (n=2), and activity limitations (n=2). No infections were observed or reported at any CGMS sensor site. Participants reported moderate to large amounts of difficulty with the CGMS monitor during showering (n=5) and sleeping (n=2). However, the majority of participants reported no difficulty wearing the CGMS (n=20) and answered "yes" when asked if they would wear the CGMS monitor again (n=18). Although only 2 participants reported difficulty understanding CGMS directions, 11 participants reported difficulty entering events such as meals, exercise, and meter data.

Table 39

Evaluation of Wearing CGMS

CGMS Evaluation Question	Frequency (n=21)	Percent
1. Skin irritation	4	19
2. Pain at sensor site	1	4.8
3. Discomfort at sensor site day 1	1	4.8
4. Discomfort at sensor site continuously	2	9.5
5. Discomfort with sensor location	0	
6. Discomfort due to monitor location	0	
7. Infection	0	
8. Activities limited	2	9.5
9. Difficulty with showering		
None	11	55
Small	4	20
Moderate	3	15
Large	2	10
10. Difficulty with sleeping		
None	17	81
Small	2	9.5
Moderate	2	9.5
Large	0	
11. Difficulty wearing CGMS		
None	20	95.2
Small	1	4.8
Moderate	0	
Large	0	
12. Difficulty remembering to enter blood sugar, meals, exercise into the meter	11	52.4
13. Difficulty with alarms	6	28.6
14. Difficulty understanding directions	2	9.5
15. Would you wear the CGMS again?		
Yes	18	85.7
No	2	9.5
Don't know	1	4.8

The CGMS has five possible alarms: 1) disconnect, 2) ISIG (initialization signal) out of range, 3) memory full, 4) calibration error, and 5) noise. A review of the sensor alarm data produced by the CGMS software revealed that the majority of participants had no alarms during the study.

Of the 27 CGMS files reviewed, CGMS disconnect alarms occurred for 3 participants. Two individuals had sensors that were disconnected. One individual caught the CGMS cable on a door and another sensor worn by an 80 year old woman became disconnected for an unknown reason. The third participant turned the monitor off for an unknown reason. No ISIG out-of-range or memory-full alarms occurred for any participant. The five calibration error alarms were caused by meter glucose readings that fell outside of the acceptable calibration factor limits used to calculate sensor glucose values. For example, one participant entered three meter values (245, 229, 209) that were rapidly decreasing over a 15 minute period causing a calibration alarm. Lastly, 2 participants had sensor-noise alarms related to rapid glucose rises >400. Of the 6 participants reporting alarms, 3 were related to lack of paired meter readings, one participant failed to properly turn off the meter, and 2 participants did not have any alarms. In contrast, 2 participants with alarm data did not report hearing the alarms and subsequently had gaps on their CGMS graphs because of lack of meter entries or lack of paired meter data.

Teachable Moments

CGMS graphs were reviewed for teachable dietary and physical activity moments based on participants' entered meter events, CGMS log, participants' report, and/or comparison to activity monitor data. A dietary teachable moment was defined as a glucose excursion in response to a meal. Similarly, a physical activity teachable moment was defined as a decline in glucose levels following a bout of physical activity. A total of 77 physical activity and 141 dietary teachable opportunities occurred over the 3-4 day CGMS monitoring period (Table 40). Most physical activity teaching opportunities (66-70%)

occurred on days 2 and 3. However, the majority of participants had dietary teachable opportunities on all 4 days of CGMS monitoring.

Table 40

CGMS Teachable Moments

Topic	Day Wearing the CGMS			
	1	2	3	4
	n (percent)	n (percent)	n (percent)	n (percent)
Physical activity				
0	18 66.7)	8 (29.6)	9 (33.3)	14 (51.9)
1	7 (25.9)	13 (48.1)	13 (48.1)	12 (44.4)
2	2 (7.4)	4 (14.8)	4 (14.8)	1 (3.7)
3		1 (3.7)	1 (3.7)	
4		1 (3.7)		
Diet				
0	10 (37)	2 (7.4)	5 (18.5)	8 (29.6)
1	15 (55.6)	6 (22.2)	6 (22.2)	12 (44.4)
2	1 (3.7)	14 (51.9)	10 (37)	6 (22.2)
3	1 (3.7)	5 (18.5)	6 (22.2)	
4				1 (3.7)

Estimates of Power, Sample, and Effect Size for Future Studies

Sample size was estimated from study data using Number Cruncher Statistical Systems (Hintz, 2004) software for use in designing future studies (Table 41). The goal was to estimate the number of subjects needed per group to have 80-90% power to detect a clinically meaningful difference in change from baseline between intervention and control groups. In order to detect a mean change from baseline of 0.5 for change in self-efficacy "Sticking to it" subscale, 73 individuals per group are needed to achieve 90% power or 54 per group to achieve 80% power. In contrast, a larger number of participants (106 and 80 respectively) are needed to detect the same amount of change for the self-efficacy "Making time" subscale. In general, approximately 100 subjects per group would be recommended

based on these results. Based on an 11% non complete rate, a 20% participant loss could be anticipated over a 1 year period. Therefore, to provide the necessary statistical power 230 participants are needed in future studies. Effect sizes were calculated by using the value of *t* and *df* from table 24 to compute a Pearson Correlation Coefficient *r* (Rosnow & Rosenthal, 2005). The effect size calculations (Table 42) show a range of small to large effects (Cohen, 1988). Variables with small effect sizes require a much larger sample to demonstrate intervention differences. In contrast, variables with moderate and large effects require fewer participants.

Table 41.

Estimated Sample Size to Detect Clinical Significant Change from Baseline

Outcome Variable	Power	Numbers per group	Mean difference	SD of change
Self-efficacy "Stick to it"	0.90 0.80	73 54	0.5 0.5	0.9 0.9
Self-efficacy "Make time"	0.90 0.80	106 80	0.5 0.5	1.1 1.1
Moderate activity (min/day)	0.90 0.80	10 7	10 10	3 3
Systolic BP (mm Hg)	0.90 0.80	51 38	10 10	15 15
Diastolic BP (mm Hg)	0.90 0.80	23 17	10 10	10 10
$A1_c$ (%)	0.90 0.80	90 67	0.5 0.5	1.0 1.0
BMI	0.90 0.80	117 89	1 1	2.3 2.3

Based on alpha of 0.05

Table 42

Effect Size Calculations for Major Outcome Variables*

Outcome Variable	Effect Size
Small Effect	
Activity Counts	(0.22)
Sedentary/Light Activity Minutes	(0.19)
Self-efficacy "Making time" Subscale	(0.07)
Diastolic BP	(0.06)
Medium Effect	
$A1_c$	(0.39)
Self-efficacy "Stick to it"	(0.38)
BMI	(0.36)
Systolic BP	(0.33)
Large Effect	
Moderate Activity Minutes	(0.72)

*Cohen's (1988) 0.10 = small effect; 0.30 = medium effect; 0.50 = large effect

Summary

The study instruments, SEBS, activity monitor, and CGMS, were generally reliable and feasible for use in this physical activity counseling intervention. A few items on the SEBS describe activities more appropriate for young adults rather than older individuals (e.g., exercise before attending parties). A small number of activity monitors failed, but participants were willing to wear the monitors again to prevent data loss. Many participants were uncomfortable wearing the activity monitor next to their skin. The CGMS was well tolerated, reliable, and provided numerous teachable opportunities. Several participants had difficulty remembering to enter event and meter data. Only a few participants had gaps in CGMS graphs and had alarms after failing to enter meter data. Finally, only a few participants found the CGMS sensor uncomfortable to wear although being attached to the monitor was somewhat burdensome.

CHAPTER V

DISCUSSION

Introduction

The purpose of this study was to test the feasibility of an intervention protocol using counseling and CGMS technology to change physical activity behavior in individuals with type 2 diabetes. The results of this study confirm the hypothesis that using CGMS with counseling in a nurse-directed intervention was feasible and more effective at increasing physical activity than standard diabetes education. In this final dissertation chapter, the findings will be discussed according to each study hypothesis and placed in context of relevant published results. Additional areas to be discussed will include any unexpected findings, study limitations, nursing implications, and directions for future work.

Research Hypotheses

Hypothesis 1: Participants in the intervention group will have higher self-efficacy scores, lower blood pressure, and higher activity counts than those in the control group.

Compared with changes found in the control group and pre- to post-intervention, participants receiving the nurse-directed counseling intervention had more confidence in their ability to stick to a regular physical activity regimen, lower systolic BP, and increased activity counts with less time spent in light activity and more time spent in moderate level activity. The findings of this study are similar to those of other studies on individuals with type 2 diabetes in which individualized, theoretically derived interventions were shown to significantly decrease BP (Kirk et al., 2003; Tudor-Locke, 2002), and increase physical activity levels (Di Loreto et al., 2003; Kirk et al., 2003;

Tudor-Locke, 2002). In contrast to this study, the control groups in those studies were not given diabetes education, but were given either routine medical care (Di Loreto et al., 2003), an exercise leaflet (Kirk et al., 2003), or no information (Tudor-Locke, 2002). Providing educational information alone (e.g., leaflets) is well known to be insufficient to change behaviors in individuals with type 2 diabetes (Brown, 1988, 1990; Padgett et al., 1988). In contrast, both groups in this study received standard diabetes education, based on essentials of the ADA curriculum, which includes diet, exercise, glucose monitoring, and foot care along with behavioral counseling strategies, such as goal setting. Therefore, this study's significant findings demonstrate the specific contribution of the physical activity counseling using CGMS in comparison to a standard ADA education.

Self-efficacy

The confidence to "Stick to" a regular physical activity regime increased significantly relative to baseline in individuals in the intervention group, but their confidence to "Make time" for regular physical activity did not change over the 8 week study period. The former increase in confidence was significantly greater than that for the control group. The confidence of the control group to "Stick to" a regimen did not improve and confidence to "Make time" actually decreased significantly relative to baseline. A possible explanation for the non-significant change in confidence to "Make time" for physical activity among intervention participants is that after engaging more frequently in physical activity, they had become more aware of the difficulties in finding time for it. In contrast, a possible explanation for the significant decrease in confidence to "Make time" for physical activity among control group participants is that they realized

they had not made a behavioral change by starting the walking plan that was given to them during the diabetes education session.

These results are difficult to compare to those of other studies, since very few intervention studies in individuals with type 2 diabetes have measured exercise self-efficacy and exercise levels over time (Allen, 2004). However, a recent study reported that a physical activity intervention targeting individuals with type 2 diabetes significantly increased self-efficacy (both "Making time" and "Resisting relapse" for regular physical activity) at 8 weeks and 6 months (Van Sluijs, Van Poppel, Twisk, Brug, & Van Mechelen, 2005). However, physical activity levels were not measured in that study.

Systolic Blood Pressure

The systolic blood pressure of participants receiving the CGMS-based physical activity counseling intervention improved (7 mm Hg, SD ±16) relative to baseline despite an absence of significant changes in anti-hypertensive medications. At baseline (pre-intervention), orthostatic BP measurements were performed to screen patients who might have significant autonomic neuropathy. Post-intervention BP readings were obtained in a seated position. As a result, data analysis was conducted by comparing BP from a supine position (pre-intervention) versus BP in a seated position (post-intervention). This may have influenced the magnitude of the reported changes in blood pressure over time. Despite the different positions during BP measurement, intervention group participants still had significantly lower systolic BP when compared to the control group pre- to post-intervention.

In studies using behavioral counseling to influence physical activity in people with type 2 diabetes, the degree of BP changes pre- to post-intervention were varied. Systolic

BP decreased 10.5 mm Hg over 16 weeks (Tudor-Locke, 2002), whereas systolic BP fell 3.7 mmHg over 6 months (Kirk et al., 2003) and 6.4 mm Hg over a 2-year period (Di Loreto et al., 2005). The greater decrease in systolic BP found in the present study may be related to its shorter intervention period similar to Tudor-Locke (2002) or to the influence of BP measurement methodology (lying pre-intervention to sitting post-intervention).

A meta-analysis of 54 randomized trials showed that mean blood pressure decreased 3.8/2.6 mm Hg in hypertensive individuals after aerobic exercise (Whelton, Chin, Xin, & He, 2002). Another meta-analysis of 16 walking studies found that blood pressure decreased on average 3/2 mmHg in normotensive and hypertensive patients (Kelley, Kelley, & Tran, 2001). In both meta-analysis, the majority of individual studies reported BP reductions were insignificant. However, most studies had small sample sizes and lacked sufficient power. By quantitatively combining individual study outcomes in a meta-analysis, the small BP changes were significant (Kelley et al., 2001; Whelton et al., 2002). The UKPDS (N=4,801) reported that a lower blood pressure (144/82 mm Hg compared with 154/87 mm Hg) over 8.4 years substantially reduced the risk of microvascular disease, stroke, and deaths related to diabetes, but not myocardial infarction (UKPDS, 1998). A further analysis (n=3,642) of the relation between systolic blood pressure over time and the risk of macrovascular or microvascular complications showed the incidence of clinical complications was significantly associated with systolic blood pressure (Adler et al., 2000). Each 10 mm Hg decrease in systolic blood pressure was associated with reductions in risk of 12% for any complication related to diabetes (95% confidence interval 10-14%, $P<0.0001$), 11% for myocardial infarction (7% to 14%, $P<0.0001$), and 13% for microvascular complications (10% to 16% $P< 0.0001$). Therefore,

a 10 mm Hg systolic BP change may be considered clinically significant in individuals with type 2 diabetes. In the current study, BP changes in the intervention group (-7 mm/Hg ± 16) trended towards significance (p=0.05). Future studies using BP as an outcome need larger sample sizes powered to detect small-moderate changes in BP.

Activity Counts

Although no participant in either group reached the ADA and American College of Sports Medicine's recommended 30 minutes of moderate level physical activity per day, significant differences were found over time within- and between-groups. By the end of the 8-week study period, objective measures showed that participants in the intervention group relative to baseline spent less time at sedentary/light activity levels, spent more time at moderate activity levels, and overall increased the number of activity counts. It is unclear why individuals did not reach the recommended 30 minutes of physical activity per day. One possibility is that participants engaged in activities not captured by the activity monitor such as bicycling, weight lifting, and swimming. Several participants in the intervention group set goals for these types of activities. However, only a few subjects recorded bicycling, weight lifting, or swimming on the activity monitor log. To prevent possible data loss in future studies, more emphasis needs to be placed on instructing participants to record all activities on the activity monitor log and/or use a subjective measure to capture all activities. Kirk et al. (2003) supplemented activity monitor findings with a subjective measure, the 7-day physical activity recall (Sallis et al., 1985). Both measures in Kirk's et al. (2003) study showed a significant increase in activity levels for intervention group participants. However, the activity monitor data was reported in counts

per week and the 7-day recall data in minutes per week thereby making a direct comparison of both measures difficult.

Two studies have used accelerometers to objectively measure physical activity in people with diabetes in ambulatory settings (Keyserling et al., 2002; Kirk et al., 2003). Direct comparison of results among studies is inappropriate due to differences in ActiGraph equipment and recording techniques.

In the study by Kirk et al. (2003) accelerometers were worn on the leg (instead of the waist as in this study). Current recommendations for accelerometer placement are at a participant's trunk on either side, but at a consistent location for all participants throughout a study (Ward, Evenson, Vaughn, Rodgers, & Troiano, 2005). Placement on the trunk is preferable in order to take full advantage of calibration studies used to derive equations for interpreting accelerometer output.

Keyserling et al. (2002) used a different type of accelerometer and reported outcomes as total energy expenditure (instead of activity counts/minutes in this study). The ActiGraph accelerometer used in this study does not report energy expenditure. Since Keyserling's et al. (2002) study was published, problems have been reported in the accuracy of equations used to predict overall energy expenditure by accelerometry (Ward et al., 2005). Therefore, activity counts were not converted to energy expenditure in this study. Studies using the current accelerometer recommendations are needed (Ward et al., 2005) to allow accelerometer data to be compared among studies in people with diabetes.

Unexpected Findings

Similar to the findings in research hypothesis 1, secondary outcomes of $A1_c$ and BMI decreased significantly from baseline in the intervention group, but not in the control

group. The secondary findings of this study are consistent with two behavioral physical activity studies in which the intervention group significantly decreased $A1_c$ (Di Loreto et al., 2003; Kirk et al., 2003) and BMI (Di Loreto et al., 2003).

Hemoglobin $A1_c$

Although $A1_c$ decreased relative to baseline for both groups, this improvement was significant only in the intervention group. Additionally, this decrease in $A1_c$ was significantly greater in the intervention than in the control group. In contrast, other physical activity studies have shown lower effects on $A1_c$ levels in individuals with diabetes. In studies that provided physical activity counseling and used behavioral strategies in individuals with type 2 diabetes, Kirk et al. (2003) reported a -0.31% $A1_c$ change over 6 months and Loreto et al. (2003) showed a -0.60% decrease in $A1_c$ over 2 years.

The large decrease in $A1_c$ (1.16%) found in the intervention group may have resulted not only from the physical activity counseling, but also from the dietary counseling provided. All participants (both intervention and control group) in this study received individualized dietary education based on a portion of the ADA curriculum. Intervention group participants received dietary education when large spikes in glucose levels were seen on individualized CGMS graphs. Dietary changes were not assessed in the current study because of the primary focus on testing a physical activity intervention. However, if $A1_c$ is a primary outcome of future physical activity studies, it will be important to asses the influence of dietary counseling on the magnitude of change in $A1_c$ levels using dietary food recall evaluations.

BMI

For participants receiving the CGMS-based physical activity counseling intervention, BMI decreased significantly over the 8 week study period. These results are similar to Loreto's et al. (2003) in which BMI decreased 0.4 kg/m^2 in people with type 2 diabetes receiving physical activity counseling although the study duration was two years and not two months. In contrast, no significant differences were reported in BMI or weight in other physical activity studies using behavioral counseling strategies in individuals with type 2 diabetes (Keyserling et al., 2002; Kirk et al., 2003; Tudor-Locke, 2002). The lack of differences in BMI results may be attributed to several causes. Unlike other similarly designed physical activity studies (Di Loreto et al., 2003; Keyserling et al., 2002; Kirk et al., 2003), participants in this current study were not taking insulin which can cause difficulty losing weight. Next, differences in the type of physical activity intervention in comparison to the current study may have caused the lack of significant BMI changes. Lastly, it is unknown if the effects of variables not measured in this study such as dietary changes including portion control, better food choices, fewer high energy density foods, or decreased appetite and improved mood related to increase physical activity may have contributed to the significant decrease in BMI.

Summary

This is the first study to examine the use of CGMS technology in a physical activity counseling intervention for individuals with type 2 diabetes mellitus. The key finding of this study was that physical activity counseling using CGMS was more effective at increasing physical activity than standard diabetes education and may reduce risk factors for diabetes-related complications. The intervention group receiving the CGMS

counseling had significant findings both in change from baseline and in comparison to the control group with an increase in self-efficacy and moderate activity minutes (with a corresponding decrease in light activity minutes) and a decrease in systolic blood pressure, $A1_c$, and BMI. Total activity counts were significantly different within the intervention group pre- to post-intervention. The control group had no significant changes in any of the parameters with the exception of a decrease in one measure of self-efficacy.

Technology innovation is expanding at a rapid rate and CGMS is one of the newer forms of technology for managing patients with diabetes mellitus. It can be expected that continuous glucose monitoring will be widely available and, based on other types of medical technology (e.g. glucose meters), will likely become less expensive in the future. The CGMS has most frequently been used to adjust insulin doses in people with type 1 diabetes. The results of this study show that it is feasible and beneficial to use CGMS in counseling individuals with type 2 diabetes thereby expanding the current use of this technology. Although intervention group participants did not reach the recommended 30 minutes of physical activity most days per week, this 8 week study adds to the growing body of research demonstrating the effectiveness of using behavioral strategies to change physical activity behaviors. The CGMS-based physical activity counseling intervention is relatively brief (90 minutes), effective, and useful tool for nurses in an ambulatory setting.

Hypothesis 2: Self-efficacy will be associated with change in activity counts, BP, and demographic variables.

Self-efficacy "Stick to it" correlates with moderate activity minutes. This is the first study to examine the relationship of self-efficacy to an objective measure of physical activity in individuals with type 2 diabetes. The study findings add to the results of

previous diabetes studies that show a correlation between self-efficacy and self-report of exercise and exercise adherence (Boykin, 1996; Glasgow et al., 1989; Kavanagh et al., 1993; Ludlow & Gein, 1995; Padgett, 1991; Plotnikoff et al., 2000; Skelly et al., 1995). "Stick to it" self-efficacy and moderate activity minutes significantly increased in the intervention group pre- to post-intervention. Moreover, the changes in pre- to post intervention scores for both self-efficacy "Stick to it" and moderate activity minutes were significantly correlated. The significant correlation between "Stick to it" self-efficacy and minutes of physical activity is similar to the relationship between self-efficacy and exercise behavior shown in several studies (Boykin, 1996; Glasgow et al., 1989; Kavanagh et al., 1993; Ludlow & Gein, 1995; Padgett, 1991; Plotnikoff et al., 2000; Skelly et al., 1995). Similarly, self-efficacy predicts exercise behavior when analyzed among several self-management behaviors (diet, medications, glucose monitoring, etc) (Boykin, 1996; Glasgow et al., 1989; Kavanagh et al., 1993; Ludlow & Gein, 1995; Padgett, 1991; Skelly et al., 1995). Since only one variable in the current study correlated with self-efficacy, a predictive analysis was not conducted.

Self-efficacy "Making time" does not correlate with moderate activity minutes. Self-efficacy to "Make time" for regular physical activity decreased significantly from pre- to post-intervention among control group participants. In contrast, self-efficacy to "Make time" for physical activity did not change significantly among the intervention group participants over the same period. No significant relationship was found in either group between the changes in pre- to post-intervention scores for self-efficacy "Making time" and for moderate activity minutes. It is difficult to discern whether the lack of correlation

between “Making time” self-efficacy and physical activity was due to the type of counseling, small sample, or scale issues.

The lack of correlation between “Making time” self-efficacy and physical activity may be due to a scoring discrepancy between the original SEBS scale and the most recent version of the scale found on Dr. Sallis’s, the author, website (www.drjamessallis.sdsu.edu). The researcher followed Dr. Sallis’s recommendation and used the most recent version of the scale with the new scoring method (J. Sallis, personal communication, December, 14, 2002) (Appendix F). Specifically, the scoring recommendations reduced the “Making time” subscale from 7 items to 4 items and added one new item “attend a party only after exercising.” The new SEBS scale needs further instrument validity and reliability testing before using it in future studies.

Another possibility for the lack of correlation between “Making time” self efficacy and physical activity might be due to this study’s small sample. In a larger study of 396 individuals with type 2 diabetes, hypertension, and/or hypercholesterolemia, self-efficacy increased significantly on both subscales, “Making time” and “Resisting relapse,” among intervention group participants at 8 weeks and 6 months while receiving physician counseling with two booster phone calls by a physical activity counselor in a primary care setting (Van Sluijs et al., 2005). At 1 year, there was no difference between the intervention and control groups on either self-efficacy scale. However, in a subgroup analysis the effect of the intervention on “Resisting relapse” but not “Making time” was significant for the inactive participants at one year (according to CDC/ACSM guideline for regular physical activity). In contrast to the current study, the actual amount of physical activity was not measured. Unfortunately, a subgroup analysis of the association of age

with the intervention was not reported. It is possible that older adults have more time than younger adults with busy schedules. Further study with a larger sample is needed to examine participants' confidence to "Make time" for physical activity and the effect of different patient characteristics (e.g. age). Also, intervention group participants might be more likely to increase their confidence to "Make time" for physical activity if counseling included more emphasis on integrating physical activity into busy schedules. Lastly, the CGMS-based intervention may be strengthened by the combination of physician and educator counseling in future studies.

Temporal relationship of self-efficacy and physical activity. It is unknown whether the association between moderate activity minutes and "Stick to it" self-efficacy would continue over time. Very few intervention studies have examined whether self-efficacy and physical activity increase over time and if these two variables are temporally associated. In similarly designed physical activity studies, strategies used to counsel participants were derived from information sources known to increase self-efficacy, performance accomplishment, vicarious experience, verbal persuasion, and physiological feedback (Di Loreto et al., 2003; Kirk et al., 2003; Tudor-Locke, 2002). Although these studies used cognitive behavioral skills and techniques when designing the counseling strategies, self-efficacy was not actually measured. A recent study in which primary care physicians counseled individuals with type 2 diabetes on physical activity reported that self-efficacy significantly increased at 8 weeks and 6 months (Van Sluijs et al., 2005). However, physical activity was not measured, preventing an analysis of the relationship among self-efficacy and physical activity behavior.

Three intervention studies involving exercise in structured programs examined self-efficacy and exercise over time and had mixed results (Glasgow et al., 1992; Rubin et al., 1989; Sadur et al., 1999). One study showed that self-efficacy and amount of exercise increased from baseline to 6 months (Rubin et al., 1989), and two studies reported no significant increase in self-efficacy or exercise from baseline to 6 months (Glasgow & Osteen, 1992; Sadur et al., 1999). The interventions in these three studies were dissimilar to the current study intervention making the comparison difficult. Rubin et al. (1989) study involved a week long diabetes education program, while Glasgow et al. (1992) evaluated a 10 session diabetes education program, and Sadur et al. (1999) examined 2 hour monthly group diabetes education sessions directed by an allied health care team. Prior research indicates the importance of self-efficacy as a mediator of behavior change in individuals with diabetes (Plotnikoff et al., 2000). However, theory building is limited when both self-efficacy and outcome variables such as physical activity are not measured. Because of the short duration of this feasibility study, it is unknown whether the association between physical activity and self-efficacy would continue over time. Previous studies have shown that the strength of the relationship between self-efficacy and exercise behavior may remain stable (Kingery & Glasgow, 1989) or vary over time (Skelly et al., 1995). Booster sessions were not offered in any of these studies. However, two studies (Glasgow et al., 1992; Sadur et al., 1999) had interventions with multiple educational contact points. Participants in Glasgow et al. (1992) study received weekly meetings for eight weeks followed by two meetings held at 2-week intervals and twice weekly group walking sessions. In Sadur et al. (1999) study, participants were contacted by a nurse every three days to twice a month and interacted with a dietician, pharmacist, and behaviorist 1-4

times during the 6 month period. To clarify the temporal relationship between self-efficacy and physical activity, a longitudinal study is needed using the physical activity counseling intervention.

Association of self-efficacy, activity counts and blood pressure. The anticipated association between the changes in pre- to post-intervention scores for self-efficacy, activity counts, and BP was not significant. Specifically, it was hypothesized that Δ self-efficacy would be associated with higher activity counts, Δ activity counts with decreased BP, and Δ self-efficacy with decreased BP. The lack of association with total activity counts might be explained by the large variability in total activity count data. The data for moderate activity minutes had less variability than activity minutes and were a more reliable measure of physical activity. In future studies, moderate activity minutes might be a more useful measure than activity counts. No association was found between change in self-efficacy and BP, nor was any previous research found that examined this relationship. The relationship between physical activity self-efficacy and blood pressure/hypertension needs further exploration in a larger sample of individuals with type 2 diabetes.

Correlation of self-efficacy and demographic variables. Race, but not ethnicity, was the only demographic variable associated with change in self-efficacy from pre- to post-intervention. Since only 5 participants were African American, this relationship could not be statistically explored. This association between race and self-efficacy raises questions about the validity of the self-efficacy construct in minority populations and/or a possible anomaly resulting from a small sample. The association between self-efficacy and self-management behaviors was addressed in a recent study (Sarkar, Fisher, & Schillinger, 2006) of a large (N=408) as well as ethnically and racially diverse sample (25% African

American, 18% Asian/Pacific Islander, 42% Latino or Hispanic, and 15% white) of individuals with type 2 diabetes. After adjusting for race, the authors found a significant association between increasing self-efficacy scores and self-management of diet (r= 0.15, SD 0.07-0.23), exercise (r=0.09, SD0.01-0.18), self-monitored blood glucose levels (SMBG) (r=1.15, SD 1.10-1.42), and foot care (r=1.24, SD 1.04-1.33). However, different instruments were used to measure self-efficacy and self-care activities than in the current study. To determine reliability of the SEBS in minority populations, future study is needed with a larger sample.

Self-efficacy was not correlated with the demographic variables of gender, ethnicity, marital status, and SES. Prior research has produced mixed results for the association of self-efficacy with demographic variables (Glasgow et al., 1989; Kavanagh et al., 1993; Kingery & Glasgow, 1989; Padgett, 1991). The current study's finding of a lack of association between self-efficacy and demographic variables is similar to that of Kavanagh et al. (1993). In contrast, a positive association was found in two studies between self-efficacy and demographic variables (Glasgow et al., 1989; Kingery & Glasgow, 1989). Demographic variables have not consistently predicted exercise levels or self-care behaviors (Glasgow et al., 1989; McCaul et al., 1987; Plotnikoff et al., 2000; Rubin et al., 1989; Skelly et al., 1995). However, the small sample in the current study might have limited the ability to detect a relationship among self-efficacy, demographics, and activity levels. Further study with a larger sample is needed to explore any relationships amongst these variables.

Unexpected Finding

Change in moderate activity minutes significantly correlated with change in $A1_c$. Previous studies have shown that moderate intensity exercise decreases $A1_c$ thus making this correlation likely. For example, a meta-analysis of 14 studies on the effect of structured, moderate intensity exercise regimens in people with type 2 diabetes found $A1_c$ decreased 0.66% in the intervention group relative to that in the control groups (Boule, Haddad, Kenny, Wells & Sigal, 2001). Furthermore, a subgroup analysis of diet and exercise studies revealed an average $A1_c$ difference between groups of 0.76. Therefore, a negative correlation between $A1_c$ and moderate activity minutes should be hypothesized in future, larger studies to further explain the relationship between these variables.

Summary

A key finding of this study is the relationship between "Stick to it" self-efficacy and minutes of moderate activity. Self-efficacy is a major construct in Bandura's Social Cognitive Theory (Bandura, 1997), which provided the basis for the theoretical framework used to develop the CGMS-based physical activity intervention. Self-efficacy is theorized to be a key factor in predicting whether people with type 2 diabetes will engage in physical activity behavior. The results of this study support the hypothesized relationships; the self-efficacy and physical activity levels of individuals in the intervention group were greater than those in the control group (Hypothesis 1), and change in "Sticking to it" self-efficacy was associated with change in physical activity levels (Hypothesis 2). Future research is needed to determine if the theoretical framework for the intervention is effective for managing clinical outcomes over a longer period of time.

Research Question 3: What are the most effective recruitment, retention, and screening strategies?

Screening and Recruitment

Recruitment proved to be one of the most challenging components of this study which targeted a population of sedentary individuals with poorly controlled type 2 diabetes. A period of 6 months was originally anticipated to be sufficient to enroll 50 participants. However, the recruitment period lasted 16 months. Several lessons were learned that may inform successful participant recruitment for future physical activity studies.

Restrictive inclusion criteria. The inclusion criteria targeted participants that were sedentary (exercise < 2 days per week), at high risk for diabetes related complications ($A1_c$ > 7.5%), and taking only oral glycemic agents. However, these criteria resulted in limiting study recruitment. The two most limiting inclusion criteria were $A1_c$> 7.5% and oral glycemic agents.

The inclusion criterion of an $A1_c$ >7.5% was designed to show an effect in uncontrolled participants with type 2 diabetes in a smaller study. However, a large number of interested individuals with diabetes did not meet this inclusion criterion (n=106). In contrast, most potential participants met the inclusion criterion of engaging in regular physical activity <2 days per week, and very few were excluded for this reason (n=17). This observation is consistent with larger studies reporting that the majority of individuals with diabetes do not engage in regular physical activity (Plotnikoff et al., 2000). However, ADA guidelines support that all individuals with diabetes, regardless of $A1_c$ level, might reduce risk factors associated with diabetes related complications by increasing levels of

physical activity. In terms of clinical outcomes, $A1_c$ was not a strong predictor of cardiovascular risk in the UKPDS (1998). Therefore, an inclusion criterion of $A1_c \geq 7.0$ would permit greater participation of sedentary individuals with type 2 diabetes not meeting the glycemic goals set by the ADA ($A1_c < 7.0\%$) or the American College of Endocrinology ($A1_c < 6.5\%$). Although a lower $A1_c$ inclusion criteria might limit the ability to show an effect, other physiological variables known to improve with physical activity, such as cholesterol, triglycerides, markers of inflammation such as C-reactive protein, BP, and BMI, could be measured to provide a more complete picture of the effect of physical activity interventions on health risks (Roberts, Won, Pruthi, Lin, & Barnard, 2006). Moreover, psychological benefits such as decreased depression and anxiety and/or improved sleep and quality of life may provide further evidence of the effectiveness of physical activity interventions.

The inclusion criteria requiring participants to be diet controlled or taking only oral glycemic agents was set to avoid the confounding influence of short acting insulin on CGMS interpretation. Short acting insulin causes glucose levels to decrease making it difficult to distinguish the effects of physical activity on glucose levels. Unfortunately, initial recruitment activity focused on two hospital-based Endocrinology practices which had a greater percentage of insulin using patients than patients typically found in primary care practices. Although only 10 participants were excluded because of insulin use, Endocrinology providers reported that many more participants using insulin were not referred to the study. It might be possible to include patients using long-acting insulin administered daily at bedtime without confounding interpretation of CGMS graphs. However, a pilot study would be needed to determine the interpretability of CGMS graphs

of participants using long-acting insulin. Since endocrinology practices generally have more patients with $A1_c$'s < 7.0% on insulin, recruitment efforts that concentrate on primary care practices may provide more eligible participants.

Referral problems. Recruitment was impaired by several unanticipated challenges at the primary study site and by an inability to garner support from affiliated primary care clinics. Both situations offered many lessons that provide insights for future recruitment efforts.

The initial recruitment plan relied heavily on referrals from endocrinologists and diabetes educators at the primary research site, Baystate Health System's Division of Endocrinology. Although most referrals from health care professionals over the 16-month recruitment period came from endocrinologists and an endocrinology nurse researcher (Table 31), 4 of 6 endocrinologists and 2 of 3 diabetes nurse practitioners left the primary site practice shortly after the study began, thereby slowing the referral rate. At the same time, a large trial relying on referrals from diabetes educators began recruiting the same population of individuals with type 2 diabetes at the primary research site. After recognizing problems with heavy reliance on a single research site, the researcher added a secondary research site in a different geographical region, resulting in several eligible participants. Implementing this strategy at the outset of future studies would likely decrease the recruitment period but increase research costs.

Staff members at BHS primary care clinics were unable to provide anticipated referrals for several reasons. These included transportation issues from the primary care clinic (High Street Clinic) to the primary research site, overwhelming provider issues with patient care responsibilities and recruitment efforts for other research studies (Mason

Square Clinic), and lack of interest in this research study (Brightwood Clinic). To address these issues, informational meetings and focus groups could be conducted at each site for health care professionals and office staff before starting a study. The informational meeting could introduce the study and researcher to clinic staff and generate interest in the project. Focus groups could identify problems with referring patients (i.e., transportation), and generate ideas for creating effective recruitment plans at that site. To assist providers with overwhelming patient care responsibilities, the researcher could ascertain any diabetes-related needs at the clinics and offer expertise and volunteer services, if appropriate. Another recruitment strategy would be to foster relationships at the clinics by hiring a case manager from within the clinics to conduct recruitment. Similarly, study protocols implemented at the primary care clinics would eliminate transportation issues to the primary research site and increase contact with clinic personnel. Unfortunately, space in busy primary care clinics is often limited. This last strategy might necessitate finding a sponsor within the health care system to advocate for the researcher, using space after clinic hours, and/or sufficient study funds to rent space.

Similar recruitment problems were reported for a large clinical trial that required a 2.0 full-time-equivalent people at each study site to obtain 135 participants over a 3-year period (Rubin et al., 2002). Although this study conducted by the Diabetes Prevention Program (DPP) Research Group targeted individuals with pre-diabetes, the intervention required behavioral change including 30 minutes of exercise most days of the week. The report identified low referrals from health care providers, but high returns on money spent in advertising. Similarly, newspaper articles were the most successful form of advertisement for this current study. Newer recruitment methods for conducting trials

within the diabetes population are needed. Prior to undertaking a larger research trial, a review of the latest literature may offer other successful strategies.

Minority recruitment. The enrollment goal of 12 African Americans and 12 Hispanic or Latino was not met. Major challenges were lack of referrals from primary care clinic providers serving these populations, transportation problems to the primary research site, and the English language requirement. The reason for low recruitment of racial/ethnic minority participants in other studies has been attributed to such barriers as child or elder care, time of visits, meals, fear of large institutional settings, and distrust of research and medical procedures (Freedman et al., 1995; Fujimoto, 1998). In the current study, the researcher did not have a direct opportunity to assess the barriers to potential participants. However, a review of recruitment issues with a Latina CDE employed at a BHS primary care clinic that serves a large minority population revealed that all of the issues identified in Fujimoto (1998) and Freedman's (1995) study were encountered during her attempts to recruit for this study. Additionally, participants speaking English as their second language were intimidated by the possibility of experiencing language barriers during the course of the study.

Successful recruitment strategies reported by the DPP (Rubin et al., 2002) were direct mail recruitment for African Americans (39.8%) and phone recruitment for Hispanic Americans (17%) and Asian Americans (13.8%). Although a general announcement of research studies at the primary research site was used in a direct mailing to all patients with a diagnosis of type 2 diabetes at the primary research site, it did not specifically target minority populations. A strategy that might increase the effectiveness of direct mailing would be to purchase mailing lists based on zip codes of minority neighborhoods.

Currently, lists of minority phone numbers are not available to the researcher but may be available to others within the Hispanic community.

Other minority-specific strategies include grassroots outreach to communicate the study message through individuals and community groups with built-in access to a specific population (Matthews, 2005). Often grassroots individuals are highly skilled health care professionals, clergy, or members of local community groups (Matthews, 2005). Examples of grassroots organizations are YMCA's, churches, cable television access and community radio. Several unsuccessful attempts at grassroots efforts were made in the current study. Posters and fact sheets were delivered to the Martin Luther King Community Center in Springfield. Unfortunately, no individuals were recruited through this approach. An African American social worker who participated in this study offered to place study brochures in her church and talk to members about the study. However, a follow-up phone call revealed that the participant had not found the time to deliver the posters. A multilingual Latino diabetes educator assisted with recruitment from one primary clinic that serves large numbers of Latinos, but as was discussed above several issues including transportation prohibited more successful referrals. Future studies should budget for minority recruitment strategies before initiation of the study. These strategies should include focus groups to identify best strategies for marketing the study to minorities, locating sponsors at health clinics serving minority communities, developing community contacts, providing paid transportation to study sites, and consulting with experienced minority-research recruiters.

Advertisement. This study's most successful form of recruitment, particularly for older individuals, was media advertisements, especially newspaper articles. Key in the

success of this strategy was support from the public relations officers at primary and secondary research sites. A similar strategy was successful in a recent osteoporosis exercise intervention trial (Ott, Twiss, Waltman, Gross, & Lindsey, 2006), which used newspaper, feature articles and paid public service announcements at four study sites and cost an average of $35.00 per enrolled participant (N=249).

In other studies direct mail has been the most successful recruitment strategy. Participants recruited in the DPP study (N= 3,234) were more likely to respond to direct mail than to radio, TV, posters, or newsletters (Rubin et al., 2002). Similarly, direct mailings were the most successful recruitment strategy for a physical activity intervention trial conducted in primary care practices (N=874) costing $58.00 per participant (Margitic et al., 1999). In the current study, direct mail to approximately 200 individuals at the primary research site was unsuccessful for several reasons, including poor timing (patients with type 2 diabetes were upset after being transitioned to primary care providers after 4 endocrinologists and 2 nurse practitioners left the primary research site practice) and a non-specific study message. Focus groups have been used to develop and test study recruitment messages used in print materials (Matthews, 2005). Direct mailings might have been more successful if relevant messages derived from focus group analysis had addressed issues important to the study population such as perceived burdens of the study, typical health behaviors, trust, and appropriate motivators for participating (Matthews, 2005). In this small 8 week feasibility study, participants did not report a high study burden or issues with trust and data were collected on retention strategies. However, a marketable recruitment message should be developed before undertaking a larger study. This recruitment message should be pilot tested to increase the likelihood of a successful

message and reduce costs if refinements are required. Additionally, branding any future trials with a catchy title with attractive images might help to create awareness for patient and health care providers of the study's unique features and generate a competitive edge for recruiting participants when several trials are in progress (Matthews, 2005). It is possible that race/ethnicity specific branding might also be an effective recruitment strategy.

Another method for informing potential participants about the study might be to use the internet of e-mail. A global e-mail to all employees at the primary research site resulted in 2 research participants. This strategy may work well in other health care institutions or larger companies. Moreover, an Internet recruitment site with the branding logo and study information could be set up and linked to the hospital's web page. However, these strategies may have a limited recruiting efficacy amongst lower SES participants that have no access to the internet.

Retention Strategies

Several retention strategies used in this study were effective, with only one participant lost to follow-up and another 5 non-completers reporting injuries or illness. Participants reported that the most effective retention strategies were reminder phone calls before visits and meeting their needs for wanting education and encouragement to help with the management of diabetes. Another effective strategy that influenced participants' decision to continue the study was seeing results/better control of diabetes via glucose meter results. Seeing positive outcomes (outcome expectancies) has been theorized by Bandura (1997) to reinforce one's self-efficacy. Outcome expectancies are beliefs that a certain consequence (improved diabetes control) will be produced by personal action

(increased physical activity). Although outcome expectancy was not measured in this study, it may be an important variable to measure in future studies. The high effectiveness of these three strategies, 1) reminder phone calls, 2) providing education and encouragement, and 3) seeing better diabetes control, in retaining participants throughout the study indicates that they should be adopted in future studies.

An unexpected finding was that the researcher-participant relationship was cited by several participants as an important reason for finishing the study. The researcher sought to establish the participants' trust by informing them of her credentials as a diabetes nurse practitioner at a large health care system endocrinology practice and by providing clinically competent education derived from the ADA. Another trust-building strategy was to consciously use respect, friendliness, enthusiasm, encouragement, and caring during education and data gathering sessions. In future studies, questions about specific qualities of the researcher-participant relationship should be explored to determine which aspects most influenced retention.

Another unexpected finding was that monetary reimbursement for time and travel was not an important reason for completing the study. The majority of participants were white and middle-class, as indicated by a middle ranking on the Hollingshead socioeconomic score. In future studies with a sample more representative of poor and minority populations, reimbursement for time and travel may be more important. Another successful retention strategy with poor and minority populations might be to offer door prizes of grocery and gas gift cards (Loftin, Barnett, Bunn, & Sullivan, 2005).

Other retention strategies reported effective with sedentary minority populations involved in a physical activity intervention study are flexible scheduling and frequent

contact (Staffileno & Coke, 2006). In the current study, attempts were made to schedule appointments in the evenings and weekends to accommodate participant's schedules, but no information was gathered on either of these strategies. Frequent contact was an inherent part of the study protocol, which required 5 researcher-participant interactions in an 8-week period. In future studies, data should be collected in a survey at the end of the study on the importance of these strategies.

The planned retention strategy of providing food and drink at counseling sessions was attempted for the first 3 months of the study. During this period, healthy snacks of vegetables, whipped low-fat cheese dip, low fat crackers, diet drinks, water, coffee and tea were provided to participants. However, providing food and drink became too time consuming, expensive, and had to be discontinued when counseling sessions were moved from a large office space into clinical exam rooms. It is worth noting that the majority of participants were not interested in the food as judged by the leftovers. Perhaps a less complex and more practical alternative might be to give participants pre-packaged diabetes-related food, snack bars, sugar free candy etc. that can be taken home.

Summary

To maximize participant involvement in a physical activity trial, several effective screening, recruitment, and retention, efforts were analyzed. One of the most important findings to shorten the recruitment period is to consider reducing the $A1_c$ inclusion criterion from >7.5% to ≥7.0%. However, reducing the $A1_c$ inclusion criteria will reduce the size of the interventions effect on $A1_c$ (moderate effect in current study). Moreover, the rate of recruitment might have been greatly improved by hiring staff dedicated to recruiting participants at a minimum of two research sites. Other effective recruitment strategies were advertising through newspapers and featured articles and yet. The already successful strategies of newspaper and featured articles might be enhanced by a marketable study logo and message and might improve the effectiveness and reach of direct mailings. Participants were interested in learning more about diabetes and how to self-manage their diabetes. Therefore, these educational areas may be key messages to use in advertising future studies.

To enhance minority involvement, more preliminary work should be done before the study such as grassroots efforts, focus groups, finding a sponsor at primary care clinics, and hiring a case manager at clinics that serve largely minority populations. Phone calls were a helpful retention strategy, but offering healthful snacks and drinks was impractical. The researcher-participant relationship appears to be important in retaining participants, but more research is needed to define which aspects of this relationship are most beneficial. Other effective retention strategies were flexible scheduling and frequent contact. Overall, recruitment efforts were challenging, yet offered opportunities to try several recruitment approaches.

Research Question 4: Are the monitors (CGMS and activity) and self-efficacy instrument (SEBS) reliable in this study population?

Self-efficacy for Exercise Behavior Scale (SEBS)

SEBS score was based on two sub-scales "Sticking to it" and "Making time". The reliability of post-intervention SEBS scores was high for both subscales but mixed for pre-intervention scores. Specifically, pre-intervention scores had high reliabilities for the subscale "Sticking to it," but low reliabilities for the subscale, "Making time" for regular physical activity. On the "Making time" subscale, one test item ("Attend a party only after exercising") had a low total-item correlation at pre-intervention. In response to this item, verbal comments from participants at pre-intervention indicated that they "didn't attend parties" and 6 participants responded "not applicable." In contrast, post-intervention responses to this item had high total-item correlations and fewer respondents marked "not applicable" (n=4). This discrepancy may have resulted from the researcher's response to participant questions about this test item. The researcher explained that the question pertained to participant's commitment to exercise before attending activities such as a party. Higher pre-item test correlations may have resulted if the researcher instructions were simply to mark the item "not applicable." Additionally, several participants commented at pre-intervention on the item, "Stick to your exercise program when you have excessive demands at work," and 12 participants responded "not applicable." In response to this item, participants stated at pre-intervention that they were retired and therefore, this item was not applicable. Despite the comments about this last item, it had high total-item correlation pre- and post-intervention.

These participant comments about SEBS instrument items raise the issue of its face validity in the older population (57 ±13.5) sampled in this study. The SEBS was initially tested in a college-age sample (Sallis et al., 1988) and has since been shown to be reliable in a sample of middle-aged women (Speck & Looney, 2001). In a study of older adults (55.5 ±9.5) with hypertension, hypercholesterolemia, and/or non-insulin requiring type 2 diabetes, the SEBS was used to evaluate a physical activity counseling intervention administered by Dutch general practice physicians (Van Sluijs et al., 2005). Unfortunately, SEBS validity and reliability data were not reported. One strategy that might validate the SEBS in an older population would be to evaluate the types of activities in which older adults typically engage in before using the SEBS instrument in future studies.

Another validity issue is the term "exercise" used in the SEBS title, stem of questions, and directions. Specifically, its directions instruct participants to think about specific types of exercises like running, swimming, brisk walking, bicycle riding, or aerobic classes when responding to items (Appendix F). Since 2004, the term "exercise" has been replaced in the diabetes literature with "physical activity" to emphasize programs that involve less structured activities that are light to moderate in intensity. However, the SEBS is correlated with participation in vigorous activity (Sallis et al., 1988). Two adaptations might improve the SEBS for use in future physical activity studies. First, examples of vigorous exercise in the instrument directions could be replaced with examples of light-to-moderate intensity activities. Second, the term "exercise" in the title and items should be replaced with "physical activity." These adaptations would require further evaluation of the instrument's validity and reliability but might improve its

congruence with the current emphasis on physical activity rather than exercise in chronic disease research.

The SEBS measures only self-efficacy expectations. However, Bandura (1997) theorizes that two types of expectations influence the cognitive control of behavior: self-efficacy expectations and outcome expectancies. Outcome expectancies are beliefs that a certain consequence will be produced by personal action and were reflected in responses of some participants (13.5%) to the open-ended retention question at the end of the study. Specifically, participants reported that "seeing good results" or achieving "better control" encouraged them to complete the study. These statements reflected information about glucose levels from glucose meter results. Physiological information about short term outcomes such as SMBG and long term outcomes such as $A1_c$, BP, and BMI might also be perceived as outcome expectancies. Future studies should measure outcome expectancies to provide further understanding about the theoretical connections between physical activity behavior and physical activity outcomes.

Activity Monitor

Using activity monitors at pre- and post-intervention proved to be a feasible method for objectively measuring physical activity. This technology provided two major benefits: 1) the ability to quantify moderate activity in minutes per day, allowing comparison with recommended activity levels, and 2) a method for capturing changes in participants' light and moderate activity in minutes per day. In contrast, total activity count data had limited usefulness because of large variability in the data and lack of comparable data from diabetes physical activity studies. However, total activity count data may have more usefulness in the future. Historically, the first published activity monitor study was in

1981, but by 1997 activity monitor use became widely accepted and resulted in numerous publications (Troiano, 2005). Activity monitors are now being used in large population surveillance research studies such the National Health and Nutrition Examination Survey (NHANES) in which 7000 participants wore activity monitors for seven days during the years of 2003-2004 (Troiano, 2005). With the expanding use of this technology, comparing data among populations might be easier and make the interpretation of data more meaningful.

Overall, the majority of participants complied with wearing the activity monitors (Pre- intervention 95%; Post-intervention 91.5%) although some reported discomfort. To enhance adherence with wearing activity monitors, participants were asked to record the time they put on the activity monitor in the morning and took it off at night. This strategy worked well; the majority of participants wore the monitors and completed the activity monitor logs for the expected 7-day period. However, this study identified several issues regarding wearing activity monitors that have not been reported elsewhere. Participants were instructed to wear the activity monitor attached to an elastic belt at their right hip and next to their skin. Many participants reported pinched (34.8%), irritated (30.4%), sweaty skin (19.6%) and had difficulty securing the monitor and belt to their waist (19.6%). These problems might have been due to participants' central obesity that made monitor placement at the waist more difficult. Since the initiation of this study, the manufacturer has released a newer model of the ActiGraph Accelerometer that is 33% smaller and designed to be worn clipped to clothing in the trunk region. This newer monitor has the potential to eliminate several of the wearing issues identified by study participants. Additional advantages of the newer technology include a direct USB connection that

avoids the need for a docking station (located far from the primary and secondary research sites), a rechargeable battery that eliminates the costs associated with disposable batteries and the labor-intense difficulties associated with changing batteries on the older model, and monitor calibration after each use is not necessary (ActiGraph). Cost for the older technology included $275.00 for each monitor, $1000.00 for a docking station, $2,495.00 for a calibrator, and $4.00 for each battery. In contrast, the only cost associated with the newer accelerometer system is $399.00 for each ActiGraph monitor (J. Schneider, personal communication, September 1, 2006).

The activity monitors were generally reliable. Of the 98 weeks activity monitors were worn, only 4 weeks of data were lost due to monitor failure. However, all 4 participants who wore monitors that failed were willing to wear a monitor for another week, preventing any loss of data. The monitors used in this study were 9 years old. With newer technology, failure of monitors might be less likely. However, with any technology data loss is always a potential issue that researchers should consider and plan for when designing studies. Therefore, researchers using newer technologies should evaluate and publish results about monitor-related problems and offer future researchers solutions that can minimize difficulties.

Continuous Glucose Monitoring System (CGMS)

This is the first study that has examined the use of CGMS to change physical activity behaviors in people with type 2 diabetes. Overall, the CGMS technology was easy to use, reliable, and provided many opportunities for teaching participants with type 2 diabetes. However, some technical problems were identified during the study. Although only 2 participants reported difficulty understanding CGMS directions, remembering to

enter events such as meals, exercise, and medications into the CGMS monitor was difficult for many participants (52.4%). In contrast, participants accurately kept a paper log of these same events. In addition, many participants did not enter the required number of glucose readings on days 1 and 4, resulting in several reports with "use clinical judgment" and gaps on one participant's CGMS graph.

In this older population, the type of technology used in this protocol may have accounted for some of the problems with entering events and remembering to enter the minimum number of glucose meter readings. Some of the pilot study data obtained during a focus group offer possible explanations. Three of 7 participants reported difficulties with remembering to enter glucose values and events into the CGMS. One participant attributed this difficulty to cognitive issues following a "heart attack" and further stated "I found it (CGMS) occupying a lot of my time and even then I think I forgot once or twice to enter (events)." Another participant stated "I just figure I'm getting old." Another participant felt they needed time to develop a routine. In the current study, the large percentage of missed CGMS entries in the older half of the cohort (83%) suggests that additional education and reinforcement might be helpful to maximize data collection. In future studies, more emphasis should be placed on educating older participants to enter events and the required number of meter glucose readings into the CGMS monitor. A reminder phone call could be made within the first 12 hours at an anticipated event (e.g., mealtime) following CGMS initiation to reinforce educational messages and to increase the number of events and glucose readings entered into the CGMS monitor.

To date, only one study could be found that identified technical issues in using CGMS (Chico et al., 2003). That study also reported that "some" of its 70 participants

with type 1 and type 2 diabetes failed to initially enter the necessary number of glucose meter readings. This problem was resolved with extra education of participants and researchers. Chico et al. (2003) study participants were younger (age 36.5 ±12 for type 1 diabetes participants; age 58, ±11 for type 2 diabetes participants) than the current study's participants and it was not reported if older participants had more difficulty using the CGMS technology. In the current study, 32 CGMS graphs had "use clinical judgment" messages on study day 1 and 3. This message resulted primarily from insufficient glucose meter entries but interpretability of the CCGM graphs was not compromised. In future studies, more emphasis on entering the 4 glucose meter results every day and a reminder phone call on the first day of monitoring may eliminate this problem.

Other problems Chico et al. (2003) reported were "error" messages after 5 sensor insertions, gaps in CGMS graphs of 28 participants, and transitions between sequential days on the CGMS graphs at midnight (Chico et al., 2003). In contrast, the current study received no "error" messages after sensor insertions, most likely due to improvements in sensor technology since the 2003 study. The transition problem between days on the CGMS graphs was resolved in the Chico et al. study by upgrading to version 1.7a of the CGMS. In the current study, version 3.0c software was used and no day/night transition problems occurred. The high number of gaps on CGMS graphs reported in the Chico et al. study might be related to older software or hardware, earlier versions of the glucose sensor, lack of paired meter readings, or too few glucose meter entries. In the current study, the 5 CGMS graphs with gaps were clearly the result of participants' failing to correctly enter meter glucose readings, or unpaired meter readings (meter reading disagreed with CGMS reading), and in one case the participant turning the monitor off. Once again, this problem

might be resolved with more emphasis on entering 4 glucose meter readings each day and a reminder phone call on the first day of monitoring.

Lastly, Chico et al. reported that non-optimal coefficient correlations were obtained in the first patients studied on at least one of the monitoring-period days. This problem was reportedly resolved by having participants enter 5-6 glucose meter results per day. Similarly, the majority of patients in the current study had missing correlation coefficients. However, in individuals with type 2 diabetes this issue might not be resolved by entering more glucose meter readings. In contrast to individuals with type 1 diabetes, people with type 2 diabetes may not have a greater than 100mg/dL range in glucose values necessary for calculating the correlation coefficient. Therefore, researchers using CGMS in individuals with type 2 diabetes can expect to see "N/A" next to the correlation coefficient on the CGMS report. Most importantly, the data are accurate and can be used for interpretation. This limited comparison of CGMS technical data to one study highlights the need for more reports of issues related to CGMS technology and of solutions that address these difficulties.

Most participants in this study were willing to wear the CGMS again and overall tolerated the procedure well. However, some participants reported minor skin irritation and discomfort, and one reported pain at the sensor site. This finding is similar to that of Chico et al. (2003) who reported 8 of 70 patients with discomfort at sensor sites. Although it is important to prepare participants for the possibility of discomfort at sensor sites, they can be reassured that the degree of discomfort has generally been transitory and not enough to deter individuals' willingness to wear the CGMS again.

Several participants reported difficulty showering with the CGMS. A newer CGMS system, Guardian® RT, is now available and may eliminate difficulties with showering and sleeping. Rather than being attached to the monitor by a cable like the CGMS unit used in the current study, the Guardian® RT sensor and monitor communicate by radio frequency waves when both devices are within 6 feet of each other. In contrast to the CGMS, for which data are downloaded to the monitor, the Guardian® RT system displays glucose levels and graphs on the monitor in real time every five minutes. Moreover, this system has an alarm that can be set by the wearer to alert him/her when glucose levels become too high or too low. This newer sensor system might be more comfortable to wear, but also might present new challenges because of the availability of real-time glucose levels. Since continuous glucose monitoring technology is rapidly advancing, further study is needed to determine the impact of CGMS real-time information on diabetes self-management.

Glucose levels decreased on the CGMS graphs in response to physical activity and were used for counseling participants. These glucose level changes are consistent with reports that moderate exercise significantly reduces blood glucose concentration in individuals with type 2 diabetes (Kang et al., 1999). A recent study reported using CGMS to quantify glucose responses to physical activity (MacDonald, Philp, Harrison, Bone, & Watt, 2006). To determine the efficacy of CGMS to monitor changes in whole-day glucose profiles and to accurately measure glucose levels during moderate exercise, 6 subjects with diabetes and 4 subjects without diabetes were studied under controlled laboratory conditions. The results showed statistically acceptable agreement between the CGMS and venous blood glucose concentrations during moderate exercise in both groups. The results

also showed that a single bout of moderate exercise improved glycemic levels for at least 24 hours in obese individuals with type 2 diabetes (MacDonald et al., 2006). These data support the acceptability of CGMS as a method for detecting changes in glucose levels in response to physical activity. Similar to the role model CGMS data used in this study, Macdonald et al. (2006) showed an approximate 1.5 (venous) -2.5 (CGMS) mmol/L (27 – 45 mg/dl) decrease in glucose concentrations immediately following exercise. However, a greater decline in glucose value (approximately 100 mg/dl) was observed on the role model CGMS graph used for the current study. The difference in the magnitude of decline in Macdonald's et al. (2006) data and the role model data can be attributed to the role model's higher baseline glucose level and/or the use of oral hypoglycemic agents. In future studies, data on changes in CGMS glucose levels after physical activity should be reported.

Glucose level changes in response to eating were also identified on participants' CGMS graphs. During the 90-minute physical activity counseling session, participants were advised to use physical activity to lower glucose excursions observed after meals on the CGMS graphs. Many of these excursions were identified after breakfast or supper. For individuals who do not work, physical activity after breakfast may represent an important opportunity to impact hyperglycemia. In a recent study (Colette et al., 2005), similar dietary glycemic excursions were observed on CGMS graphs of individuals with type 2 diabetes. That study examined postprandial (4 hours after a meal) and interprandial (all times except postprandial period) glucose levels before and at the end of an 18-day calorie-restricted diet. The results indicated that caloric restriction significantly improved interprandial hyperglycemia, whereas postprandial glucose excursions after breakfast did not change (Colette et al., 2005). These observations may have been due to higher insulin

resistance in the mornings from the release of growth hormone, cortisol, glucagon, and epinephrine. Morning postprandial glucose excursions may be decreased by physical activity after breakfast (Poirier et al., 2001) in combination with either eating less food at breakfast or eating food with a lower glycemic index. The CGMS provides a feasible method for observing changes in glucose levels due to dietary and physical activity behaviors. Further research is needed to determine if CGMS in combination with physical activity and dietary counseling is an effective strategy to decrease post-prandial glucose excursions in individuals with type 2 diabetes.

Summary

The SEBS, activity monitor and CGMS were generally reliable for use in a physical activity study. However, several strategies might improve the utility of these instruments in future studies. The SEBS should be adapted to reflect the current emphasis on physical activity instead of exercise. In addition, the specific types of activities in which older individuals engage should be examined to improve the validity of the SEBS in this population. The activity monitors provided useful data for objectively measuring physical activity and for quantifying light and moderate activity in minutes per day. However, the activity monitors did not provide useful total activity count data. Several wearing issues were identified that may be resolved with the newer model activity monitors that are smaller and can be clipped to clothing at the waistline instead of worn next to the skin at the abdomen. The CGMS data provided many opportunities to teach participants about the interaction/relationship between glucose levels, physical activity, and diet in this sample of individuals with type 2 diabetes

The sample of older adults in this study used the paper CGMS logs better than the CGMS monitor to record events such as exercise, meals, and meter glucose values. Participants' ability to correctly use the CGMS might be increased by more education and a follow-up phone call by the researcher. Wearing issues with the CGMS might be resolved with the newer CGMS RT® system that doesn't have a cable connecting the monitor to the sensor. Future studies are needed to examine the reliability and wearability of the new CGMS and activity monitors in this population. Lastly, the CGMS provides a feasible method for examining glucose responses to diet and physical activity and for providing information that might enhance participants' diabetes self-management skills.

Implications for Practice

Nurses and diabetes educators are well positioned to incorporate the CGMS-based physical activity intervention into their practice. Patient education is a primary focus in nursing educational programs and in nursing practice. Therefore, diabetes education using behavioral interventions, such as the CGMS-based physical activity intervention, is a natural extension of nursing practice. Moreover, many diabetes educators complete a certification process that includes extensive education and testing based on the principles of behavioral change. Therefore, nurses are ideally suited to conduct the CGMS-based physical activity intervention.

Successful implementation of the CGMS-based physical activity intervention requires time for inserting the CGMS and behavioral counseling. Physicians providing care for people with diabetes in the U.S. are reimbursed for appointment times averaging 10-20 minutes per visit. In contrast, nurses are allowed more time to spend in patient education. Generally, diabetes education visits last between 60-90 minutes per session. Once a nurse

is familiar with CGMS insertion techniques, the procedure can be completed on average 20 minutes or less. As in this study, patients can remove the CGMS at home, return it at the next educational session, and receive 90 minutes of CGMS-based physical activity counseling during the following visit.

CGMS graphs are straightforward to interpret for non-insulin requiring type 2 diabetes patients. Consistent with pilot study results, participants in this study could interpretglucose elevations and declines in response to food and physical activity. Since all participants were taking long-acting sulfonylureas, biguinaides, and/or glitazones, the glucose response to food and physical activity was simple to interpret. CGMS graphs of insulin-treated individuals are more difficult to interpret because decreases in glucose level may result from physical activity or the effect of insulin. Therefore, RNs and Certified Diabetes Educators can expect to quickly master CGMS interpretation of diet and physical activity in individuals with non-insulin requiring type 2 diabetes. In summary, since changing physical activity behavior is difficult for individuals with diabetes, nurses can benefit from counseling strategies such as CGMS-based behavioral interventions to maximize the care of individuals with type 2 diabetes.

Limitations

The results of this feasibility study have some limitations. Only short-term outcomes were analyzed; thus, it is unknown whether significant changes in self-efficacy, physical activity, BP, $A1_c$ and BMI could be sustained over time. The small sample prohibits generalizing findings to a larger group of people with diabetes and analyzing participant characteristics such as race. The sample size also limited statistical analyses.

Other possible limitations are that decreases in $A1_c$, BP, and BMI could have been influenced by several variables that were not measured, e.g., dietary changes, blood glucose monitoring and other psychological/sociological constructs. Outcomes of BP might have been biased by measuring each participants BP in a lying (pre) and sitting position (post). In future studies, BP should be measured with participants in the same position for more accurate interpretation of BP changes. Moreover, the significant increase in "Stick to it" self-efficacy as well as the lack of significant changes in "Making time" self-efficacy might be the result of changes to the SEBS scale and scoring. The new scale has one new item "attend a party only after exercising" and one item was deleted "get up earlier to exercise." The new subscale for "Making time" changed from 7 items to 4 items and the "Resisting relapse" subscale was renamed "Sticking to it" with eight items instead of five. Personal communication with the instrument's author revealed that no factor analysis has been completed on the new scale, but a reassessment of the scale's reliability had been examined (personal communication, J. Sallis, September 11, 2006). Unfortunately, the researcher was unable to find evidence of the reliability reassessment. Therefore, caution should be used when interpreting the results of the SEBS. Before using the SEBS in future studies, the scale needs to have further validity and reliability testing.

It is possible that participants in this study experienced a desirability effect. Results may have been biased because the researcher and participants were not blinded to placement in the control or intervention group. Participants in the intervention group may have performed more physical activity based on the knowledge they were receiving a specialized intervention. Conversely, participants in the control group knew they were not receiving the specialized intervention and therefore might have put forth less effort. Also,

the researcher was not blinded to a participant's group assignment which presents an opportunity for bias during a participant's educational session and follow-up. In future studies, it will be important to control for this possible bias by having two consent forms; one for the intervention group that explains the CGMS-based intervention and one for the control group that explains standard care. Furthermore, two diabetes educators will be necessary; one dedicated to delivering the intervention and the other for delivering standard diabetes care. Lastly, changes in physical activity behavior could have been due to the behavioral intervention alone or to CGMS feedback alone, rather than their combination. To determine the impact of each intervention component on physical activity behavior, a study would need to include three groups: behavioral intervention, CGMS without behavioral intervention, and CGMS-based physical activity intervention. Careful interpretation of this study's findings should be used in light of the identified limitations.

APPENDIX A

Nurse-Directed Counseling Intervention

_____Participant Number
_____Date

1. Review CGMS graphs

_____a. Explain time axis, glucose level axis, SMBG symbol, meal medication marker and physical activity marker.

_____b. Identify periods of low blood sugar (< 70 mg/dL), normal blood sugar (70-140 mg/dL), and elevated blood sugar (>140 mg/dL) as well as the relationship between blood sugar level and physical activity, medications and meals.

_____c. Identify periods of physical activity (using marked or logged events) and their relationship to glucose values (expect to see lower glucose values immediately following physical activity and subsequent meal) to provide positive feedback.

_____d. Present CGMS graph and story of a successful exerciser with type 2 diabetes:

_____1. Identify lower glucose values after physical activity events.

_____2. Identify lower baseline glucose levels following physical activity and compare to pre-physical activity glucose levels.

_____3. Identify lower post-prandial glucose levels with faster return to baseline glucose values following physical activity.

2. Describe the effect of increased physical activity on blood glucose values. Give handout reasons to walk.

_____a. Independent of weight loss, physical activity improves body's use of glucose and sensitivity to insulin, resulting in lower $A1_c$

_____b. Reduces high BP, high cholesterol, and cardiac risk factors;

_____c. Can reduce anxiety and depression.

_____d. People who increase their physical activity often report improved quality of life.

3. On a 1–10 scale (with 10 as the highest), how confident are you that you can increase your physical activity level. Use visual scale on handout

_____ Score

4. Why did you not choose a higher score?

_____
_____
_____
_____

Nurse-Directed Counseling Intervention

5. What would it take to score 9 or 10?

_____
_____
_____
_____
_____
_____

_____ **Summarize participant's responses.**

6. Please tell about your previous experiences with physical activities. (Any problems with time, money, arthritis, boredom, family support, pain, energy, lack of facilities, skills, age)

_____
_____
_____
_____
_____

7. What do you think could make physical activity different this time? Do you have any ideas for solving some of the problems you identified with your last attempt to increase physical activity?

_____
_____
_____

8. May I offer you some ideas that have worked for others? Use handout.

_____a. Find someone to walk with that is supportive or include a family member in your walk [walk with a family member]
_____b. Find a place to walk such as the mall before the stores open, YMCA, parks, walking clubs
_____c. Set up a training schedule and stick to it. (Get up early, walk after dinner, walk during lunch hour at work)
_____d. Dancing, gardening, or other activities that may prevent boredom
_____e. Park the car far away from one's destination
_____f. Never take elevators and use the stairs instead
_____g. Walk twice a day for short time periods
_____h. Play basketball with the kids
_____i. Walk the dog
_____j. Say no to extra responsibilities
_____k. Select rewards every week such as athletic equipment or clothing

Nurse-Directed Counseling Intervention

9. Present walking program based on the ADA's recommendations

_____a. Warm up
_____b. Brisk walk
_____c. Cool down
_____d. Activity Do's and Don'ts
_____e. Where to walk
_____f. Get the Most from your walk

10. Write individualized physical activity program prescription

11. You may experience some tiredness, muscle aches after starting your walking program. This is normal and will get better after 1- 2 weeks. Most people have more energy and feel better if they can just stick to their program for 2 weeks. What, if any, problems do you anticipate with starting your physical activity program?

_____
_____
_____
_____

12. Elicit patient solutions for anticipated problems with starting and maintaining physical activity programs and reinforce plans.

_____
_____
_____
_____
_____
_____
_____
_____

13. Review handout on preventing physical activity related problems

14. Give participant Activity Log

◊ ◊ ◊ Reasons to Walk ◊ ◊ ◊

Walking makes your body:

- Use glucose better
- More sensitive to insulin
- Reduces blood pressure
- Reduces high cholesterol
- Reduces cardiac risk factor

Other benefits:

- Improves mood and decrease anxiety
- Increases energy and stamina
- Controls weight
- Better quality of life

How confident are you that you can increase your physical activity level?

1 2 3 4 5 6 7 8 9 10

Low Confidence **High Confidence**

◇◇ Walking Ideas That Work ◇◇

- Find someone to walk with such as a family member or friend
- Set up a training schedule and stick to it (Get up early, walk after dinner)
- Ask co-workers to walk with you at lunch
- Instead of watching an evening TV show, talk a sunset walk
- When faced with a problem, step outside or in the hall and walk it off
- Dancing, gardening, or other activities may prevent boredom
- Park the car far away from your destination
- Take the stairs instead of the elevators
- Walk twice a day for short time periods
- Play basketball with the kids
- Walk the dog
- Say no to extra responsibilities
- Select a reward every week such as athletic equipment or clothing

◊ ◊ ◊ ◊ ◊ ◊ ◊ Where To Walk ◊ ◊ ◊

Outdoors

- Public parks or nature trails
- Parking lots of churches, schools, and shopping areas
- Residential streets
- The grounds of museums and historic sites
- High school or college campuses and running tracks
- City street

Indoors

- School gyms and/or hallways (inquire whether local schools are open to the public at certain hours)
- Indoor tracks at YMCAs and other facilities, including some high schools and colleges
- Community centers
- Shopping malls
- Airports
- Warehouses and other storage facilities at your workplace

◊ ◊ ◊ ◊ Get the Most From Your Walk ◊

- Relax
- Let your arms swing naturally
- Keep your head up and eyes forward.
- After strolling for a few minutes of warm-up gradually increase to a brisk pace
- Your breathing should quicken
- If you don't have enough breath left over to talk, you're walking too fast.
- It's normal to breathe harder than usual during your walk but you shouldn't be wheezing or gasping.

◊ ◊ Physical Activity Prescription ◊ ◊

I plan to do the following activity(s):

_____
_____
_____
_____
_____
_____
_____

How often do I plan to be active?

_____
_____
_____

How hard do I plan to do my activities?

_____
_____
_____

How long do I plan to do my activities?

_____
_____
_____

_____

Patient Signature

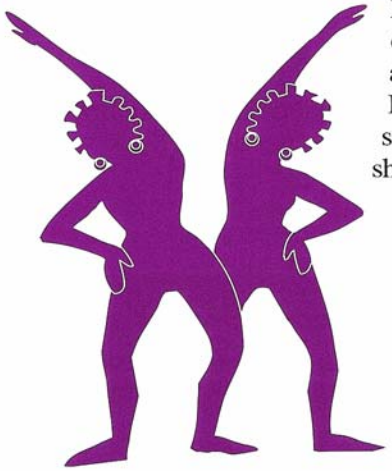
_____

Nurse Signature

How do I warm up?

Before you start to walk, do the stretches shown here. Remember not to bounce when you stretch. Perform slow movements and stretch only as far as you feel comfortable.

Side Reaches

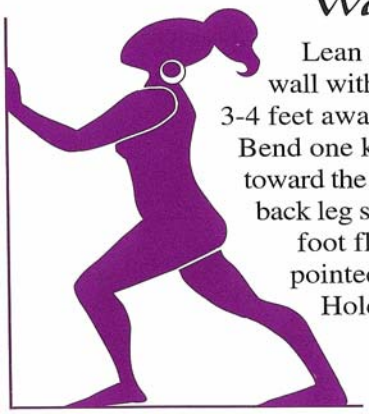


Reach one arm over your head and to the side. Keep your hips steady and your shoulders straight to the side. Hold for 10 seconds and repeat on the other side.

Knee Pull

Lean your back against a wall. Keep your head, hips, and feet in a straight line. Pull one knee to your chest, hold for 10 seconds, then repeat with the other leg.

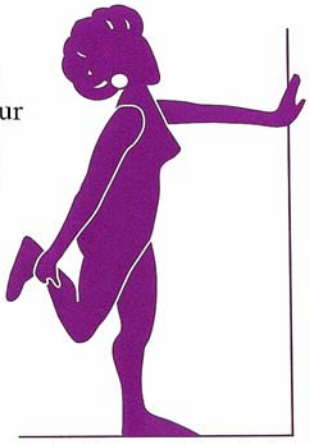
Wall Push



Lean your hands on a wall with your feet about 3-4 feet away from the wall. Bend one knee and point it toward the wall. Keep your back leg straight with your foot flat and your toes pointed straight ahead. Hold for 10 seconds and repeat with the other leg.

Leg Curl

Pull your right foot to your buttocks with your right hand. Keep your knee pointing straight to the ground. Hold for 10 seconds and repeat with your left foot and hand.



Here are some things you should know about preventing exercise-related problems:

- Always perform a 2- to 3-minute warm up and cool down such as a slow walk.
- Wear shoes that can give you good support such as tennis shoes with a gel or air midsole
- Use polyester or cotton/polyester socks to prevent blisters and keep feet dry.
- Inspect your feet daily after exercise for blisters or areas of redness. Stop exercise if you find these signs and seek medical attention.
- Avoid physical activity outdoors when it's extremely hot or cold.
- Avoid physical activity when your fasting blood sugar is greater than 300 or greater than 250 with ketones
- Drink fluids before and during exercise, such as 17 ounces of fluid 2 hours before exercise.
- Check your blood sugar before exercising and carry your glucose monitor with you during exercise.
- Carry a fast acting carbohydrate with you, such as glucose tablets.
- Wear a diabetes identification bracelet during activity or carry a card that identifies you as having diabetes.
- **Stop** physical activity and seek medical attention immediately if you have chest pain or tightness, nausea, indigestion, shoulder pain, and/or shortness of breath.

◊◊◊◊◊◊◊ Walking Plan ◊◊◊◊◊◊◊

Week 1	Week 2	Week 3	Week 4
Warm up: 2-min stroll 10-min brisk walk 5-7 days Cool down: 2-min stroll	Warm up: 2-min stroll 12-min brisk walk 5-7 days Cool down: 2-min stroll	Warm up: 2-min stroll 15-min brisk walk 5-7 days Cool down: 2-min stroll	Warm up: 2-min stroll 20-min or two 10-min brisk walk(s) 5-7 days Cool down: 2-min stroll
Week 5	**Week 6**	**Week 7**	**Week 8**
Warm up: 2-min stroll 20-min or two 10-min brisk walk(s) 6-7 days Cool down: 2-min stroll	Warm up: 2-min stroll 25-min brisk walk or break into 2-3 sessions 6-7 days Cool down: 3-min stroll	Warm up: 2-min stroll 30-min brisk walk or break into 2-3 sessions 6-7 days Cool down: 3-min stroll	Warm up: 2-min stroll 30-min brisk walks 4-7 days/wk and 35-min brisk walks 2-7 days/wk Cool down: 3-min stroll

DO	DON'T
Start today. Start slow and easy if you've been inactive Choose a route where you feel comfortable. Choose a smooth, flat course at first	Wait for a "perfect" time to start. It will never come Undertake a five-mile hike your first time out. Feel intimidated about who's watching. Most likely, no one is. Fitness walkers are an everyday sight nowdays. Get too hung up on time or measurement.

ooooooooooo ACTIVITY LOG ooooooooo

Write in the number of minutes you are active each day

	MON	TUES	WED	THURS	FRI	SAT	SUN
GOAL	min	min	min	min	min	min	min
WEEK 1							
GOAL							
WEEK 2							
GOAL							
WEEK 3							
GOAL							
WEEK 4							
GOAL							
WEEK 5							
GOAL							
WEEK 6							
GOAL							
WEEK 7							
GOAL							
WEEK 8							

APPENDIX B

_____Participant Number

Pre-Physical Activity Medical History

__ / __ / _____ Date

Demographics

1. Date of Birth; ____ / ____ / _____ (mm / dd / yyyy)

2. Gender
    1. Male
    2. Female

3. Race
    1. White
    2. African American
    3. Pacific Islander
    4. Asian
    5. American Indian

4. Ethnicity
    1. Hispanic or Latino
    2. Not Hispanic or Latino

5. Marital Status
    1. Single
    2. Married
    3. Divorced
    4. Widowed

6. Occupation: _____

7. Spouse's occupation_____

8. Education
    1. Graduate or professional training
    2. College or university graduate
    3. Partial college education
    4. High school graduate
    5. Partial high school education
    6. Junior high school
    7. Less than seven years of school

Pre-Physical Activity Medical History

9. Number of years diagnosed with diabetes: _____ yrs

History of any of the following: **1= Yes** **2=No** **3=Don't Know**

_____10. Chest pain such as pressure, tingling, pain, heaviness, burning, tightness, squeezing, or numbness in the chest, jaw, back, or arms (angina pectoris)

_____11. Heart attack

_____12. Rapid heart rate

_____13. Irregular heart rate (palpitations)

_____14. Cramps in your legs when you walk (intermittent claudication)

_____15. High blood pressure (SBP $\geq$ 130, DBP $\geq$80, or taking antihypertensives)

_____16. Asthma

_____17. Emphysema

_____18. Bronchitis

_____19. Stroke

_____20. Temporary loss of speech, changes in vision, with weakness or numbness in arms or legs (transient ischemic attacks)

_____21. Anemia

_____22. Deep vein blood clot (DVT)

_____23. Blood clot that moved (emboli)

_____24. Arthritis or joint swelling

History of heart procedure(s)? **1= Yes** **2=No** **3=Don't Know**

_____25. Angioplasty

_____26. Coronary stents

_____27. Atherectomy

_____28. Coronary bypass surgery

_____29. Valvular surgery (aortic or mitral valve disease)

_____30. Left ventricular aneurysmectomy

_____31. Cardiac transplantation

_____32. Pacemaker

_____33. Implantable cardioverter defibrillator

Pre-Physical Activity Medical History

Complications from diabetes? **1= Yes** **2=No** **3=Don't Know**

_____34. Changes in the back of your eyes because of your diabetes (retinopathy)

_____35. Protein in your urine (nephropathy)

_____36. Feet that are numb, tingle, or painful because of diabetes (neuropathy)

_____37. Dizziness when going from a sitting to standing position (autonomic neuropathy)

Past problems with physical activity **1= Yes** **2=No** **3=Don't Know**

_____38. Low blood sugars

_____39. High blood sugars

_____40. Shortness of breath

_____41. Rapid heart beats

_____42. Irregular heart beats

_____43. Foot problems

_____44. Knee problems

_____45. Hip problems

_____46. Back problems

Cigarette Smoking **1= Yes** **2=No** **3=Don't Know**

_____47. Have you ever smoked cigarettes?

_____48. Are you currently smoking?

If yes, answer the following: **8 = Not applicable**

_____49. Date stopped smoking

_____50. Total years you smoked

_____51. Packs per day

Pre-Physical Activity Medical History

Has anyone in your family had any of the following conditions?

1= Yes 2=No 3=Don't Know

_____52. Premature heart disease/death (father ≤ 55 yrs, mother ≤ 65 yrs)

_____53. Heart attack

_____54. Stroke

Physical Activity **1= Yes 2=No 3=Don't Know**

_____55. Can you walk ¼ mile or two blocks in 10 minutes?

56. Current type of physical activity
    1. None
    2. Treadmill/walking
    3. Bicycling
    4. Weights/Universal
    5. Swimming
    6. Other _____

57. Frequency
    1. None
    2. One day per week
    3. Two days per week
    4. Other

58. Duration
    1. None
    2. 5-10 min/day
    3. 11-20 min/day
    4. 21-30 min/day
    5. 31-60 min/day
    5. Other _____

59. Intensity
    1. None
    2. Light
    3. Moderate
    4. Heavy

Pre-Physical Activity Medical History

Diabetes Medications **1= Yes** **2=No** **3=Don't Know**

_____60. Sulfonylurea

_____61. Glitazone (Avandia, Actos)

_____62. Metformin

_____63. Alpha-glucosidase inhibitor (Acarbose, Miglitol, Voglibose)

_____64. Meglitinide analogs (Prandin)

_____65. **How many times have you meet with a Diabetes Educator in the last year?**

Blood Pressure Medication **1= Yes** **2=No** **3=Don't Know**

_____66. ACE Inhibitor

_____67. ARB

_____68. Beta Blocker

_____69. Calcium Channel Blocker

_____70. Diuretics

_____71. Alpha- Adrenergic Blocking Agents

_____72. Other _____

List of Medications

_____
_____
_____
_____
_____
_____

Pre-Physical Activity Medical History

Laboratory Data

73. $A1_c$ date drawn ___/___/_____ (mm / dd / yyyy)

74. $A1_c$ result _____

75. Date blood drawn for fasting lipid panel ___/___/_____ (mm / dd / yyyy)

76. Total cholesterol_____

77. Triglycerides_____

78. HDL_____

79. LDL_____

80. Creatinine (serum)_____

81. Microalbumin/Creatinine Ratio_____

82. TSH_____

83. T_4 _____

Physical Examination

84. Weight (kg)_____

85. Height (cm)_____

86. Systolic blood pressure (after lying for 5 min.)_____

87. Diastolic blood pressure (after lying for 5 min._____

88. Standing systolic blood pressure (after standing for 2 min.)_____

89. Standing diastolic blood pressure (after standing for 2 min.)_____

90. Pulse Lying _____

91. Pulse Standing_____

Pre-Physical Activity Medical History

Non-Coded Items

Eye examination **1= Yes** **2=No** **3=Don't Know**

_____92. Pupils, equal, round, and reactive to light

_____93. Fundus exam without exudates, hemorrhage or neovasculization

94. Other _____

Palpation and auscultation of carotid arteries **1= Yes** **2=No** **3=Don't Know**

_____95. No bruits

96. Other _____

Auscultation of heart sounds **1= Yes** **2=No** **3=Don't Know**

_____97. Regular rate and rhythm

_____98. No murmurs, gallops, or rubs

99. Other_____

Auscultation of lung sounds **1= Yes** **2=No** **3=Don't Know**

_____100. No rales

_____101. No wheezes

102. Other_____

Palpation and auscultation of femoral arteries **1= Yes** **2=No** **3=Don't Know**

_____103. No bruits

104. Other _____

Abdominal palpation **1= Yes** **2=No** **3=Don't Know**

_____105. No masses

_____106. No organmegaly

_____107. No tenderness

108. Other_____

Pre-Physical Activity Medical History

Lower extremity examination **1= Yes** **2=No** **3=Don't Know**

_____109. Normal hair growth

_____110. No edema

_____111. Knee reflex present

_____112. Ankle reflex present

_____113. Palpable dorsalis pedis pulse

_____114. Palpable posterior pedialis pulse

_____115. Normal monofilament sensation

_____116. Normal vibratory sensation

_____117. No lesions

_____118. Toenails well groomed

119. Other

_____
_____
_____
_____

12 Lead ECG results **1= Yes** **2=No** **3=Don't Know**

_____120. Normal

_____121. Abnormal_____
_____
_____

APPENDIX C

_____Participant Number

Screening and Study Recruitment Assessment Tool

1. Who informed you about this study?

1. Nurse Practitioner
2. Physician
3. Diabetes educator
4. Nurse
5. Medical assistant
6. Receptionist
7. None of the above

2. How did you learn about this study?

1. Poster
2. Fact sheet
3. Radio
4. Newspaper
5. Church bulletin
6. Word of mouth
7. None of the above

3. From which clinic were you referred to this study?

1. 3300 Main Street Endocrinology Clinic
2. Mason Square Neighborhood Clinic
3. High Street Health Center
4. Other_____

4. Which of the following encouraged you to complete the study? (Check all that apply.)

1. Reminder phone calls
2. Refreshments during appointments
3. Money for time and travel
4. Family or friend support
5. None of the above
6. Other _____

APPENDIX D

Informed Consent- Baystate Medical Center

MEDICAL RESEARCH INFORMED CONSENT FORM

Patient _____

Baystate Medical Center Study #: 04-147

Principal Investigator: Stuart Chipkin, MD

Study Sponsor: NIH F31 NR008818-01; Minimed Small Equipment Grant

Title of Project: Changing Physical Activity Behavior Using Continuous Glucose Monitoring Feedback

By signing this consent form you, _____, indicate that you willingly agree to participate in this project. The essence of this project is as follows:

PURPOSE OF RESEARCH:

You are invited to volunteer for a research study that will examine two different ways to provide diabetes education. With this in mind, the purpose of the study is to find out whether adding feedback from a 72-hour glucose monitor to a diabetes education program affects your ability to increase physical activity levels. Feedback in this study means a discussion about how your blood sugars change with meals and physical activity over 3 days. You have been invited to participate in this research because you have diabetes and are not currently involved in a physical activity program. This project involves two separate pieces of equipment- a 72-hour glucose monitor and an activity monitor.

Since no one knows yet whether feedback from a 72-hour glucose monitor in addition to diabetes education program is helpful, not everyone in the study will receive this feedback information. Each volunteer in the study will be assigned by chance, as in the flip of a coin, to either get diabetes education alone (diabetes education group) or with the feedback from the 72 hour glucose monitor (glucose feedback group). This process allows more objective study information and helps the researcher to find differences in the two ways of providing diabetes education.

PROCEDURES:

If you decide to participate in the study, you will be asked to complete two questionnaires, which will take 15 minutes of your time, wear an activity monitor next to your skin at your waistline throughout your waking hours for seven days, and give one sample of blood, about 2 tablespoons, to evaluate your diabetes and cardiovascular risk.

If you are assigned to the glucose feedback group, you will also be asked to wear a glucose monitor all day and night for 72 hours during the first seven days of the study. The sensing part of the glucose monitor is inserted with a short, small needle into the fatty tissue of your abdomen. The needle will be removed leaving a short plastic catheter under your skin that is attached to the glucose sensor. The glucose sensor is attached to a small cable. The cable is connected to a pager-sized monitor that is worn on your belt or inside a pocket. You will be asked to check you blood sugar four times a day while wearing the glucose monitor. It will take approximately 45 minutes to insert the glucose sensor (which is attached to the glucose monitor) and to teach you how to wear the glucose monitor. After wearing the glucose monitor for three days, the glucose sensor will be removed.

No matter which group you are in, you will attend a diabetes education class lasting an hour and a half. The researcher will contact you by telephone four weeks later to discuss your physical activity levels. Eight weeks after the start of the study, you will be asked to give one sample of blood, about 2 tablespoons, to evaluate your diabetes and cardiovascular risk, complete one questionnaire again and to wear the activity monitor for another seven days**.** If you are assigned to the glucose feedback group, you and your health care provider will be given a copy of the 72- hour glucose monitor information.

RISKS AND DISCOMFORTS:

There are no known risks that could occur from diabetes education or wearing the activity monitor. The potential risks of the glucose sensor may be a slight pin-prick-feeling during insertion and a tiny amount of bleeding where the catheter enters your skin that may leave a small bump or bruise on your skin. You may experience skin irritation from the dressing that holds the glucose sensor in place. There have been no reported skin infections at the insertion sites. If an infection were to occur, it could be treated. You may experience skin irritation from the dressing used to hold the glucose sensor in place. The glucose sensor could become dislodged; if that were to happen, we would want you to contact Nancy Allen at 794-7206.

The possible risks of low to moderate physical activity might be fatigue, muscle soreness, injury such as a sprained ankle or pulled muscle, worsened arthritic joint pain, foot sores, low or high blood pressure, low blood sugar reaction, and chest pain or heart attack. You will be given a physical exam, including a screening of your heart with an EKG, before starting your physical activity program. You will also be counseled on how to decrease risks associated with physical activity.

BENEFITS:

You may or may not benefit directly from being in this research study by learning more about how to care for your diabetes. If you are placed in the glucose feedback group, you may learn how physical activity affects your blood glucose levels. Your participation may help others as a result of the knowledge gained from the research.

COSTS & COMPENSATION:

You will be offered $25.00 at the end of your participation in the study for your time. There will be no additional cost to you for being in this research study. Participation in this research project will not affect any of the ordinary or customary hospital or out-patient charges associated with the treatment of your condition. Baystate Medical Center does not have a program for compensating patients for injury or complications arising from medical research but medical care will be made available as needed at usual charges.

PATIENT ENROLLMENT/LENGTH OF STUDY:

It is expected that 50 patients will be enrolled in this study. You will be informed of any new findings that could affect your treatment and willingness to continue your participation. This study is expected to last for 1 year, but your participation is expected to last for 8 weeks.

CONFIDENTIALITY:

You will be asked to sign an authorization form to release your medical information needed for this research study. Medical information produced by this study may become part of your clinic record and will be subject to the confidentiality and privacy regulations of Baystate Medical Center. (Information regarding privacy and confidentiality is explained in the patient guide available on all nursing units and in the Administrative Operations Manual, which may be accessed online by Baystate personnel.)

If the data are used for publication in the health literature no names will be used. It is possible that your medical and research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), or federal or state government agencies, in the course of carrying out their duties. If your record is inspected by the study sponsor (and/or its agents), or by any of these agencies, your confidentiality will be maintained to the extent permissible by law.

VOLUNTARY PARTICIPATION:

You are under no obligation to participate in this project. You may withdraw your participation at any time without prejudice to your medical treatment at Baystate Medical Center. If you do not want to participate in this research study but still want diabetes education, a referral will be made to the Baystate Diabetes Education Program.

REQUEST FOR ADDITIONAL INFORMATION:

Should you have any questions about your treatment or any other matter relative to your participation in this project, you may call: Nancy Allen at 413-794-7206. If you

experience a research related injury at any time during this study, you may contact: Dr. Chipkin at 413-433-7418. If you would like to discuss your rights as a participant in a research study, or wish to speak with someone not directly involved in the study you may contact the Medical Research Office at (413) 794-4356.

SUBJECT STATEMENT OF VOLUNTARY CONSENT:

When signing this form I am agreeing to voluntarily enter this study. I understand that, by signing this document, I do not waive any of my legal rights. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. A copy of this signed Informed Consent Form has been given to me.

_____
Patient/Parent Guardian's Name (Print or type)

_____ _____
Signature Date

_____
If required: Witness (Print or type) to ☐ Discussion ☐ Signature

_____ _____
Signature Date

STUDY REPRESENTATIVE STATEMENT:

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered any questions to the best of my ability.

_____
Study Representative Name (Print or Type)

_____ _____
Signature Date

Informed Consent- Berkshire Medical Center

MEDICAL RESEARCH INFORMED CONSENT FORM

Patient _____

BMC Study #:_____

Principal Investigator: Steven Leveston, MD

Study Sponsor: NIH F31 NR008818-01; Minimed Small Equipment Grant

Title of Project: Changing Physical Activity Behavior Using Continuous Glucose Monitoring Feedback

By signing this consent form you, _____, indicate that you willingly agree to participate in this project. The essence of this project is as follows:

PURPOSE OF RESEARCH:

You are invited to volunteer for a research study that will examine two different ways to provide diabetes education. With this in mind, the purpose of the study is to find out whether adding feedback from a 72-hour glucose monitor to a diabetes education program affects your ability to increase physical activity levels. Feedback in this study means a discussion about how your blood sugars change with meals and physical activity over 3 days. You have been invited to participate in this research because you have diabetes and are not currently involved in a physical activity program. This project involves two separate pieces of equipment- a 72-hour glucose monitor and an activity monitor.

Since no one knows yet whether feedback from a 72-hour glucose monitor in addition to diabetes education program is helpful, not everyone in the study will receive this feedback information. Each volunteer in the study will be assigned by chance, as in the flip of a coin, to either get diabetes education alone (diabetes education group) or with the feedback from the 72 hour glucose monitor (glucose feedback group). This process allows more objective study information and helps the researcher to find differences in the two ways of providing diabetes education.

PROCEDURES:

If you decide to participate in the study, you will be asked to complete two questionnaires, which will take 15 minutes of your time, wear an activity monitor next to your skin at your waistline throughout your waking hours for seven days, and give one sample of blood, about 2 tablespoons, to evaluate your diabetes and cardiovascular risk.

If you are assigned to the glucose feedback group, you will also be asked to wear a glucose monitor all day and night for 72 hours during the first seven days of the study. The sensing part of the glucose monitor is inserted with a short, small needle into the fatty tissue of your abdomen. The needle will be removed leaving a short plastic catheter under your skin that is attached to the glucose sensor. The glucose sensor is attached to a small cable. The cable is connected to a pager-sized monitor that is worn on your belt or inside a pocket. You will be asked to check you blood sugar four times a day while wearing the glucose monitor. It will take approximately 45 minutes to insert the glucose sensor (which is attached to the glucose monitor) and to teach you how to wear the glucose monitor. After wearing the glucose monitor for three days, the glucose sensor will be removed.

No matter which group you are in, you will attend a diabetes education class lasting an hour and a half. The researcher will contact you by telephone four weeks later to discuss your physical activity levels. Eight weeks after the start of the study, you will be asked to give one sample of blood, about 2 tablespoons, to evaluate your diabetes and cardiovascular risk**,** complete one questionnaire again and to wear the activity monitor for another seven days**.** If you are assigned to the glucose feedback group, you and your health care provider will be given a copy of the 72- hour glucose monitor information.

RISKS AND DISCOMFORTS:

There are no known risks that could occur from diabetes education or wearing the activity monitor. The potential risks of the glucose sensor may be a slight pin-prick-feeling during insertion and a tiny amount of bleeding where the catheter enters your skin that may leave a small bump or bruise on your skin. You may experience skin irritation from the dressing that holds the glucose sensor in place. There have been no reported skin infections at the insertion sites. If an infection were to occur, it could be treated. The glucose sensor could become dislodged; if that were to happen, we would want you to contact Nancy Allen at 413-794-7206.

The possible risks of low to moderate physical activity might be fatigue, muscle soreness, injury such as a sprained ankle or pulled muscle, worsened arthritic joint pain, foot sores, low or high blood pressure, low blood sugar reaction, and chest pain or heart attack. You will be given a physical exam, including a screening of your heart with an EKG, before starting your physical activity program. You will also be counseled on how to decrease risks associated with physical activity.

BENEFITS:

You may or may not benefit directly from being in this research study by learning more about how to care for your diabetes. If you are placed in the glucose feedback group, you may learn how physical activity affects your blood glucose levels. Your participation may help others as a result of the knowledge gained from the research.

COSTS & COMPENSATION:

You will be offered $25.00 at the end of your participation in the study for your time. There will be no additional cost to you for being in this research study. Participation in this research project will not affect any of the ordinary or customary hospital or out-patient charges associated with the treatment of your condition. Berkshire Medical Center does not have a program for compensating patients for injury or complications arising from medical research but medical care will be made available as needed at usual charges.

PATIENT ENROLLMENT/LENGTH OF STUDY:

It is expected that 50 patients will be enrolled in this study. You will be informed of any new findings that could affect your treatment and willingness to continue your participation. This study is expected to last for 1 year, but your participation is expected to last for 8 weeks.

CONFIDENTIALITY:

You will be asked to sign an authorization form to release your medical information needed for this research study. Medical information produced by this study may become part of your clinic record and will be subject to the confidentiality and privacy regulations of Berkshire Medical Center.

If the data are used for publication in the health literature no names will be used. It is possible that your medical and research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), or federal or state government agencies, in the course of carrying out their duties. If your record is inspected by the study sponsor (and/or its agents), or by any of these agencies, your confidentiality will be maintained to the extent permissible by law.

VOLUNTARY PARTICIPATION:

You are under no obligation to participate in this project. You may withdraw your participation at any time without prejudice to your medical treatment at Berkshire Medical Center. If you do not want to participate in this research study but still want diabetes education, a referral will be made to the Berkshire Diabetes Education Program.

REQUEST FOR ADDITIONAL INFORMATION:

Should you have any questions about your treatment or any other matter relative to your participation in this project, you may call: Nancy Allen at 413-794-7206. If you experience a research related injury at any time during this study, you may contact: Dr. Leveston at 413-496-6838. If you would like to discuss your rights as a participant in a

research study, or wish to speak with someone not directly involved in the study you may contact the Medical Research Office at (413) 447-7833.

SUBJECT STATEMENT OF VOLUNTARY CONSENT:

When signing this form I am agreeing to voluntarily enter this study. I understand that, by signing this document, I do not waive any of my legal rights. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. A copy of this signed Informed Consent Form has been given to me.

_____
Patient/Parent Guardian's Name (Print or type)

_____ _____
Signature Date

_____
If required: Witness (Print or type) to ☐ Discussion ☐ Signature

_____ _____
Signature Date

STUDY REPRESENTATIVE STATEMENT:

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered any questions to the best of my ability.

_____
Study Representative Name (Print or Type)

_____ _____
Signature Date

APPENDIX E

_____Participant Number

Activity Monitor and CGMS Assessment Tool

1. **What issues, if any, did you have with the continuous glucose monitor?**

    1. Skin irritation
    2. Pain at sensor site on study day one
    3. Pain at sensor site throughout the study
    4. Discomfort at sensor site on study day one
    5. Discomfort at sensor site throughout the study
    6. Discomfort because of sensor location
    7. Discomfort because of monitor location
    8. Infection at sensor site
    9. Limited my activities
    10. Remembering to enter blood sugar, meals, exercise into the meter
    11. Alarms
    12. Understanding the directions
    13. None

2. Would you wear the continuous glucose monitor again?

1. Yes
2. No
3. Don't Know

3. How much difficulty did you experience when showering with the continuous glucose monitor?

1. None
2. Small amount
3. Moderate amount
4. Large amount

4. How much difficulty did you experience when sleeping with the continuous glucose monitor?

1. None
2. Small amount
3. Moderate amount
4. Large amount

_____Participant Number

Activity Monitor and CGMS Assessment Tool

5. How much difficulty did you experience while wearing the continuous glucose monitor during the daytime?

1. None
2. Small amount
3. Moderate amount
4. Large amount

6. What issues did you have with the activity monitor?

1. Sweaty skin
2. Irritated skin
3. Pinched skin
4. Securing monitor tightly to your waist
5. Understanding directions
6. Forgetting to put monitor on
7. Forgetting to take monitor off
8. None

APPENDIX F

_____Participant Number **___/___/_____Date**

EXERCISE CONFIDENCE SURVEY

Below is a list of things people might do while trying to increase or continue regular exercise. We are interested in exercises like running, swimming, brisk walking, bicycle riding, or aerobics classes. Whether you exercise or not, please rate how confident you are that you could really motivate yourself to do things like these consistently, *for at least six months.* Please circle one number for each question.

How sure are you that you can do these things?

	I know I Cannot		**Maybe I can**		**I know I can**	**Does Not Apply**
1. Get up early, even on weekends, to exercise.	1	2	3	4	5	(8)
2. Stick to your exercise program after a long, tiring day at work.	1	2	3	4	5	(8)
3. Exercise even though you are feeling depressed.	1	2	3	4	5	(8)
4. Set aside time for a physical activity program that is; walking, jogging. swimming, biking or other continuous activities for at least 30 minutes, 3 times per week	1	2	3	4	5	(8)
5. Continue to exercise with others even though they seem too fast or too slow for you.	1	2	3	4	5	(8)
6. Stick to your exercise program when undergoing a stressful life change (e.g., divorce, death in the family, moving).	1	2	3	4	5	(8)
7. Attend a party only after exercising.	1	2	3	4	5	(8)
8. Stick to your exercise program when your family is demanding more time from you.	1	2	3	4	5	(8)
9. Stick to your exercise program when you have household chores to attend to.	1	2	3	4	5	(8)
10. Stick to your exercise program even when you have excessive demands at work.	1	2	3	4	5	(8)
11. Stick to your exercise program when social obligations are very time consuming.	1	2	3	4	5	(8)
12. Read or study less in order to. exercise more	1	2	3	4	5	(8)

APPENDIX G
Hollingshead Two Factor Index

The Occupational Scale

1. Higher Executives of Large Concerns, Proprietors, and Major Professionals

A, Higher Executives (Value of corporation $500,000 *and above as rated by Dun and Bradstreet)*

Bank
Presidents Vice-Presidents
Vice-Presidents
Assistant vice-presidents

Business
Assistant vice-presidents
Executive secretaries
Research directors
Treasurers

B. Proprietors (Value over $100,000 by Dun and Bradstreet)

Brokers
Contractors
Dairy owners
Farmers
Lumber dealers

C. *Major Professionals*

Accountants (CPA)
Actuaries
Agronomists
Auditors
Architects
Artists, portrait
Astronomers
Bacteriologists
Chemical engineers
Chemists
Clergymen (professional trained)
Dentists
Economists
Engineers (college graduates)
Foresters
Geologists
Judges (superior courts)
Lawyers
Metallurgists
Military: commissioned officers, major and above
Officials of the executive branch of, government, federal, state local: e.g., Mayor, City manager, City plan director, Internal Revenue director
Physicians
Physicists, research
Psychologists, practicing
Symphony conductor
Teachers, university, college
Veterinarians (veterinary surgeons)

2. Business Managers, Proprietors of Medium-Sized Businesses, and Lesser Professionals

A. Business Managers in Large Concerns (Value $500,000)

Advertising directors
Branch managers
Brokerage salesmen
Directors of purchasing
District managers
Executive assistants
Export managers, international concerns
Government officials, minor, e.g., Internal Revenue agents
Manufacturer's representatives
Office managers
Personnel managers
Police chief; Sheriff
Postmaster
Production managers
Sales engineers
Sales managers, national concerns
Store managers

B. Proprietors of Medium Businesses (Value $35,000-$I00,000)

Advertising
Clothing store
Contractors
Express company
Farm owners
Fruits, wholesale
Furniture business
Jewelers
Poultry business
Real estate brokers
Rug business
Store
Theater

C. *Lesser Professionals*

Accountants (not CPA)
Chiropodists
Chiropractors
Correction officers
Director of Community House
Engineers (not college graduate)
Finance writers
Health educators
Labor relations consultants
Librarians (full-time)
Military: commissioned officers, lieutenant, captain
Musicians (symphony orchestra)
Nurses
Opticians
Optometrists, D.O.
Pharmacists
Public health officers (MPH)
Research assistants, university
Social workers

3. Administrative Personnel, Owners of Small Businesses, and Minor Professionals

A. Administrative Personnel

Advertising agents
Chief clerks
Credit managers
Insurance agents
Managers, departments
Passenger agents, railroad
Private secretaries
Purchasing agents
Sales representatives
Section heads, federal, state and local governmental offices
Section heads, large businesses and industries
Service managers
Shop managers
Store managers (chain)
Traffic managers

B. Small Business Owners ($6,000-$35,000)

Art gallery
Auto accessories
Awnings
Bakery
Beauty shop
Boat yard
Brokerage, insurance
Car dealers
Cattle dealers
Cigarette machines
Cleaning shops
Clothing
Coal businesses
Contracting businesses
Convalescent homes
Decorating
Dog supplies
Dry goods
Engraving business
Feed
Finance companies, local
Fire extinguishers
Furniture
Garage
Gas station
Glassware
Grocery, general
Hotel protection
Jewelry
Machinery brokers
Manufacturing
Monuments
Music
Package stores (liquor)
Paint contracting
Poultry
Real estate
Records and radios
Restaurant
Roofing contractor
Shoe
Signs
Tavern
Taxi company

B. Small Business Owners ($6,000-$35,000) continued

Funeral directors
Five and dime
Florist
Food equipment
Food products
Window shades
Tire shop
Trucking
Trucks and tractors
Upholstery

C. *Semiprofessionals*

Actors and showmen
Army, master sergeant
Artists, commercial
Appraisers (estimators)
Clergymen (not professionally trained)
Concern managers
Deputy sheriffs
Dispatchers, railroad
Interior decorators
Interpreters, courts
Laboratory assistants
Landscape planners
Morticians
Navy, chief petty officer
Oral hygienists
Physiotherapists
Piano teachers
Publicity and public relations
Radio, TV announcers
Reporters, court
Reporters, newspapers
Surveyors
Title searchers
Tool designs
Travel agents
Yard masters, railroad

D. Farmers

Farm owners ($20,000-$35,000) Technicians, and Owners of Little Businesses (Value under $6,000)

4. Clerical and Sales Workers,

A. Clerical and Sales Workers

Bank clerks and tellers
Bill collectors
Bookkeepers
Business machine operators, offices
Claims examiners
Clerical or stenographic
Conductors, railroad
Factory storekeepers
Factory supervisors
Post Office clerks
Route managers
Sales clerks
Sergeants and petty officers, military services
Shipping clerks
Supervisors, utilities, factories
Supervisors, toll stations

B. Technicians

Dental technicians
Draftsmen
Driving teachers
Expediter, factory
Experimental tester
Instructors, telephone company, factory
Inspectors, weights, sanitary, railroad, factory
Investigators
Laboratory technicians
Locomotive engineer
Operators, PBX
Proofreaders
Safety supervisors
Supervisors of maintenance
Technical assistants
Telephone company supervisors '"
Timekeepers
Tower operators, railroad
Truck dispatchers
Window trimmers (stores)

C. Owners of Little Businesses ($3,000-$6,000)

Flower shop
Grocery
Newsstand
Tailor shop

D. Farmers Owners (Value $10,000-$20,000)

5. Skilled Manual Employees

Auto body repairers
Bakers
Barbers
Blacksmiths
Bookbinders
Boilermakers
Brakemen, railroad
Brewers
Bulldozer operators
Butchers
Cabinet makers
Cable splicers
Carpenters
Casters (founders)
Cement finishers
Cheese makers
Chefs
Compositors
Diemakers
Diesel engine repair and maintenance (trained)
Diesel shovel operators
Electricians
Engravers
Exterminators
Firemen, city
Firemen, railroad
Fitters, gas, steam
Foremen, construction, dairy
Gardeners, landscape (trained)
Glass blowers
Glaziers
Gunsmiths
Gauge makers
Hair stylists
Heat treaters
Horticulturists
Linmen, utility
Linotype operators
Lithographers
Locksmiths
Loom fixers
Machinists (trained)
Maintenance foremen

5. Skilled Manual Employees continued:

Linoleum layers (trained)
Masons
Masseurs
Mechanics (trained)
Millwrights
Moulders (trained)
Painters
Paperhangers
Patrolmen, railroad
Pattern and model makers
Piano builders
Piano tuners
Plumbers
Policemen, city
Postmen
Printers
Radio, television maintenance
Repairmen, home appliances
Rope splicers
Sheetmetal workers (trained) ,
Shipsmiths
Shoe repairmen (trained)
Stationery engineers (licensed)
Stewards, club
Switchmen, railroad
Tailors (trained)
Teletype operators
Tool makers
Track supervisors, railroad
Tractor-trailer trans.
Typographers
Upholsterers (trained)
Watchmakers
Weavers
Welders
Yard supervisors, railroad

6. Machine Operators and Semiskilled Employees

Aides, hospital
Apprentices, electricians, printers, steam fitters, toolmakers
Assembly line workers
Bartenders
Bingo tenders
Bridge tenders
Building superintendents (construction)
Bus drivers
Checkers
Coin machine fillers
Cooks, short order
Deliverymen
Dressmakers, machine
Elevator operators
Enlisted men, military services
Filers, sanders, buffers
Foundry workers
Garage and gas station attendants
Greenhouse workers
Practical nurses
Pressers, clothing
Pump operators
Receivers and checkers
Roofers
Setup men, factories
Shapers
Signalmen, railroad
Solderers, factory
Sprayers, paint
Steelworkers (not skilled)
Standers, wire machines
Strippers, rubber factory
Taxi drivers
Testers
Timers
Tire moulders
Trainmen, railroad
Truck drivers, general
Waiters-waitresses ("better placed")
Weighers

6. Machine Operators and Semiskilled Employees continued:

Guards, doorkeepers, watchmen
Hairdressers
Housekeepers
Meat cutters and packers
Meter readers
Operators, factory machines
Oilers, railroad
Welders, spot
Winders, machine
Wiredrawers, machine
Wine bottlers
Wood workers, machine
Wrappers, stores and factories

7. Unskilled Employees

Amusement park workers (bowling alleys, pool rooms)
Ash removers
Attendants, parking lots
Cafeteria workers
Car cleaners, railroad
Carriers, coal
Countermen
Dairy workers
Deck hands
Domestics
Farm helpers
Fishermen (clam diggers)
Freight handlers
Garbage collectors
Gravediggers
Hod carriers
Hog killers
Hospital workers, unspecified
Hostlers railroad
Janitors (sweepers)
Laborers, construction
Farmers
Sharecroppers
Laborers, unspecified
Laundry workers
Messengers
Platform men, railroad
Peddlers
Porters
Relief, public, private
Roofer's helpers
Shirt folders
Shoe shiners
Sorters, rag and salvage
Stage hands
Stevedores
Stock handlers
Street cleaners
Struckmen, railroad
Unemployed (no occupation)
Unskilled factory workers
Waitresses ("hash houses")
Washers, cars
Window cleaners
Woodchoppers

Hollingshead Two Factor Index

The Educational Scale

1. *Graduate professional training:* Persons who completed a recognized professional course that led to the receipt of a graduate degree were given scores of 1.
2. *Standard college or university graduation:* All individuals who had completed a four-year college or university course leading to a recognized college degree were assigned the same scores. No differentiation was made between state universities and private colleges.
3. *Partial college training:* Individuals who had completed at least one year but not a full college course were assigned this position.
4. *High school graduation:* All secondary school graduates, whether from a private preparatory school, public high school, trade school, or parochial school, were given this score.
5. *Partial high school:* Individuals who had completed the tenth or eleventh grades, but had not completed high school were given this score.
6. *Junior high school:* Individuals who had completed the seventh grade through the ninth grade were given this position.
7. *Less than seven years of school:* Individuals who had not completed the seventh grade were given the same scores irrespective of the amount of education they had received.

Factor	Scale Score	x	Factor Weight	=	Partial Score
Occupation	_____		7	=	_____
Education	_____		4	=	_____
Index of Social Position Score				=	_____

Five Social classes:
Class I: 11-17
Class II: 18-31
Class III: 32-47
Class IV: 48-63
Class V: 64-77

APPENDIX H

How to Wear Your Activity Monitor

_____Participant Number
_____Date

Instructions:

- **Wear the monitor from the time you get out of bed in the morning until you get into bed for the night. Record on the table below the times the monitor was put on and taken off.**
- Attach the monitor firmly to your right hip using the elastic strap.
- Make sure the monitor is right side up. You should be able to see the "dots" on top of the monitor.
- Wear the monitor in the same place every day.
- The monitor is NOT waterproof. Take the monitor off for bathing or swimming, but don't forget to put it back on afterward. Record the time(s) the monitor was removed during the day.
- Record the time you start and stop activities such as lifting weights, swimming, or bicycling
- If you have questions about what you are suppose to do, please call Nancy A. Allen, APRN, PhD-c at 794-7206.

Date	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Start Time (Morning)							
Stop Time (Bedtime)							
Time(s) Removed for bathing							
Start and Stop time for weights, bicycling, swimming							

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