

COMPARISON OF DEMOGRAPHIC, CLINICAL, AND SOCIAL–
COGNITIVE FACTORS ASSOCIATED WITH PHYSICAL ACTIVITY
AMONG MIDDLE-AGED WOMEN WITH AND WITHOUT DIABETES

By

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ABSTRACT

COMPARISON OF DEMOGRAPHIC, CLINICAL, AND SOCIAL-COGNITIVE FACTORS ASSOCIATED WITH PHYSICAL ACTIVITY AMONG MIDDLE-AGED WOMEN WITH AND WITHOUT DIABETES

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Background: Middle-aged women are at high risk for diabetes and cardiovascular disease. Despite the known benefits, 80% of middle-aged women do not meet the physical activity recommendations, especially those with diabetes. The U.S. Department of Health and Human Services recommendation for middle-aged women includes 150 minutes per week of moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity or an equivalent combination of moderate- and vigorous-intensity physical activity (MVPA) spread throughout the week. While appropriate interventions are needed to increase physical activity in middle-aged women with and without diabetes, there is little information about the differences in demographic, clinical, and social-cognitive factors associated with MVPA between these two groups of women. **Framework:** The conceptual framework for this study, the Behavioral Model of Physical Activity, was based on Social Cognitive Theory and the Theory of Planned Behavior and the demographic, clinical and social-cognitive factors found to be associated with physical activity in the literature. **Purpose:** The primary purpose of the study was to explore the demographic, clinical, and social-cognitive factors associated with minutes per day of MVPA in middle-aged women with and without diabetes and to compare the two groups on these factors and their MVPA. A secondary purpose was to determine the degree of agreement between a self-report measure, the International Physical Activity Questionnaire (IPAQ) short form, and accelerometry for measuring minutes per day of MVPA. **Research Questions:** What were the

differences between middle-aged women with and without diabetes in their minutes per day of MVPA as measured by the two physical activity measures and their associated demographic, clinical, and social–cognitive factors? What was the degree of agreement in minutes per day of MVPA between the IPAQ short form and the accelerometer? Which demographic, clinical and social–cognitive factors of middle-aged women with and without diabetes were associated with minutes per day of MVPA as measured by the (a) IPAQ short form, and (b) accelerometer?

Sample and Setting: Women, 42 with diabetes and 67 without diabetes, between the ages of 45 and 64, were recruited from four urban primary care clinics. Women who fulfilled the inclusion criteria met individually with the investigator at an initial clinic appointment to complete a paper-and-pencil survey and to obtain height and weight. Each woman was provided with an accelerometer and a daily log to complete during the wear-time. During a second clinic appointment with the investigator, the women returned the accelerometer and daily log and completed the IPAQ short version. **Results:** The majority of women were overweight or obese ($n = 93, 86.1\%$). Women with diabetes had fewer minutes per day of vigorous physical activity than women without diabetes. Middle-aged women with diabetes were more likely to be non-White and have higher body mass index (BMI), higher comorbidity index, lower perceived benefits of physical activity, and lower physical activity self-efficacy than those without diabetes. Minutes per day of MVPA in the women were negatively associated with educational level, BMI, and depressive symptom severity. **Implications:** Nursing interventions through increased MVPA are needed to decrease high rates of overweight and obesity in middle-aged women with and without diabetes. Nursing strategies targeted toward enhancing perceived benefits of physical activity and physical activity self-efficacy may be promising for achieving this objective for middle-aged women with diabetes.

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This dissertation is dedicated to my husband, best friend, and life partner,
Kurt L. Vanden Bosch,
who has provided support and encouragement in my pursuit of
personal and professional goals.

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“I can do all things through Christ who gives me strength.” Philippians 4:13

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Chapter One

Background and Significance

The United States Department of Health and Human Services (U.S. DHHS; 2008) guidelines recommend (a) at least 150 minutes per week of moderate-intensity physical activity, or (b) at least 75 minutes per week of vigorous-intensity physical activity, or (c) a comparable combination of moderate- to vigorous-intensity physical activity (MVPA) during three or more days per week for all adults less than 65 years of age. Following these physical activity recommendations has been shown to prevent diabetes and lower cardiovascular disease risk (CVD; Buse, Ginsberg, Bakris, & Clark, 2007; Diabetes Prevention Program [DPP] Research Group, 2002; Holman, Paul, Bethel, Matthews, & Neil, 2008; Lindstrom et al., 2006; Wilcox, Parra-Medina, Thompson-Robinson, & Will, 2001).

Diabetes contributes to CVD, the second leading cause of death in middle-aged women (Heron et al., 2009). Analysis of data between 1999 and 2003 from the National Health and Nutrition Examination Survey (NHANES; Towfighi, Saver, Engelhardt, & Ovbiagele, 2007) found that women in the age group of 45 through 54 years have double the risk of stroke, a type of CVD, compared with men of the same age, (odds ratio [OR] = 2.39, 95% CI [1.32, 4.33], $p < .01$). Women with diabetes have even higher odds of stroke than women without diabetes (OR = 3.50, 95% CI [1.16, 10.57], $p = .03$) and men with diabetes (OR = 2.84, 95% CI [1.01, 7.97], $p < .05$; Towfighi et al., 2007). Another alarming finding was that during the four years of study, the incidence of CVD continued to increase in women while declining in men (Towfighi et al., 2007; Towfighi, Zheng, & Ovbiagele, 2009).

Between 45 and 64 years of age (Wild, Roglic, Green, Sicree, & King, 2004), the incidence of diabetes greatly increases for all adults (Centers for Disease Control and Prevention

[CDC], 2011a, 2011b; Wray, Alwin, McCammon, Manning, & Best, 2006), which raises the risk for CVD and associated mortality in this middle-aged group (Hu et al., 2002; Manson et al., 1991). Because middle-aged women with diabetes are at especially high risk for CVD mortality (Gregg, Gu, Cheng, Narayan, & Cowie, 2007; Towfighi et al., 2007, 2009; Wild et al., 2004), effective interventions to increase physical activity in this population are important.

In order to design interventions that specifically meet their needs, factors associated with recommended physical activity among middle-aged women must be more thoroughly understood. Comparison of factors associated with recommended physical activity would help to inform whether differing interventions are needed between middle-aged women with diabetes and those without diabetes. Because of the multiplicity of potential factors associated with physical activity, the investigator has categorized relevant factors as demographic, clinical, and social–cognitive.

Despite the large number of studies of the association between demographic, clinical, and social–cognitive factors and physical activity, there is a paucity of studies comparing middle-aged women with and without diabetes on these factors. The investigator found only one article comparing adults with and without diabetes on social–cognitive factors associated with physical activity (Plotnikoff, Karunamuni, & Brunet, 2009). Therefore, the primary purpose of this study was to explore the demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA in middle-aged women with and without diabetes and to compare the two groups on these factors and their MVPA. The investigator used two tools to measure physical activity, the International Physical Activity Questionnaire (IPAQ) short form and accelerometry. A third measure, a daily log, was used to provide contextual information. A secondary study purpose was to determine the degree of agreement between self-report and accelerometry for

measuring minutes per day of MVPA.

The major topics discussed in Chapter One are related to the phenomena of interest, which focuses on (a) middle-aged women and their risk for diabetes and CVD, (b) the importance of lifestyle behavioral changes to decrease risk for and control of diabetes and CVD, (c) physical activity definition and recommendations, (d) use of a behavioral theoretical model, (e) difficulty with measurement of physical activity, and (f) a lack of consistency in factors associated with physical activity. The chapter closes with a discussion of the significance of this research to nursing followed by the study purpose and research questions.

Middle-Aged Women: Risk for Diabetes and CVD

Middle age is defined as being between 45 and 64 years of age (Campbell, 1965; Wild et al., 2004). Over the past 10 years, the incidence of diabetes has increased by 30% and is estimated to affect 12.6 million women, of which 5.6 million are middle-aged, in the United States in 2011 (CDC, 2011b). The most prevalent type of diabetes is Type 2 diabetes (T2D), which accounts for 90% to 95% of cases (CDC, 2011a). Because of the differing types of diabetes and high prevalence of T2D, the investigator used an abbreviation when referring to a specific type and the general term of diabetes when referring to all types.

The incidence of new cases of T2D is highest in adults between 40 and 59 years of age compared with those who are at least 60 years of age or older (Kahn, Cheng, Thompson, Imperatore, & Gregg, 2009; National Diabetes Information Clearinghouse [NDIC], 2007). New cases of diabetes doubled in adults during middle-age compared with those between 20 and 40 years of age (CDC, 2011b). While prevalence of diabetes is the same by sex, more women than men have diabetes because women live longer, and the onset of T2D increases with age across both sexes (Wild et al., 2004). T2D is associated with obesity and lack of physical activity (Colditz, 1999; Helmrigh,

Ragland, Leung, & Paffenbarger, 1991; NDIC, 2007). Many middle-aged women are at risk for the development of diabetes as a result of increased obesity and sedentary behavior (Deshpande, Harris-Hayes, & Schootman, 2008). Currently, women of Asian American, African American and Hispanic race and ethnicity have higher risk for diabetes than non-Hispanic Whites (CDC, 2011b). The prevalence and incidence of diabetes in middle-aged women combine to make this a significant research topic.

In 2007, the annual economic costs of health care for diabetes were estimated at \$174 billion, accounting for one out of every 10 health care dollars spent (CDC, 2011b). At the current projected rate of a 30% increase every 5 years, the annual cost of diabetes in the year 2012 is expected to exceed \$220 billion and currently accounts for more than 88 billion lost work days and permanent disability costs of \$7.5 billion annually (CDC, 2009b). The emergent impact of diabetes on public health is important because of its pervasiveness and the prevalence, economic costs, and difficulty of managing diabetes-related complications.

Diabetes contributes significantly to CVD, the leading cause of death in the United States (Gouni-Berthold, Berthold, Mantzoros, Böhm, & Krone, 2008; Towfighi et al., 2007, 2009). Diabetes, which is the greatest risk factor, accounts for 84% of CVD deaths in adults over age 65 years (CDC, 2011b; NDIC, 2007). For adults between the ages of 55 and 64 years, 31.1% of all deaths are caused by CVD or diabetes (Heron et al., 2009). Other serious complications of diabetes include microvascular damage to the eyes (retinopathy), kidneys (nephropathy), and nervous system (neuropathy; Kilpatrick, Rigby, & Atkin, 2008; Lopes-Virella et al., 2008). Macrovascular complications of diabetes include blood vessel damage that causes high blood pressure (hypertension) and decreased blood circulation to the legs (peripheral vascular disease) and heart and brain (CVD) (Kilpatrick et al., 2008; Lopes-Virella et al., 2008). While all of the complications of

diabetes are potentially life threatening, CVD is the second major cause of death in middle-aged women (American Association of Clinical Endocrinologists, 2000; American Diabetes Association (ADA), 2006; American Heart Association [AHA], 2006; Heron et al., 2009).

Differences by sex and diabetes have also been noted for CVD risk. Middle-aged women between the ages of 45 and 54 without diabetes have greater than twice the risk of CVD compared with men of the same age (Towfighi et al., 2007). Middle-aged women with diabetes are at higher risk for CVD-related events than either middle-aged men with diabetes or middle-aged adults without diabetes (Agency for Healthcare Research and Quality (AHRQ), 2009; Gouni-Berthold et al., 2008).

Middle-aged women with diabetes are also at increased risk for mortality when experiencing a CVD event (Franco, Steyerberg, Hu, Mackenbach, & Nusselder, 2007). Although deaths from CVD have decreased by 27% over the past 30 years for women without diabetes, CVD deaths for women with diabetes have increased by 23% (AHA, 2006; Gregg et al., 2007). Middle-aged women have more uncontrolled risk factors for CVD, such as hypertension, high blood glucose levels (hyperglycemia), and high cholesterol or triglyceride levels (hyperlipidemia) than men (McCollum, Hansen, Lu, & Sullivan, 2005; Towfighi et al., 2009; Wexler, Grant, Meigs, Nathan, & Cagliero, 2005). Uncontrolled CVD risk factors of hyperglycemia, hypertension, and hyperlipidemia in middle-aged women with and without diabetes are potentially modifiable with lifestyle behavioral changes.

Importance of Lifestyle Behavioral Changes

Lifestyle behavioral changes have demonstrated a positive effect on diabetes and its related CVD risk factors (DPP Research Group, 2002; Holman et al., 2008; Lindstrom et al., 2006). Lifestyle behavioral changes for diabetes self-management as recommended by the

American Association of Diabetes Educators (AADE) include adequate physical activity, healthy eating, self-monitoring of blood glucose, taking medication as prescribed, problem solving, healthy coping and reducing risks for complications (Hayes, Herbert, Marrero, Martin, & Muchnick, 2008; Peeples, Tomky, Mulcahy, Peyrot, & Siminerio, 2007). These seven behaviors were at least 90% under the direct control of patients with diabetes (Funnell & Anderson, 2004). Dietary and physical activity lifestyle behaviors consume the majority of the 2 hr per day needed to manage diabetes (Russell, Suh, & Safford, 2005). Therefore, one important, but time-consuming, lifestyle behavior under the direct control of middle-aged women with and without diabetes is physical activity.

Physical Activity Definition and Recommendations

For this study, physical activity was defined as any movement caused by skeletal muscles that expends energy (Caspersen, Powell, & Christenson, 1985). The four defining attributes of physical activity include intensity, duration, frequency, and context (Caspersen et al. 1985; Nagi, 2005). The recommendations for physical activity are defined by intensity and duration in minutes (Haskell et al., 2007a, 2007b). Physical activity intensity levels are defined as light, moderate, or vigorous (Freedson, Melanson, & Sirard, 1998). Context is the type or environment in which the physical activity is performed such as occupational or daily living. The opposite of physical activity has been defined as sedentary behavior (Ekelund, Brage, Griffin, & Wareham, 2009; Healy et al., 2008; Rhodes & Blanchard, 2008).

As mentioned previously, the U.S. DHHS (2008) guidelines for all adults aged 65 years and younger include (a) at least 150 minutes per week of moderate-intensity physical activity, or (b) at least 75 minutes per week of vigorous-intensity physical activity, or (c) a comparable combination of MVPA during three or more days per week. Organizations such as the American

Table 1

Physical Activity Recommendations for Adults by Agency with Evidence Level

Agency Recommendations	Moderate Physical Activity	Vigorous Physical Activity	Comments
ACSM and AHA (AHA, 2007; Haskell et al., 2007a, 2007b)	30 minutes at least 5 days/week ^a	20 minutes at least 3 days/week ^b	Combination of MVPA. Strength training 10–15 repetitions of 8–10 exercises 2–3 times per week. Perform physical activity in at least 10-min bouts ^b
AADE (Hayes et al., 2008)	30 min/day ^a		Physical exam by provider before beginning
ADA (Sigal et al., 2007)	150 min/week ^a	90 min/week ^b	Over at least 3 days/week with not more than 2 consecutive days without physical activity. At least 4 hr/week of MVPA and/or resistance exercise to prevent CVD ^b . T2D: resistance exercise 3 times per week.
CDC, 2009c	At least 2.5 hr/week (150 min)	75 min/week	Muscle strength training on 2 days/week. Increase benefits: 300 min/week of moderate or 150 min/week of vigorous physical activity.
U.S. DHHS, 2008	At least 150 min/week ^a	At least 75 min/week	Equivalent combination of MVPA. Episodes of at least 10 min duration spread throughout the week.

Note. PA = physical activity. ^a Evidence level A = data derived from multiple randomized controlled trials. ^b Evidence level B = data derived from single randomized controlled trial or nonrandomized studies.

College of Sport Medicine (ACSM) and the AHA (AHA, 2007; Haskell et al., 2007a, 2007b), the AADE (Hayes et al., 2008), the ADA (Sigal et al., 2007), and the CDC (2009c) also have made recommendations for physical activity in adults as shown in Table 1.

A lack of adequate physical activity has been significantly associated with increased obesity, diabetes, and CVD events (Buse et al., 2007; Carnethon, Gulati, & Greenland, 2005;

DPP Research Group, 2002). Recommended levels of physical activity have been found not only to reduce the risk for diabetes but also the related cardiovascular risk factors (DPP Research Group, 2002; Hayes et al., 2008; Hu et al., 2001; Nelson, Reiber, & Boyko, 2002; Sigal et al., 2007). Despite the benefits related to achieving the recommended levels of physical activity, only 64.6% of U.S. adults reported being physically active and 26.4% reported no leisure-time physical activity per week based on CDC guidelines (2009c). In several national studies, middle-aged women reported performing less MVPA than men (Hu et al., 2001; Nelson et al., 2002; Pi-Sunyer et al., 2007; Sigal et al., 2007), and adults with diabetes were identified as the least physically active (Nelson et al., 2002).

The percentage of subjects meeting the 2008 U.S. DHHS physical activity goals was higher for adults between 45 and 54 years of age (65.2%) than for those between 55 and 64 years of age (60.0%; Carlson et al., 2008). Of the total sample of adults, only 64.5% met the 2008 U.S. DHHS recommendations, which are comparable to the CDC findings. These statistics indicate that a high percentage of U.S. adults are not achieving national physical activity recommendations. Research has noted discrepancies in outcomes of physical activity based on dissimilar recommendations by various agencies (Carlson et al., 2008). The investigator chose the U.S. DHHS (2008) recommendations to assess MVPA for the outcome of this study because the two attributes of duration and intensity were specifically defined.

Inadequate primary care counseling on physical activity may contribute to the lack of physical activity in middle-aged women (Jacobs-van der Bruggen et al., 2009; VanWormer, Pronk, & Kroeninger, 2009). The small percentage of providers (<40%) who initiate physical activity counseling has not changed during the past 25 years, perhaps due to perceptions that patient barriers were too great (Wechsler, Levine, Idelson, Rohman, & Taylor, 1983). Barriers to

physical activity in middle-aged women include fatigue; low priority; lack of time, motivation, social support, and convenient access; psychological or physical limitations; and work and family responsibilities (Cannioto, 2010; Keller & Fleury, 2006; Kowal & Fortier, 2007).

By identifying the associated barriers and other related social–cognitive factors in middle-aged women with and without diabetes, findings from this study could be used to develop tailored protocols within primary care to increase physical activity among this population of middle-aged women. Little is known about the similarities or differences in factors associated with MVPA between middle-aged women with and without diabetes and whether interventions should be similar or need to be tailored differently for those with diabetes. The following section describes the behavioral theoretical approaches used by researchers to study physical activity in women and adults with diabetes. Measurement of physical activity is discussed by comparing self-report to objective measures. Finally, the lack of consistent evidence for factors associated with physical activity is discussed.

Behavioral Theoretical Approaches

Theoretical approaches to making lifestyle behavioral changes are an important consideration when designing interventions. Glasgow, Peeples, and Skovlund (2008) reported that the Institutes of Medicine (2001) have suggested a shift from a treatment model based on only clinical outcomes to a behavioral model when considering interventions. Much of the diabetes research to date has used a treatment model to investigate the relationship of MVPA to clinical outcomes such as HgbA1c, blood pressure, lipid levels, blood glucose levels, and body mass index (BMI; Boulé, Haddad, Kenny, Wells, & Sigal, 2001; Kavookjian, Elswick, & Whetsel, 2007; Thomas, Elliott, & Naughton, 2006). While treatment models assist providers to guide medical interventions, these models may not provide essential information about the social–cognitive

factors for formulating primary care behavioral interventions capable of promoting healthy behaviors (Conn, Hafdahl, Brown, & Brown, 2008; Ruggiero, 2000). Therefore, more studies of physical activity are needed that use behavioral models especially in their examination of middle-aged women (Gandhi et al., 2008; Kirk & Leese, 2009).

While some researchers have utilized single behavioral models to study physical activity in women and in adults with diabetes (Barrett, Plotnikoff, Courneya, & Raine, 2007; Belza 2004; Conn, Burks, Minor, & Mehr, 2003; Jilcott, Everson, Laraia, & Ammerman, 2007; Keyserling et al., 2002; Kohlbry, 2006; Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2010), others have suggested that studies of diabetes necessitate a more multi-factorial conceptual approach (Whittemore, Bak, Melkus, & Grey, 2003). The investigator contributes toward the advances made by these nurse researchers in theoretical approaches by developing and applying a multi-factorial behavioral model to explore physical activity in middle-aged women with and without diabetes. The model specifically focuses on the behavior of physical activity as the primary study outcome and provides a framework for the study of multiple factors associated with physical activity in the study population. The major concepts, relationships, assumptions, and theoretical approach of the model for the study design are discussed in Chapter Two.

Measurement of Physical Activity

Physical activity has primarily been measured using self-report. While major benefits include time efficiency and cost-effectiveness, one major shortcoming of self-reported physical activity measurement is recall bias (Courneya, Jones, Rhodes, & Blanchard, 2003; Prince et al., 2008). Recall bias is related to forgetfulness, social desirability, and difficulties understanding the definitions of physical activity intensity levels (Matthews et al., 2005; Prince et al., 2008). Recent meta-analyses of physical activity behavioral interventions in adults with chronic diseases,

including diabetes, indicated the need for more accurate and sensitive physical activity measures (Conn, Hafdahl, Brown, et al., 2008). Other studies have also noted a lack of reliable and consistent physical activity measures (Brown & Werner, 2008; Troiano et al., 2008).

To address limitations inherent in self-report, researchers have recommended the use of more objective measures of physical activity such as accelerometry (Bonomi, Goris, Yin, & Westerterp, 2009; Brown & Werner, 2008; Freedson et al., 1998; Troiano et al., 2008). Accelerometry uses a small electromechanical device (an accelerometer) to measure acceleration by detecting vibration caused by movement. Accelerometers have also been used to measure physical activity in adults with and without diabetes (Bonomi et al., 2009; Freedson et al., 1998; Paschali, Goodrick, Kalantzi-Azizi, Papadatou, & Balasubramanyam, 2005; Trost, McIver, & Pate, 2005).

To improve the measurement of physical activity for this study the investigator employed both a self-report tool, the IPAQ short form (Craig et al., 2003), and an objective measure, accelerometry. Further review and synthesis of the literature concerning physical activity measurements are addressed in Chapter Three, which also includes a synthesis of factors associated with physical activity in middle-aged women with and without diabetes. The following section provides an overview of factors associated with physical activity.

Lack of Consistent Evidence for Factors Associated with Physical Activity

Factors associated with physical activity have been difficult to isolate because many intervention trials target multiple health behaviors (Orozco et al., 2008; Thomas et al., 2006). Preliminary research by this investigator indicated the existence of differences between factors associated with physical activity and other health-related behaviors such as diet (Vanden Bosch, Corser, Xie, & Holmes-Rovner, 2011). Few randomized controlled trials have specifically

enrolled middle-aged women as subjects (Church, Earnest, Skinner, & Blair, 2007; Elavsky & McAuley, 2007; Folta et al., 2009; Rimmer, Rauworth, Wang, Heckerling, & Gerber, 2009; Wilcox et al., 2001). Studies comparing women with diabetes to those without diabetes were not found. The investigator also noted that some of the factors associated with physical activity have been ambiguous or contradictory in the literature (Troiano et al., 2008); this research issue is discussed in Chapter Three.

In response to the lack of consistent evidence for factors associated with physical activity, this study was designed to examine whether and how middle-aged women with and without diabetes differed in their MVPA and the numerous demographic, clinical, and social–cognitive factors associated with MVPA. Further review and synthesis of the demographic, clinical, and social–cognitive factors associated with physical activity in adults in general and specifically in middle-aged women with and without diabetes are discussed in Chapter Three, and the measurement of these factors is discussed comprehensively in Chapter Four.

Significance to Nursing

The significance of this study to nursing was to inform the design of future nursing interventions to increase MVPA by exploring and comparing factors associated with MVPA in middle-aged women with and without diabetes. Because few middle-aged women meet the national recommendations for physical activity, information obtained from this study was needed to elucidate important factors that can be addressed in interventions specifically designed for those with and without diabetes to enhance effectiveness. Although all women can benefit from interventions to assist them in increasing their physical activity, the need is particularly urgent during middle-age, especially for those with diabetes, to reduce the risk for CVD and resultant early death.

Because many middle-aged women with diabetes are regularly evaluated in primary care settings, a nursing intervention specifically addressing the needs of this group can be a fruitful approach for assisting them to increase their MVPA. Therefore, the study targeted middle-aged women with and without diabetes who were receiving primary care in four clinics as a means of thoroughly exploring the demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA.

Study Purpose

The primary purpose of the study was to explore the demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA in middle-aged women with and without diabetes and to compare the two groups on these factors and their MVPA. A secondary purpose was to determine the degree of agreement between self-report and accelerometry for measuring minutes per day of MVPA.

Research Questions

The following research questions were addressed:

Research question one. What were the differences between middle-aged women with and without diabetes in their minutes per day of MVPA as measured by the two physical activity measures and their associated demographic, clinical, and social–cognitive factors?

Research question two. What was the degree of agreement in minutes per day of MVPA between the International Physical Activity Questionnaire (IPAQ) short form (Kroenke et al., 2001) and the accelerometer?

Research question three. Which demographic, clinical and social–cognitive factors of middle-aged women with and without diabetes were associated with minutes per day of MVPA as measured by the (a) IPAQ short form, and (b) accelerometer?

Summary

A major contribution of this study to nursing science includes new knowledge of the factors associated with MVPA as measured by both self-report and accelerometry among women with and without diabetes and any differences that exist between the two groups. To further contribute to nursing knowledge about behavioral approaches, the investigator used a behavioral theory to study physical activity in middle-aged women. The significance of this study to nursing was its primary focus on middle-aged women in primary care who may be either at risk for diabetes or diabetes-related CVD due in part to a lack of adequate MVPA and the factors associated with their MVPA. Comparing factors associated with MVPA between middle-aged women with and without diabetes was important to inform the development of primary care interventions to increase MVPA in these groups. Comparison of middle-aged women with diabetes to those without diabetes was significant due to a lack of information about the differences between these two groups. Study findings could assist primary care providers in determining if interventions need to be tailored for women with diabetes or can be similar for all middle-aged women.

The following chapters provide a discussion of the behavioral theoretical approach for the study (Chapter Two), a review of the literature on factors associated with physical activity in middle-aged women with and without diabetes (Chapter Three), the study design and methods used to analyze the research questions (Chapter Four), the findings of the study (Chapter Five), and implications for nursing (Chapter Six).

Chapter Two

Theoretical Approach

This chapter describes the theoretical approach or model on which the study design was based. A theoretical model is a meaningful and testable description of the concepts and assumptions related to a phenomenon about individuals, groups, situations, or events (Fawcett, 2005). The phenomena of interest for this study were the demographic, clinical, and social–cognitive factors associated with the behavioral outcome of physical activity in middle-aged women with and without diabetes. As noted in Chapter One, physical activity is defined as any movement caused by skeletal muscles that expends energy (Caspersen et al., 1985), and middle age lies between 45 and 64 years of age (Campbell, 1965). Examining physical activity was important to the study design because achieving the recommended level is associated with a decreased risk of diabetes and the related CVD risk factors (DPP Research Group, 2002; Hu et al., 2001).

Theories used to guide the study of physical activity in adults are social cognitive theory (SCT; Bandura, 1977) and the theory of planned behavior (TPB; Ajzen, 1991). Glanz, Rimer, and Viswanath (2008) noted that SCT depicts the personal and environmental influences leading to behaviors, while the TPB depicts the motivating thought processes that influence behaviors. Therefore, integration of these theories provided a more comprehensive theoretical approach to the study of the multidimensional concept of physical activity. The TPB and SCT provided the appropriate background for the study model because these theories have been used extensively in physical activity research (Armitage, 2005; Barrett et al., 2007; Blue, 2007; Conn, Tripp-Reimer, & Maas, 2003; Hunt & Gross, 2009; Parrott, 2006; Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2008, 2010; Tavares, Plotnikoff, & Loucaides, 2009; White, Terry, Troup, & Rempel,

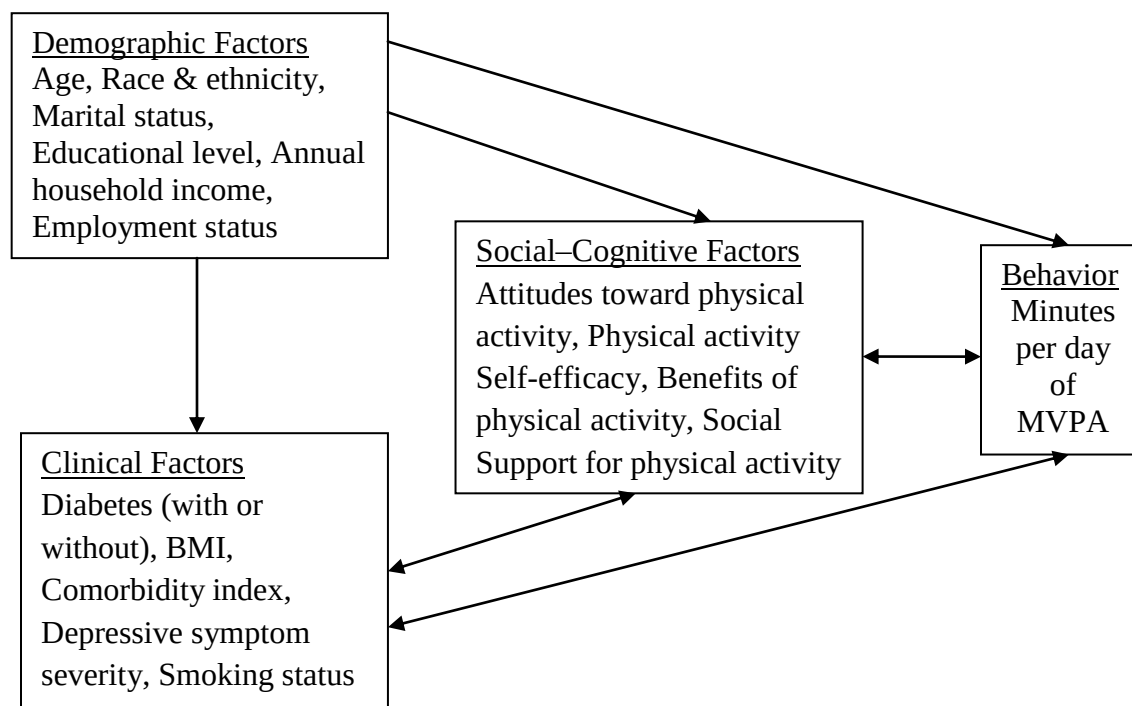


Figure 1. Behavioral model of physical activity.

2007). For this study, the theoretical model was titled the Behavioral Model of Physical Activity (BMPA) and is presented in Figure 1. The BMPA includes the demographic, clinical, and social-cognitive factors that influence the behavior of middle-aged women with and without diabetes or, more specifically, the number of minutes per day spent in MVPA.

Behavioral Model of Physical Activity

Evaluation of theoretical models. To better understand the concepts and assumptions of the BMPA, a thorough evaluation of the theoretical model was warranted. The evaluation criteria described by Fawcett (2005) were used to evaluate the BMPA. The evaluation criteria include the theory (a) context, (b) focus and scope, and (c) content. Theory context includes the historical approach contributing to the development of the theory and the current use of the theory in nursing. Theory focus includes the unique characteristics of the theory to nursing and how the theory uses the metaparadigm concepts of person, environment, health, and nursing. Theory

scope includes the breadth of the nursing viewpoint, such as broad or narrow. Theory content includes concepts, relationships between the concepts, and assumptions that are specified by the relationships (Fawcett, 2005). The utility of the BMPA to the study design is discussed below while comparing and contrasting it to SCT and the TPB.

Evaluation of the BMPA. As depicted in Figure 1, the BMPA was particularly suited to this study of physical activity in middle-aged women with and without diabetes. The primary reasons for use of the BMPA include (a) appropriate scope, (b) significant content to cover the phenomena of interest, and (c) context based on SCT and the TPB, two models previously used to predict physical activity. Comparisons between the BMPA and SCT and the TPB indicate the similarities and differences between theory concepts and relationships between concepts. (See Table 2 for the comparisons between SCT, the TPB, and the BMPA.)

Theory context. According to Fawcett (2005), theory context is the identification of concepts and assumptions based on the historical and current environment in which nursing interventions occur. While all three are considered to be social–cognitive theories, both SCT and the TPB provide the theoretical context for the BMPA. Therefore, a discussion of both theories was necessary for the historical and current context.

SCT. The historical context of SCT is based on social learning theory (Miller & Dollard, 1941) and the work of Albert Bandura (1977, 1989, 1997, 2001, 2004). Bandura developed a model of SCT based on a model of perceived self-efficacy from his observations of patients with snake and spider phobias. SCT is used in a variety of disciplines, including education, health promotion, and disease management (Bandura, 2004; Liu & Larose, 2008; Toobert, Strycker, Glasgow, Barrera, & Bagdade, 2002). One nurse researcher developed a seven-step exercise program for older adults based on SCT (Resnick, 2000). The significance of SCT to the present

Table 2

Comparison Between Social Cognitive Theory (SCT), the Theory of Planned Behavior (TPB), and the Behavioral Model of Physical Activity (BMPA).

Theory/Model	SCT (Bandura, 2001)	TPB (Ajzen, 1991)	BMPA
Major concepts	Person Environment Self-efficacy Outcomes Expectancy behavior	Intention Perceived control Subjective norms Attitudes Behavior	Demographic factors Clinical factors Social–cognitive factors Behavior: MVPA
Similar concepts	Person Self-efficacy Outcomes Expectancy Behaviors: any	Attitudes Behaviors: any	Demographic factors Physical activity self-efficacy Attitudes toward physical activity Benefits of physical activity Behavior: MVPA
Differing concepts	None	Perceived control Subjective norms Intention	Physical activity self-efficacy Social support for physical activity Clinical factors
Relationship between concepts	Reciprocal determinism	Linear with mediation by intention	Reciprocal determinism

study has been demonstrated by the large number of studies that used SCT to examine factors influencing physical activity (Barrett et al., 2007; Keller, Fleury, Gregor-Holt, & Thompson, 1999; Keller, Fleury, Sidani, & Ainsworth, 2009; Plotnikoff et al., 2008; Tavares et al., 2009). Concepts specific to SCT include person, environment, behavior, self-efficacy, and outcome expectations. Self-efficacy has been demonstrated to be a significant predictor of physical activity (Barrett et al., 2007; Keller et al. 1999; Perkins, Multhaup, Perkins, & Barton, 2008; Plotnikoff et al., 2008).

TPB. The historical context of the TPB is based on work by Fishbein (2008) and Ajzen (2002) in theories of learning, attitudes, and decision making (Glanz et al., 2008). The TPB was

developed as an extension of the theory of reasoned action, which explains the relationships between attitudes, intentions, and behaviors (Ajzen; Fishbein). Early research by Ajzen indicated that attitudes toward a specific behavior were a much better predictor of the actual behavior than attitudes toward the disease process (Glanz et al., 2008). The theory of reasoned action also uses the concept of subjective norm, which is the perceived social pressure to perform a specific behavior (Ajzen, 1991). Like attitudes, subjective norm predicts intention and subsequent behavior.

Further research revealed that a new concept in the theory of reasoned action, perceived control, also predicted behavioral intention and change (Ajzen, 1991). With the addition of perceived control, which is similar to self-efficacy, the TPB was created (Glanz et al., 2008). The explanatory utility of the TPB related to health promotion has been noted in a variety of research settings; it includes factors associated with physical activity in various settings and populations such as middle-aged women with and without diabetes (Courneya, Keats, & Turner, 2000; Plotnikoff, Lippke et al., 2010; Rhodes, Fiala, & Conner, 2009; Rhodes, Blanchard, Courneya, & Plotnikoff, 2009; Rhodes & Courneya, 2003a; Rhodes, Jones, & Courneya, 2002).

Theory focus and scope. The focus of the BMPA was on the demographic, clinical, and social-cognitive factors associated with physical activity. According to Fawcett (2005), scope is defined by the range of a theory. Theory scope is considered to be grand, middle range, or situation specific (Peterson & Bredow, 2004). The range of a grand nursing theory is abstract and unstructured, and it functions to differentiate nursing from other health professions (Peterson & Bredow, 2004). Middle-range theories are generally less abstract and narrower in scope because they involve fewer concepts and assumptions and have a more specific view of nursing that is often related to practice. Situation-specific theories are very narrow in scope; they focus on one

aspect of nursing to define the activities and outcomes (Peterson & Bredow, 2004).

In comparison to SCT and the TPB, which are both middle-range theories, the BMPA is a situation-specific model. The specific situation for use of the BMPA in this study was the demographic, clinical, and social–cognitive factors associated with physical activity in middle-aged women with and without diabetes. The nursing metaparadigm of person and environment are major concepts in SCT, and their use is implied by the demographic, clinical and social–cognitive factors of the BMPA. Nursing is implied by interventions used to increase the number of minutes per day of MVPA

Theory content. Two concepts derived from the SCT concept of person and used in the BMPA were the demographic and clinical factors. Demographic factors include age, race and ethnicity, marital status, educational level, annual household income, and employment status. Clinical factors in the BMPA include diagnosis of diabetes, BMI, comorbidities, depressive symptom severity, and smoking status.

Social–cognitive factors in the BMPA were derived from both SCT and the TPB. BMPA social–cognitive factors include attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, and social support for physical activity. The primary concept derived from the TPB and included in the BMPA was attitudes toward physical activity. Attitudes toward physical activity were defined for this study as the perceived evaluation of physical activity as being favorable or unfavorable (Ajzen, 1991).

The concept of self-efficacy was derived from SCT and has been defined as “beliefs in one’s capabilities to organize and execute the course of action required to produce given attainments” (Bandura, 1977, p. 3). For the BMPA, the given attainment was minutes of MVPA as recommended by the U.S. DHHS (2008). The TPB uses the concept of perceived control,

which includes both self-efficacy and the amount of control one has over the behavior (Ajzen, 2002; Rhodes & Courneya, 2003b, 2004). While perceived control measures confidence (motivation) and control and predicts intention, self-efficacy assumes motivation and intention to do the behavior (Rhodes & Courneya, 2003b).

Rhodes and Courneya (2003b) compared self-efficacy, controllability, and intention and found that the self-efficacy component of perceived control was a better predictor of intention and behavior than controllability. Ajzen (1991, 2001) agreed with these findings of self-efficacy as a predictor of intention. In factor analysis, self-efficacy was found to measure the same items as intention, which indicates redundancy between the items. An interesting finding in the study was that self-efficacy loaded higher on intention in a younger and more physically able sample and higher on controllability in an older cancer-survival sample (Rhodes & Courneya). This indicates that self-efficacy was also a better measure of variability between groups and was able to capture both confidence (motivation) and controllability. Thus, while similar in content, perceived control and self-efficacy were different concepts, with self-efficacy being more parsimonious for research purposes. Therefore, the BMPA incorporated physical activity self-efficacy as influential to physical activity in middle-aged women with and without diabetes.

The BMPA also includes the concept of perceived benefits, which has been associated with physical activity in the research literature (Keller & Fleury, 2006; Marquez, McAuley, & Overman, 2004; Resnick, Zimmerman, Orwig, Furstenberg, & Magaziner, 2000). Beneficial effects of physical activity include increased cardiovascular, metabolic, and musculoskeletal systems function; disease prevention; and emotional well-being (Bandura, 1997). Benefits were associated with the positive expected outcomes of a behavior (Bandura, 1997). Barriers were the negative aspect of outcome expectations. In the BMPA, barriers were assessed by physical

activity self-efficacy despite the barriers. Benefits were assessed separately.

For the present study, social support for physical activity was defined as what important others do or say to either encourage or discourage a person to perform the specific physical activity. Social support for physical activity can be perceived as positive or negative. Positive social support was perceived as being assistive to the person in maintaining the physical activity. Negative social support was perceived as being demanding, nagging, or controlling even though the intent may be to give positive support.

Social support for physical activity in the BMPA was derived from the SCT concept of environment and person and differs from the TPB concept of subjective norms. The major difference between the two concepts is that subjective norms are perceived social pressures and social support is positively perceived assistance in performing the specific behavior (Rhodes et al., 2002). Research has indicated that social support is a better predictor of actual physical activity performance than subjective norms (Courneya et al., 2000). Therefore, the BMPA incorporates perceived social support as influential to physical activity in middle-aged women with and without diabetes.

Table 3 alphabetically lists and defines the major concepts in the BMPA. One concept of central importance to the TPB that was not used in the BMPA is intention. In the TPB, intention precedes behavior and is defined as readiness to perform the specific behavior (Ajzen, 2002). Intention was not included in the present study for several reasons. One reason was that the outcome of interest in the study was actual performance of physical activity, not intended behaviors. Differences between a person's hypothetical intentions and actual behavior have been found to be disparate due to social desirability (Ajzen, Brown, & Carvajal, 2004). Moreover, intentions have not always been an adequate predictor of actual performance of physical activity

Table 3

Definitions of Major Concepts in the Behavioral Model of Physical Activity

Concept	Definition	Reference
Attitudes toward physical activity	“the degree to which a person has a favorable or unfavorable evaluation or appraisal” of performing the minutes per day of MVPA	Ajzen, 1991, p. 188
Behavior	the actual performance of minutes per day of MVPA	Glanz et al., 2008
Benefits of physical activity	perceived positive consequences of performing the minutes per day of MVPA	Bandura, 1997
Physical activity	any movement caused by skeletal muscles that expends energy	Caspersen et al., 1985
Physical activity self-efficacy	“beliefs in one’s capabilities to organize and execute the course of action required to produce ” minutes per day of MVPA	Bandura, 1997, p. 3
Social support for physical activity	a person’s perception of what important others do or say to either encourage or discourage performing physical activity	Based on subjective norm from Ajzen (1991)

(Conn, Tripp-Reimer et al., 2003; Hagger & Chatzisarantis, 2009). Intention explained only 10% more of the 30% variance explained by other factors in a meta-analysis of physical activity (Hagger & Chatzisarantis, 2009). These studies support the observation that persons with intentions do not always perform the intended behaviors, a phenomenon that may be particularly evident in physical activity. In one study that used a self-report tool, intention was usually overestimated by persons seeking to increase their physical activity and underestimated actual changes in unhealthy behaviors (Matthews et al., 2005). Because of the qualitative differences between intentions and behaviors for physical activity, only actual behaviors were of interest for

this study.

Assumptions of the BMPA. The basic assumption of the BMPA was reciprocal determinism in which one group of factors influences another and vice versa (Bandura, 1997). Not all of the factors of interest have reciprocal effects. For example, while demographic factors can influence physical activity, physical activity does not influence demographic factors, which indicates a unidirectional effect. Reciprocal determinism is explained by the relationship between the clinical factor of depressive symptom severity and physical activity. Research has demonstrated that depressive symptom severity decreases performance of physical activity (Brown, Ford, Burton, Marshall, & Dobson, 2005; Collins-McNeil, Holston, Edwards, Benbow, & Ford, 2009; Delahanty, Conroy, & Nathan, 2006; Morrato, Hill, Wyatt, Ghushchyan, & Sullivan, 2007) and increased physical activity decreases depressive symptom severity (Conroy et al., 2007; Greer & Trivedi, 2009).

Similar reciprocal effects have been demonstrated for diabetes being influenced by physical activity (DPP Research Group, 2002), and having an influence on physical activity (Morrato et al., 2007; Nelson et al., 2002). While BMI has been strongly associated with physical activity (Bryan & Katzmarzyk, 2009; Harris, Owen, Victor, Adams, & Cook, 2009; Strath, Holleman, Ronis, Swartz, & Richardson, 2008), less of an effect of physical activity on BMI has been demonstrated (Lee, Djousse, Sesso, Wang, & Buring, 2010). The reciprocal effect has been noted by comorbidity index influencing the amount and frequency of physical activity (Ayotte, Margrett, & Hicks-Patrick, 2010) and by physical activity decreasing the comorbidity index by lowering risk factors for diabetes and CVD (Buse et al., 2007; DPP Research Group, 2002; Holman et al., 2008; Lindstrom et al., 2006; Wilcox et al., 2001). Smoking status has indicated some potential for a reciprocal effect on physical activity in studies using accelerometers (Strath

et al., 2008).

Reciprocal determinism was also assumed between social–cognitive factors and physical activity (Allen, 2004; Rhodes, Fiala et al., 2009; Berry & Carson, 2010). A second assumption of the BMPA was that positive attitudes of the middle-aged women toward physical activity would be positively correlated with greater minutes of physical activity (Rhodes, Fiala et al., 2009). A third assumption of the BMPA was that women who had a higher perceived physical activity self-efficacy would perform more minutes of physical activity (Allen, 2004). A fourth assumption was that middle-aged women who perceive great benefit would have more minutes of performing physical activity (Clark & Dodge, 1999; Kim, Kim, Park, & Kim, 2010; Moore, Dolansky, Ruland, Pashkow, & Blackburn, 2003). Conversely, women who perceive negative or no benefit from performance will be less likely to perform the physical activity (Plotnikoff et al., 2008). Positive social support was assumed to increase the performance of physical activity (Kirk & Leese, 2009). The social–cognitive factors of the BMPA were hypothesized to be particularly modifiable through nursing intervention (Allen, 2004; Daley, Fish, Frid, & Mitchell, 2009; Moore et al., 2003; Rhodes, Fiala et al., 2009).

Summary

The utilization of concepts from SCT and the TPB, both of which have been used for research with physical activity, enabled the investigator to formulate the BMPA, a theoretical model relevant to the analysis of factors associated with physical activity in middle-aged women with and without diabetes as part of the study design. The BMPA was a relatively parsimonious model that was appropriate for use within several busy primary care practices. The model was also situation specific for applicability to the study of physical activity in the population of interest, middle-aged women with and without diabetes. Utilization of concepts from SCT and

the TPB provided clear and measureable definitions. Assumptions for the BMPA included reciprocal determinism and an influence of demographic, clinical, and social–cognitive factors on minutes per day of MVPA. Research questions related to the demographic and clinical factors will be discussed in Chapter Three in the review of the research literature. The review of the research literature includes the state of the science for physical activity in middle-aged women and the factors associated with physical activity in those with and without diabetes.

Chapter Three

Integrated Review of the Literature

The review of literature was specific to the phenomena of interest, physical activity in middle-aged women with and without diabetes and the associated demographic, clinical, and social–cognitive factors. Physical activity, including its definitions, recommendations, measurement, and beneficial effects, is the first topic of review. The second topic of literature review considers the key factors associated with physical activity, first among adults in general and, when analyzed, among middle-aged women with and without diabetes. The discussion of key factors associated with physical activity is guided by the theoretical model discussed in Chapter Two. The chapter concludes with a summary of the gaps in the research literature of factors associated with physical activity in women with and without diabetes.

Physical Activity Definitions

As discussed in Chapter One and used in this study, physical activity is any movement caused by skeletal muscles that expends energy (Caspersen et al., 1985). Expended energy is determined by the amount of muscle that produces movement and the duration, intensity, and frequency of the movement (Caspersen et al., 1985). Therefore, duration, intensity, and frequency are three of the four defining attributes of physical activity. The fourth attribute is the context in which the physical activity is performed.

For this study, *duration* was defined as the amount of time spent performing the physical activity; time is usually measured in minutes or in bouts (episodes) of 10 or more consecutive minutes of physical activity (Strath et al., 2008). *Intensity* was defined according to the CDC (2011b) definition as the amount of energy used by skeletal body movement per minute of duration. Moderate activity is equal to 3.5 to 7 kcal/min or 3.0 to 6.0 metabolic equivalents of

task (METs) and vigorous activity is greater than 7 kcal/min or 6.0 METs when one MET is the energy expended by an average adult of 70 kg (154 lb) while sitting quietly (Ainsworth et al., 2000). Intensity has been categorized as light, moderate, and vigorous by comparison with the amount of oxygen used during the physical activity (Haskell et al., 2007a, 2007b). *Frequency* was defined as the number of 10-minute episodes or bouts at a certain level of intensity (Haskell et al., 2007a). *Context* was defined as the circumstance or situation in which physical activity occurs. Examples of physical activity context include exercise, occupational, leisure time, and daily living, which have been difficult to accurately measure in women (Wilbur, Miller, Dan, & Holm, 1989).

All defining attributes of physical activity were measured during the study. However, the major study outcome included only duration and intensity as minutes per day of MVPA performed by middle-aged women with and without diabetes.

All human beings are physically active to varying degrees. As defined in Chapter One, the opposite of physical activity is sedentary behavior (Ekelund, Brage, Besson, Sharp, & Wareham, 2008; Healy et al., 2008; Rhodes & Blanchard, 2008). For this study, any behavior that did not fall into the categories of light-, moderate-, or vigorous-intensity physical activity was considered sedentary.

Adherence to Physical Activity Recommendations

Despite the established U.S. DHHS recommendations, adults with diabetes (Collins-McNeil et al., 2009; Gleeson-Kreig, 2006; Goodall & Halford, 1991; Karjalainen et al., 2008) and without diabetes (van Sluijs et al., 2005) have difficulty meeting and maintaining the recommended MVPA. Therefore, Healthy People 2020 has established a goal of increasing “the proportion of adults who engage in aerobic physical activity of at least moderate intensity for at

least 150 min/week, or 75 min/week of vigorous intensity, or an equivalent combination by 4.4%” (U.S. DHHS, 2011). Another Healthy People 2020 goal is to “reduce the proportion of adults who engage in no leisure-time physical activity by 3.6%” (U.S. DHHS, 2011).

Utilizing large databases that include data from national representative sampling was appropriate for determining the percentage of adult populations meeting the recommendations for MVPA. In the 2007 Behavioral Risk Factor Surveillance System (BRFSS), 43.5% of all adults met the recommendations for MVPA (Adabonyan, Loustalot, Kruger, Carlson, & Fulton, 2010), with males being more active (48.3%) than females (38.9%). Similar differences by sex have been demonstrated in the NHANES studies (Kriska et al., 2006; Nelson et al., 2002; Troiano et al., 2008; Wood, 2002) except for 60- to 69-year-old subjects in one study (Troiano et al., 2008).

Diabetes has been significantly associated with inactivity, especially in women (Kruger, Ham, & Sanker, 2008; Wood, 2002). Data from the NHANES III (1999–2002) indicated that less than a third (31%) of adults with diabetes met the recommended levels of MVPA (Nelson et al., 2002). Other smaller sample studies have also found that recommended MVPA has not been met by between 50% to 75% of adults with diabetes (Cox, Carpenter, Bruce, Poole, & Gaylord, 2004; Nothwehr & Stump, 2000; Plotnikoff et al., 2006; Vanden Bosch et al., 2011). Cox et al. (2004) indicated that while 80% of their sample of low-income racially diverse adults with T2D had been counseled to exercise, only 25% were performing the recommended physical activity. Reasons given by adults with diabetes for a lack of physical activity included the perceived difficulty of physical activity, tiredness, distraction by television viewing, lack of time, and lack of local facilities (Thomas, Alder, & Leese, 2004).

Physical Activity Measurement

Methods of physical activity measurement are generally defined as either subjective or objective (Reiser & Schlenk, 2009). Subjective methods include all self-report measures. Self-report measures have been used in both experimental and non-experimental studies of physical activity including four meta-analyses (Lee, Folsom, & Blair, 2003; Oguma & Shinoda-Tagawa, 2004; Wendel-Vos et al., 2004; Zheng et al., 2009). The Women's Health Initiative and the Nurse's Health Study were two of the studies analyzed in the meta-analysis (Oguma & Shinoda-Tagawa, 2004).

Some objective methods of physical activity measurement include accelerometry, pedometers (Welk et al., 2000), and oxygen consumption measures (Dunn et al., 1999; Rankin, Briffa, Morton, & Hung, 1996). Accelerometers have been used in observational studies including a nationally representative sample (Troiano et al., 2008), an elderly cohort at the National Institutes of Health (Dinger, Oman, Taylor, Vesely, & Able, 2004), a CDC population study of obesity (Strath et al., 2008), and a pulmonary disease study at the Veterans Administration (Steele et al., 2003). None of these larger sample studies were specific to middle-aged women with or without diabetes. Of the nine identified studies using accelerometers to measure MVPA in adults with diabetes (Allen, Jacelon, & Chipkin, 2009 ; Balkau et al, 2008; De Greef, Deforche, Tudor-Locke, & De Bourdeaudhuij, 2010; Harris et al., 2009; Healy et al., 2008; Keyserling et al., 2002; Kirk, Mutrie, Macintyre, & Fisher, 2004; Paschali et al., 2005; Voon, Celler, & Lovell, 2009), all recruited males and females of various age groups except one which recruited 200 African American middle-aged women (Keyserling et al., 2002).

While several experimental studies have used accelerometers to measure MVPA in adults with diabetes (Allen et al., 2009; Kirk et al., 2001) or at risk for diabetes (Healy et al., 2007), comparative

studies using accelerometer-measured MVPA in adults with and without diabetes were not found by the investigator. Sample size has also been problematic in several studies using accelerometers (Allen et al., 2009; Kirk et al., 2001).

The major benefit of self-report methods is the ability to measure large sample studies for which objective measures would be costly and less efficient (Troiano & Freedson, 2010). Self-report methods are also able to gather perceptual and some contextual information. The major benefit of accelerometry compared with self-report is the ability to measure intensity by distinct cut-points and continuously throughout daily living. Reliability of measurement has been reported as being higher in objective compared with self-report measures, especially for measuring MVPA (Karjalainen et al., 2008).

Discrepancies between the two measures have resulted in self-report demonstrating more minutes of MVPA than accelerometry (Brown & Werner, 2008; Troiano et al., 2008), especially in obese participants (Brown & Werner, 2008). Self-report discrepancies include survey wording, response scale bias, and recall error (Courneya et al., 2003). Overestimation of socially desirable and underestimation of socially undesirable physical activity behaviors have also been noted in self-report (Adams et al., 2005). A risk bias analysis of 46 studies comparing self-report to objective measures noted that correlations ranged widely, from -0.071 to 0.96 (Prince et al., 2008). Other factors limiting comparisons of self-report to objective measures included differing physical activity attributes measured and lack of consideration by sex of the participant.

Despite the large number of physical activity studies, relatively few meta-analyses were found (Boulé et al., 2001; Boulé, Kenny, Haddad, Wells, & Sigal, 2003; Conn, Hafdahl, Brown, et al., 2008; Hagger & Chatzisarantis, 2009; Lee et al., 2003; Oguma & Shinoda-Tagawa, 2004; Thomas et al., 2006; Wendel-Vos et al., 2004; Zheng et al., 2009) and only one used physical

activity as the outcome of interest (Conn, Hafdahl, Brown, et al., 2008). Problems inherent in physical activity meta-analyses have included a lack of randomization or controls, missing data, and quality of the measures (Banks-Wallace & Conn, 2002; Lee et al., 2003; Oguma, Sesso, Paffenbarger, & Lee, 2002; Oguma & Shinoda-Tagawa, 2004; Wendel-Vos et al., 2004; Zheng et al., 2009). Specific measurement problems have included a lack of clearly defined cut-points for intensity levels and homogeneity of attributes being measured, and studies based solely on self-report (Kriska et al., 2006; Oguma et al., 2002; Oguma & Shinoda-Tagawa, 2004)..

Beneficial Effects of Physical Activity

In general, regular and recommended physical activity has beneficial effects for adults on risk of CVD, diabetes, and mortality. The CDC (2009c) also mentions beneficial effects of physical activity in women for colon cancer prevention; maintaining healthy bones, muscles, and joints to control arthritis pain or decrease bone loss; control of weight and body fat; reduction of symptoms of anxiety and depression; and improved feelings of well-being. Other benefits of physical activity reported by women include greater self-efficacy or confidence to do the physical activity despite the barriers, greater perceived benefits, and better quality of life (Conroy et al., 2007). Further literature review analyzed the effects of physical activity specific to CVD, diabetes, and mortality in adults and, when available, in middle-aged women.

CVD prevention. Heart disease and stroke, two types of CVD, were associated with high incidence and mortality in the U.S. (Lee et al., 2003; Pate et al., 1995). Therefore, studies analyzing the effect of physical activity on CVD are important to public health. The benefits of physical activity have been found to be associated with lowering the CVD risk factors of hyperlipidemia, hypertension, and diabetes. Physical activity lowers total cholesterol and low-density lipoprotein levels associated with atherosclerosis and raises high-density lipoprotein

levels associated with protection against atherosclerosis (Wilund, Feeney, Tomayko, Weiss, & Hagberg, 2009). Physical activity also decreases the vascular resistance, adrenal response to stress, fibrinolysis, and endothelial dysfunction associated with hypertension (Cornelissen & Fagard, 2005). Recommended physical activity was associated with CVD risk reduction not only by decreasing the causative blood vessel endothelial damage (Pedersen & Saltin, 2006) but also by the prevention and control of diabetes (DPP Research Group, 2002; Hu et al., 2001; Lindstrom et al., 2006; Nelson et al., 2002; Pi-Sunyer et al., 2007). These beneficial effects of physical activity on CVD were especially important for women since 42% of women who suffer a heart attack die within the first year as compared with 24% of men (AHRQ, 2009).

Results of four meta-analyses indicated that self-reported physical activity decreased adults' risk for CVD (Lee et al., 2003; Oguma & Shinoda-Tagawa, 2004; Wendel-Vos et al., 2004; Zheng et al., 2009). Two of the four meta-analyses were based on observational studies of stroke incidence (Lee et al., 2003; Wendel-Vos et al., 2004). The study by Lee et al. (2003) of 18 cohort and five case-control studies indicated that the relative risk (*RR*) of a stroke decreased by 27% for highly active adults compared with those who had lower levels of physical activity (*RR* = 0.73, 95% CI [0.67, 0.79]). Another study indicated a protective effect for total stroke incidence for both moderate-intensity occupational physical activity (*RR* = 0.64, 95% CI [0.48, 0.87]) and leisure-time physical activity (*RR* = 0.85, 95% CI [0.78, 0.93]) compared with sedentary behavior (Wendel-Vos et al., 2004).

While moderate physical activity decreased risk of stroke incidence, vigorous physical activity had an even greater beneficial effect in these two studies (Lee et al., 2003; Wendel-Vos et al., 2004). These findings indicated that physical activity intensity as well as duration was beneficial to CVD prevention. In another study, 30 minutes of walking for 5 days per week was

associated with a 19% risk reduction in heart disease (95% CI [.14, .23]) and the amount of reduction was dose dependent (Zheng et al., 2009). The only meta-analysis studying women exclusively included 30 studies from 1996 through 2004 and found that 1 hr per week of physical activity was associated with reduced risk for CVD in women (Oguma & Shinoda-Tagawa, 2004).

Limitations of meta-analysis included a lack of female study participants and male-biased questionnaires (Oguma & Shinoda-Tagawa, 2004). Another limitation noted by the investigator was the use of a variety of tools, some general, some disease-specific and some specific to physical activity making comparison across studies difficult. Limited assessment of physical activity attributes also made meta-analysis difficult (Lee et al., 2003; Wendel-Vos et al., 2004) and was especially evident when assumptions about duration and intensity were made in order to calculate *RR* based on the full data (Zheng et al., 2009).

Diabetes prevention. A randomized controlled trial (DPP Research Group, 2002), a national representative study of the U.S. population (Nelson et al., 2002), and a study in Finland (Laaksonen et al., 2005; Lindstrom et al., 2006) have demonstrated that physical activity as part of a behavioral intervention reduced the risk for diabetes. Participation in 150 minutes of MVPA per week along with diet reduced the risk of developing T2D by 58%, which was higher than the effect of Metformin, an oral anti-diabetic medication (31%; DPP Research Group, 2002). The Finnish Diabetes Prevention Study noted that at least 4 hr per week of physical activity decreased the onset of T2D in a physically active group compared with a sedentary group (Lindstrom et al., 2006). The Nurses' Health Study findings indicated that self-reported MVPA at a frequency of at least once per week decreased the development of T2D by 33% (Manson et al., 1991). The measurement of physical activity by Manson et al. (1991) was based on

frequency in days per week and intensity level of moderate to vigorous but did not include duration. In a study of runners, Williams (2008) noted sex differences such that women who increased their intensity of running by one m/s decreased their odds of taking diabetes medications by 75%, while this same intensity increase in male runners produced a 50% decrease in odds. Medications were lowered by 46% for hypertension and 48% for low-density lipoprotein for women who ran one m/s more than other women runners. Williams' study indicated the importance of intensity of physical activity to decrease CVD risks, including diabetes, especially in women.

Diabetes control. Physical activity was an important health behavior for adults with diabetes and was listed as one of the seven self-management behavioral educational objectives (AADE, 2003). Physical activity has been associated with increased control of diabetes by decreasing blood glucose (Allen, Fain, Braun, & Chipkin, 2008) and insulin resistance in the muscle cells (Balkau et al., 2008; Boulé et al., 2001; Sigal et al., 2007; Thomas et al., 2006) and by weight or central adiposity control (Boulé et al., 2001). A comprehensive overview of the benefits of physical activity for adults with diabetes has been described by Zinman, Ruderman, Campaigne, Devlin, and Schneider (2004). Therefore, the discussion of physical activity and diabetes control was not exhaustive but simply an overview of studies on adults and, when specified, middle-aged women.

In two meta-analyses of adults with diabetes, physical activity has been noted to lower the 4-month average of blood glucose levels (HgbA1c) to clinically significant levels despite a lack of change in BMI (Boulé et al., 2003; Thomas et al., 2006). Average physical activity of 53 minutes for 3 days per week decreased central adiposity, a risk factor for diabetes (Mozaffarian et al., 2009). Several systematic reviews of physical activity and diabetes have also indicated that

regular and recommended physical activity demonstrated beneficial effects for diabetes, CVD risk factors, and weight loss (Kavookjian et al., 2007; Kirk & Leese, 2009; Sigal et al., 2007). Limitations of studies reviewed for meta-analysis and systematic reviews included a lack of differentiation by sex, short study duration, using multiple clinical (glycemic control, CVD risk factors) and behavioral (physical activity, diet, blood glucose monitoring) outcomes, and not measuring physical activity by similar attributes or methods.

In one prospective randomized controlled trial, the effect of physical activity intervention on lowering insulin resistance in muscle cells lasted longer in women than in men (Vanninen, Uusitupa, Sittonen, Laitinen, & Lansimies, 1992). Findings indicate a potential for sex differences in response to physical activity for diabetes. In a small observational study of nine adults with diabetes, two of whom were women, the effect of 60 minutes of physical activity decreased blood glucose levels for 7 hr after the activity (Allen et al., 2009). The physical activity also flattened the 2-hr post-meal (postprandial) blood glucose peaks so that they were not as high as peaks without the activity. These observations were important, particularly as another study reported that postprandial blood glucose levels were an independent risk factor for CVD events in T2D, especially in women (Cavalot et al., 2006). Also, because a 1% increase in HgbA1c predicts an 18% increase in CVD event risk, small decreases in blood glucose can significantly reduce this diabetes comorbidity (Selvin et al., 2004).

The specific physical activity attributes of duration and intensity have been associated with beneficial effects for diabetes (Balkau et al., 2008; Boulé et al., 2003). Greater duration but not intensity of physical activity was significantly associated with decreased insulin resistance in the European Relationship between Insulin Sensitivity and Cardiovascular Risk Study (Balkau et al., 2008). Conflicting results have been noted in a meta-analysis in which intensity was a greater

predictor of insulin resistance than duration (Boulé et al., 2003). Differences in these two studies' findings may be the result of how physical activity was measured. One study used accelerometers for a one-week study period (Balkau et al., 2008), and the other measured oxygen consumption of 50% to 75% VO_2^{max} during 49-min sessions 3.4 times per week for 20 weeks (Boulé et al., 2003). In addition, one study considered adults at risk for diabetes (Balkau et al., 2008), and the other studied adults with diabetes (Boulé et al., 2003). In a quasi-experimental study, higher intensity of physical activity decreased the 10-year CVD risk for T2D by between 0.6% to 2.6% (Loreto et al., 2005). Loreto et al. used 30 minutes per day of physical activity as compared with 60 minutes per day in the study by Balkau et al. (2008). Thus, lower intensity for longer duration or higher intensity for shorter duration of recommended physical activity demonstrated beneficial effects for CVD in women with diabetes.

Mortality prevention. Women who do not meet the MVPA recommendations have an increased risk for mortality (Martinson, O'Connor, & Pronk, 2001; Matthews et al., 2007). Meta-analysis of the beneficial effects of physical activity on CVD mortality in women (Oguma et al., 2002; Oguma & Shinoda-Tagawa, 2004) has significance because 42% of women with diabetes die within the first year after a CVD event (heart attack) compared with 24% of men (AHRQ, 2009). A lack of physical activity increased the risk of mortality for women (4.7, 95% CI [2.2, 9.8]) compared with men (3.4, 95% CI [2.0, 5.8], Warburton, Nicol, & Bredin, 2006). Warburton et al. (2006) found that a small increase in physical activity energy expenditure (one MET level) decreased mortality by 20%. Middle-aged women with less than 1 hr of physical activity per week doubled their CVD mortality compared with women who had more than 1 hr of physical activity per week (Warburton et al.).

Despite the advancement of medical treatments and the decline in the risk for all-cause

mortality and CVD, NHANES data from 2000 indicated that women between the ages of 35 and 74 with diabetes have approximately the same high risk for all-cause mortality (25.9, 95% CI [19.2 to 32.7]) compared with men with diabetes (24.4, 95% CI [16.3 to 32.6]; Gregg et al., 2007). While men with diabetes still have the highest heart disease mortality, their risk has declined over the past 20 years and has increased during the same time period for women with diabetes (Gregg et al., 2007). The difference in CVD mortality rates between women with diabetes and those without diabetes has been attributed to age at time of event (Barengo et al., 2004; Gouni-Berthold et al., 2008), although this does not account for the high stroke risk in middle-aged women, especially those with diabetes, compared with men (Towfighi et al., 2007). Some researchers have attributed the high risk for CVD events in middle-aged women to lack of treatment for hypertension, hyperlipidemia, and obesity (Towfighi et al., 2007). Another contributing factor may be the lack of physical activity in middle-aged women, especially those with diabetes.

Discussion of Physical Activity Literature

The review of literature indicated that physical activity was a highly beneficial health behavior for prevention of risk factors for CVD, T2D, and mortality (DPP Research Group, 2002; Laaksonen et al., 2005; Lindstrom et al., 2006; Lee et al., 2003; Nelson et al., 2002; Oguma & Shinoda-Tagawa, 2004; Wendel-Vos et al., 2004; Zheng et al., 2009). Physical activity was also shown to decrease the insulin resistance of T2D and hyperglycemia of diabetes (Boulé et al., 2003). Risk factors for CVD were deadly and debilitating to middle-aged women, especially those with diabetes (CDC, 2011b; Towfighi et al., 2009). Despite the known beneficial effects of recommended MVPA, less than 40% of U.S. and Canadian females participate in recommended levels of physical activity (Adabonyan et al., 2010; Plotnikoff et al.,

2006), with even less participation by females during middle age and by those with diabetes (Kriska et al., 2006; Morrato et al., 2007; Nelson et al., 2002). Therefore, interventions to increase MVPA in middle-aged women with and without diabetes are needed. To design interventions appropriate for middle-aged women with and without diabetes, this study examined the factors that influence physical activity and compared current level of MVPA between these two groups.

Physical activity has been difficult to measure, and reliable tools have not been established. Self-report surveys, while frequently used to measure physical activity, generally were specific to exercise or leisure time. Objective methods such as accelerometry were available but not often used. A variety of physical activity, including occupational activity and housework, can be measured by accelerometry as compared with self-report. To study the differences in measures of physical activity in middle-aged women with and without diabetes, this study examined physical activity by utilizing two measures, the IPAQ short version and accelerometry. A third measure, the daily log, was used only for contextual information.

For the purposes of this study, accelerometry was the baseline for physical activity measurement, with comparisons made to the IPAQ short version. Accelerometry allowed for data gathering on at least two attributes of physical activity, duration and intensity. Both duration and intensity of physical activity have demonstrated beneficial effects for women with and without diabetes (Balkau et al., 2008; Boulé et al., 2003; Lee et al., 2003, Wendel-Vos et al., 2004). As indicated by meta-analyses, the lack of systematic continuous measurement of physical activity has made it difficult to compare duration and intensity across studies for assessing dose response (Boulé et al., 2001; Boulé et al., 2003; Conn, Hafdahl, Brown, et al., 2008; Hagger & Chatzisarantis, 2009; Lee et al., 2003; Oguma & Shinoda-Tagawa, 2004;

Thomas et al., 2006; Wendel-Vos et al., 2004; Zheng et al., 2009). Thus, the science of physical activity has identified its potential benefits but has failed to identify the specific amount or dose of intervention needed for prevention. In response to the limitations of previous studies, the present study measured physical activity by treating minutes per day of MVPA as a continuous measurement. Differences in duration and intensity of MVPA between women with and without diabetes were compared to evaluate the possible influence of diabetes on physical activity in this middle-aged sample.

Because use of several measures simultaneously may enhance the reliability of physical activity measurement, both self-report and accelerometry were used to measure MVPA in middle-aged women with and without diabetes. To further analyze the differences between minutes per day of MVPA, the self-report and accelerometry methods were compared on their degree of agreement.

The next section discusses the key factors associated with physical activity. The literature review begins with key factors associated with physical activity in adults and becomes more specific to women, particularly those of middle age and with diabetes.

Key Factors Associated with Physical Activity

The key factors influencing physical activity were categorized by the investigator as demographic, clinical, or social–cognitive according to the theoretical model presented in Chapter Two. While there was an abundance of literature on the key factors associated with physical activity, these three groups of factors have rarely been studied collectively (Cardinal, Tuominen, & Rintala, 2004; Plotnikoff, Brez, & Brunet, 2003).

Although factors associated with physical activity have been studied extensively in the general population and in subjects with diabetes, only two meta-analyses were found for

interventions to increase physical activity in chronic illness and in diabetes (Boulé et al., 2001; Conn, Hafdahl, LeMaster, et al., 2008). While these meta-analyses were useful to assess population factors that influence physical activity, they were not specific to middle-aged women with diabetes. Research literature specific to middle-aged women and diabetes has been limited to observational and cross-sectional analyses. Only three studies were noted in which adults with and without diabetes were compared on factors associated with physical activity (Plotnikoff et al., 2003, 2009; Rhodes & Blanchard, 2008). While SCT and TPB constructs have some validity for analysis of physical activity, little research has assessed these constructs in comparative studies of adult behavior (Plotnikoff et al., 2003, 2009; Rhodes & Blanchard, 2008), and none were specific to middle-aged women with and without diabetes and all used self-report.

The following sections discuss the key factors associated with physical activity by demographic, clinical, and social–cognitive categories. In general, the first section provides a general overview followed by a more in-depth discussion of each factor associated with physical activity in women with and without diabetes. A brief discussion of the demographic, clinical, and social–cognitive factors follows each review of the literature.

Demographic factors. Demographic factors associated with physical activity in adults with or without chronic disease have included sex, age, race and ethnicity, marital status, educational level, annual household income, and employment status (Delahanty et al., 2006; Garber, Allsworth, Marcus, Hesser, & Lapane, 2008; Kim, Kim, Park & Kim, 2009; McCollum et al., 2005; Nelson et al., 2002; O’Hea, Wood, & Brantley, 2003; Osler, McGue, Lund, & Christensen, 2008; Oster et al., 2006; Plotnikoff et al., 2009; Troiano et al., 2008; Wanko et al., 2004).

Sex. As previously mentioned, large population-based studies such as BRFSS, the

Medical Expenditure Panel Survey, and NHANES have found differences by sex in physical activity, with men being more active than women (Adabonyan et al., 2010; Kriska et al., 2006; Nelson et al., 2002; Troiano et al., 2008; Wood, 2002). Other smaller sample studies of adults have also noted differences by sex in physical activity behavior (Barrett et al., 2007; Delahanty et al., 2006; Garber et al., 2008; Williams-Piehotta et al., 2009).

Studies of adults with diabetes have demonstrated differences by sex similar to those in the general adult population (Kriska et al., 2006; Morrato et al., 2007; Nelson et al., 2002; Plotnikoff et al., 2006; Wood, 2002). Among the few studies that used accelerometry, findings were in agreement with self-report methods that males perform more recommended physical activity than females, including those with diabetes (Harris et al., 2009; Healy et al., 2008; Troiano et al., 2008).

A systematic review of interventions for physical activity suggested that differences by sex may occur in how physical activity was initiated (Kavookjian et al., 2007). Differences in physical activity initiation by sex were exemplified by the attributes. Intensity differs by sex with women engaging in more moderate and less vigorous physical activity than men (Bergman, Grjibovski, Hagströmer, Bauman, & Sjöström, 2008). Preferences for context and predictors of physical activity also differ by sex (Dowda, Ainsworth, Addy, Saunders, & Riner, 2003; Young, King, Oka, & Haskell, 1994; Young, Miller, Wilder, Yanek, & Becker, 1998).

Preference for context of physical activity may account for some differences by sex. Self-report methods usually measure exercise or leisure-time physical activity (Andersen, Schnohr, Schroll, & Hein, 2000; Barrett et al., 2007; Cleland et al., 2010; Fitzhugh, Klein, & Hayes, 2008; Godin, Jobin, & Bouillon, 1986; Kandula & Lauderdale, 2005; Karjalainen et al., 2008; Marquez & McAuley, 2006; Marquez et al., 2004; Wendel-Vos et al., 2004; Wood, 2002). Exercise and

leisure-time physical activity were less common in women who reported more daily life physical activity (Belza, 2004). Some women considered leisure-time physical activity to be a waste of time (Im et al., 2010).

Also, certain questionnaires for measuring physical activity may be sex-biased by asking questions about activities that tend to attract either male or female participation, such as sports or yoga, respectively. In response to this bias, the investigator used an objective measure to assess physical activity during daily life, which was when women were reported to be the most physically active (Belza, 2004). In response to both the large volume of literature that was either not sex specific or focused on men's physical activity and the lack of studies on middle-aged women who were most at risk for low levels of physical activity, the present study design included only middle-aged women.

Age. Studies indicate that, in general, physical activity declines with age over the lifetime, with adults over 65 years of age being the least active (Amireault, Godin, Vohl, & Perusse, 2008; Garber et al., 2008; Harris et al., 2009; Nelson et al., 2002; Plotnikoff et al., 2006; Resnick, Foster, Bardsley & Ratner, 2006; Ribisl et al., 2007; Troiano et al., 2008; Wilcox, Bopp, Oberrecht, Kammermann, & McElmurray, 2003; Williams-Piehotta et al., 2009). Several of these studies enrolled adults with diabetes exclusively (Nelson et al., 2002; Plotnikoff et al., 2006; Resnick et al., 2006; Williams-Piehotta et al., 2009). In one study comparing factors that influence physical activity by sex, physical activity decreased across each decade of age in both sexes (Ribisl et al., 2007).

In contrast to the general decline in physical activity with aging, several studies have noted that adults between the ages of 45 to 59 years of age were less active than those over age 60 (Bergman et al., 2008; Kriska et al., 2006; Morrato et al., 2007). In a comparative study of

two large databases, NHANES III and the DPP study, differences in physical activity were noted by age (Kriska et al., 2006). The NHANES III found that females aged 60 years or older (26%) were more inactive than those between 45 and 59 years of age (23%). In contrast, the DPP found that women over age 60 (14%) were less inactive than those between 45 and 59 years of age (16%; Kriska et al., 2006). The DPP findings were in agreement with a comparative study of adults with and at risk for diabetes by age that found that physical activity declined with age except in adults between 60 and 69 years of age (Morrato et al., 2007).

In a study using accelerometry, physical activity increased in adults after age 60, especially in women (Matthews et al., 2008). In summary, discrepancies in physical activity have been noted by age based on sex, diabetes, and measures. Therefore, this study included only middle-aged women and used two measures of physical activity to compare subjects with and without diabetes. Because middle age is the time when incidence of T2D more than doubles (CDC, 2011a), the study of physical activity in middle-aged women was age appropriate.

Race and ethnicity. In a study of the 2003–2004 NHANES data with accelerometers, Hispanic males of all ages and Hispanic women between the ages of 20 and 59 years performed the most minutes of MVPA compared with all other races (Troiano et al., 2008). Hispanic women over the age of 60 years were the least active, and African American adults were less active than non-Hispanic Whites (Troiano et al., 2008). The findings that African American adults were less physically active than non-Hispanic Whites were in agreement with other studies using self-report and VO_2^{max} measures (Oster et al., 2006; Ribisl et al., 2007). However, results conflicted with other self-report studies that indicated Hispanics were the least physically active group (Adabonyan et al., 2010; Morrato et al., 2007; Oster et al., 2006; Resnick et al., 2006). For women with diabetes, an older study found that Black race was a stronger predictor of

inactivity than White race (Estacio et al., 1998).

Differences in physical activity between adults with and without diabetes by race and ethnicity were noted in the 2003 Medical Expenditure Panel Survey (Morrato et al., 2007). Adults without diabetes reported differences by race and ethnicity while adults with diabetes reported no differences (Morrato et al., 2007). In an analysis of adults with diabetes from the NHANES III, Mexican Americans and African Americans were more likely to self-report no physical activity, but in multiple regression analysis, race was not a predictor of physical activity (Nelson et al., 2002). A smaller sample ($n = 278$) of adults with diabetes also noted no differences in physical activity by race and ethnicity (Deshpande et al., 2008).

Differences between findings for race and ethnicity could be attributed to type of measure, such as self-report versus accelerometry or being with or without diabetes. Self-report measures indicate race and ethnic differences, with African American and Hispanic being the least active (Morrato et al., 2007; Nelson et al., 2002), while the accelerometry measures indicate greater physical activity in Hispanic adults than was self-reported (Troiano et al., 2008). Studies of adults with diabetes also indicate racial and ethnic differences. To better inform the differing influences of race and ethnicity on physical activity, the present study design recruited multiple racial and ethnic groups and allowed subjects to self-identity with more than one race and ethnic group. To test the hypothesis that diabetes equalizes the influence of race and ethnicity on physical activity, the difference in physical activity by race and ethnicity between middle-aged women with and without diabetes was compared. Other factors that may have differentiated physical activity by race and ethnicity in previous studies were context, such as occupation (Troiano et al., 2008). Therefore, this study measured physical activity during daily living by accelerometry.

Marital status. Being married has been shown to be a positive predictor of physical activity in several studies of women (Kim et al., 2009; Osler et al., 2008; Wilcox et al., 2003). While physical activity scores did not differ significantly when comparing twin pairs of middle-aged men and women, scores were the same across all marital statuses for women and higher for men who were married (Osler et al., 2008). These findings indicate that marital status may benefit physical activity in men more than women. Being single was associated with less physical activity in a study of middle-aged Australian women (Brown et al., 2005).

For adults with diabetes, Plotnikoff et al. (2006) found that being single was a predictor of a higher level of physical activity in Type 1 diabetes (T1D) but not in T2D. No significant difference in physical activity by marital status was found for 278 adults with diabetes (Deshpande et al., 2008). Several of these studies were conducted outside of the United States, and therefore it may not be possible to generalize these findings to U.S. populations (Brown et al., 2005; Kim et al., 2009; Plotnikoff et al.).

As this review shows, the results of studies about the association between marital status and physical activity were somewhat conflicted and vary by sex, race, and diabetes type. Further research was needed to understand the effect of marital status on physical activity. Therefore, this study included marital status as a potential factor associated with physical activity in middle-aged women. The investigator hypothesized that the influence of marital status on physical activity in middle-aged women may differ by age and diabetes.

Educational level. Higher educational level has been associated with more self-reported physical activity (Adabonyan et al., 2010; Bergman et al., 2008; Brown et al., 2005; Carlson et al., 2008; Kamphuis et al., 2008; Kim et al., 2009; Plotnikoff et al., 2006; Resnick et al., 2006; Trost, Owen, Bauman, Sallis, & Brown, 2002; Umstad & Hallam, 2007; Yang, 2005), high

accelerometer-measured physical activity (Sanchez et al., 2008), and higher physical activity intensity (Albert, Glynn, Buring, & Ridker, 2006). In the 2007 BRSFF, researchers noted that 70.3% of college graduates met the guidelines for physical activity compared with 52.2% of those who had less than a high school education (Carlson et al., 2008).

Lower educational levels were associated with lower levels of physical activity in one study of middle-aged women (Brown et al., 2005). Some conflicting research has indicated less physical activity in Swedish adults with a university degree (Bergman et al., 2008). The difference may be cultural, as studies in Latvia and Germany had similar results (López, Bryant, & McDermott, 2008; Rathmann et al., 2005), or it may be related to the level of college education attained, as baccalaureate, masters, or doctoral was rarely measured.

In adults with diabetes, no differences in physical activity have been noted by educational level in some research (Deshpande et al., 2008; Morrato et al., 2007), while other research has found education to be positively correlated to physical activity (Plotnikoff et al., 2006; Resnick et al., 2006). Research noting no difference in physical activity by educational level included rural adults (Deshpande et al., 2008) and women older than 40 years of age (Eyler et al., 1999). Women with diabetes generally have less education than women without diabetes (CDC, 2001), and therefore education may be an important distinguishing factor between women with and without diabetes associated with MVPA.

Limitations of studies for physical activity by education level included small sample size, observational methods, and self-reported physical activity measures. Trost et al. (2002) provided a systematic review that overcame some of these limitations, and there were a few exceptions to the limitation of small sample size (Carlson et al., 2008; Morrato et al., 2007; Plotnikoff et al., 2006). The investigator expected to find that educational level was positively associated with

physical activity in all women.

Annual household income. Higher income has been associated with greater self-reported participation in physical activity in numerous studies of adults in general (Amireault et al., 2008; Barrett, 2000; Barrett et al., 2007; Kamphuis et al., 2008; Morrato et al., 2007; Nelson et al., 2002; Rathmann et al., 2005; Trost et al., 2002; Umstattd & Hallam, 2007; Yang, 2005), adults with diabetes (Morrato et al., 2007; Nelson et al., 2002; Plotnikoff et al., 2006), and middle-aged women with T2D (Barrett et al., 2007). In an analysis of the demographic factors of age, gender, marital status, and employment, only 20% of women with lower incomes performed physical activity compared with 67% of those with higher incomes (Barrett et al., 2007).

There was general consensus in the self-report literature that annual household income was a positive predictor of physical activity in women with and without diabetes. A paucity of literature was found comparing annual household income and physical activity measured by accelerometry and the one study noted that higher income was associated with greater participation in accelerometry-measured physical activity (Sanchez et al., 2008). Therefore, annual household income was included in this study using accelerometry measures of physical activity. The influence of educational level and annual household income on physical activity may be a result of factors that also explain the higher prevalence of T2D in those with lower socioeconomic status (CDC, 2001). These factors were the poverty-related competing demands of cost versus healthy nutrition, physical activity, and medication use (AHRQ, 2009).

Employment status. Few studies were found exploring the relationship of employment to physical activity. Literature focused mainly on occupation rather than employment in association with physical activity (Brown et al., 2005; Kim et al., 2009; Salmon, Owen, Bauman, Schmitz, & Booth, 2000; Trost et al., 2002; Wilbur, Naftzger-Kang, Miller, Chandler, & Montgomery,

1999). Full-time employment was associated with decreased physical activity in one study (Barrett, 2000) and with more moderate and less vigorous physical activity in another study in Sweden (Bergman et al., 2008). One study of obese minority women indicated that full-time employment offered more risk for unhealthy behaviors such as lack of physical activity (Sanchez et al., 2008). In another study, as hours of work increased, physical activity decreased until retirement, after which white collar workers showed an increase in physical activity (Mein, Shipley, Hillsdon, Ellison, & Marmot, 2005).

Employment can also be a risk factor for the development of diabetes in women, a finding that was theorized to be caused by the stress of competing demands on the women's time (Heraclides, Chandola, Witte, & Brunner, 2009). Beneficial effects of employment for women were noted by Hibbard and Pope (1992) in a longitudinal study of social support and mortality. These studies demonstrate conflicting results that may be the result of differences by sex in type of occupation as reported in one study (Salmon et al., 2000). This study assessed differences between middle-aged women with and without diabetes in MVPA by employed versus not employed.

Discussion of demographic factors. Population-based and observational studies of adults indicate sex differences in physical activity. Shorter study duration and diabetes seem to lessen the difference by sex. The sex differences noted in the literature, especially in adults without diabetes, makes this an important issue that merits further research. In response, the investigator recruited only women to explore the factors associated with physical activity.

While increasing age was generally associated with decreasing physical activity, women between the ages of 45 and 59 years may be at increased risk for less physical activity than women over the age of 60 (Kriska et al., 2006; Morrato et al., 2007). Factors having a negative

influence on physical activity include being of African American or older aged Hispanic ethnicity (Nelson et al., 2002; Troiano et al., 2008). The demographic factors noted to have a positive influence on physical activity for women include educational level and annual household income (Brown et al., 2005; Morrato et al., 2007; Nelson et al., 2002; Plotnikoff et al., 2006).

The influence of marital status and employment status on physical activity in women was not known. Another unknown was whether these factors will have similar results for physical activity when measured by self-report versus accelerometer, because many studies of demographic factors did not use accelerometry. One study using accelerometry to measure physical activity found conflicting race and ethnicity influence compared with data collected by self-report (Troiano et al., 2008). Therefore, the present study assessed the influence of demographic factors of age, race and ethnicity, marital status, educational level, annual household income, and employment status on MVPA in women with and without diabetes. The next section discusses the clinical factors that have been associated with physical activity.

Clinical factors. Clinical factors associated with physical activity in adults have included diabetes (Morrato et al., 2007; Plotnikoff et al., 2006), BMI (Plotnikoff et al., 2006), comorbidity index (Clark & Dodge, 1999; Conn, 2003; Fryar, Hirsch, Eberhardt, Yoon, & Wright, 2010; McCollum et al., 2005; Moore et al., 2003), depressive symptom severity (Collins-McNeil et al., 2009; Delahanty et al., 2006; Kruger, Ham, & Prohaska, 2009; Wanko et al., 2004), and smoking status (Estacio et al., 1996; Kaczynski, Manske, Mannell, & Grewal, 2008; Plotnikoff et al., 2006; Salmon et al., 2000; Strath et al., 2008). Two clinical factors associated with physical activity in adults with diabetes were duration and type (Plotnikoff et al., 2006). Each of these clinical factors is discussed in the following paragraphs.

Diabetes. Studies have indicated that adults with diabetes perform less physical activity than those without diabetes despite the fact that physical activity is an important and highly recommended component of diabetes self-management (Clark & Dodge, 1999; Morrato et al., 2007; Nelson et al., 2002). Clark and Dodge (1999) noted that 66% of the adults with diabetes self-reported being sedentary compared with 59% of those without diabetes. While these results were reported over 10 years ago, more recent studies indicate that adults with diabetes were still not meeting physical activity recommendations (Allen, 2004; Morrato et al., 2007). While adults with diabetes were more likely to receive advice from providers to increase physical activity (Cox et al., 2004; Resnick et al., 2006) compared with those without diabetes (Resnick et al., 2006), adherence to recommended physical activity was low, with between 37% and 60% of those with diabetes not participating in any physical activity (Allen, 2004).

Duration of diabetes in years has also been negatively associated with physical activity (Plotnikoff et al., 2006, 2007; Resnick et al., 2006; Ribisl et al., 2007). Diabetes duration was highly related to comorbidities, which may make physical activity more difficult to perform (Kalyani, Saudek, Brancati, & Selvin, 2010; Wong, Molyneaux, Constantino, Twigg, & Yue, 2008). Types of diabetes, such as T1D and T2D, vary in pathophysiology of disease and manifestations of factors associated with physical activity (Plotnikoff et al., 2008). Differences in factors influencing physical activity by diabetes type included marital status and smoking for T1D, and sex, educational level, and BMI for T2D. An increased number of barriers for physical activity also have been associated with less physical activity in T2D (Plotnikoff et al., 2008).

The investigator predicted that middle-aged women with diabetes would perform shorter duration and lower intensity levels of physical activity than those without diabetes. The investigator evaluated how diabetes type and duration in complete years were associated with

physical activity in the subgroup sample of middle-aged women with diabetes.

BMI. Measured using height and weight, BMI was predictive of excess body fat in adults (CDC, 2009a). While not a gold standard for measurement of body fat percentage, BMI does assist the provider to determine whether an adult is at risk for being overweight or obese. Cut-points established by the CDC (2010) include healthy weight, underweight, overweight, and obese. *Healthy weight* has been defined as a BMI between 18.5 and 24.9 kg/m². *Underweight* has been defined as a BMI below 18.5 kg/m². *Overweight* and *obesity* have been defined as a BMI between 25 and 29.9 kg/m² and greater than 30 kg/m², respectively (CDC, 2010).

Adult BMI has been found to be negatively associated with physical activity in large national representative samples (Bryan & Katzmarzyk, 2009), including women (Bergman et al., 2008) and adults with diabetes (Deshpande, Baker, Lovegreen, & Brownson, 2005; Morrato et al., 2007; Williams-Piehota et al., 2009; Ribisl et al., 2007; Wing et al., 2007), especially for T2D (Plotnikoff et al., 2006). Studies, using accelerometry methods (Harris et al., 2009; Strath et al., 2008) and observational methods (Salmon et al., 2000), have confirmed this negative association. A BMI below 30 kg/m² was associated with more physical activity in Swedish women compared with those with BMI over 30 kg/m² (Bergman et al., 2008). Hispanic women with a BMI at or below healthy weight limits had a higher proportion of meeting the physical activity recommendations (Boeckner, Pullen, Walker, & Hageman, 2006; Kohlbry, 2006). A higher percentage of healthy-weight women (29.8%) engaged in the recommended level of physical activity compared with overweight (23.2%) and obese (16.5%) women (Kruger et al., 2009). Limitations of the study were analysis of leisure-time physical activity only in older women.

For adults with diabetes, healthy weight has been associated with higher levels of physical activity (Deshpande et al., 2005; Morrato et al., 2007; Nelson et al., 2002; Plotnikoff et al., 2006, 2007; Williams-Piehota et al., 2009). Some research has indicated that BMI was a better predictor of physical activity for women than men (Bergman et al., 2008), while other studies have noted no differences by sex in influence of BMI on physical activity (Estacio et al., 1996). BMI was more highly associated with physical activity in adults with T2D compared with other types of diabetes (Plotnikoff et al., 2006). Because BMI has been noted to have a strong negative association with physical activity in women with and without diabetes, this factor was included in the study design.

Comorbidity index. Comorbidities have been defined as other diseases besides the one being explored and have been measured using a comorbidity index (Charlson, Pompei, Ales, & MacKenzie, 1987). For women with diabetes, comorbidities have been a common problem due to the pathophysiology of the disease on the cardiovascular, neurological, renal, and sensory systems (CDC, 2001). Racial disparities have been noted in the incidence of comorbidities (Fryar et al., 2010). Non-Hispanic Black adults (49.6%) were more likely to have at least one of the conditions of diabetes, hypertension, or hypercholesterolemia compared with non-Hispanic White adults (45.1%). At least one additional condition and all three comorbidities were more likely in non-Hispanic Blacks (16.4% and 4.6%, respectively) compared with non-Hispanic Whites (12.8% and 2.5%, respectively; Fryar et al., 2010).

Comorbidities have been negatively associated with physical activity in adults (Ayotte et al., 2010), including those with diabetes (Plotnikoff et al., 2007) and middle-aged women without diabetes (Brown et al., 2005; Kohlbray, 2006; McCollum et al., 2005; Moore et al., 2003). In a cardiac rehabilitation study of women, a number of whom had diabetes, fewer comorbidities

were associated with higher intensity and frequency of physical activity (Moore et al., 2003). Comorbidities were an important factor to consider in the present study when comparing the differences between physical activity in middle-aged women with and without diabetes. Because over half of the women in this study did not have diabetes, comorbidities included all diseases and were measured as a comorbidity index.

Depressive symptom severity. A meta-analysis of 42 studies found that the odds of depression in adults with diabetes were twice as high as the odds of those without diabetes (Anderson, Freedland, Clouse, & Lustman, 2001). Depression prevalence for adults with diabetes was significantly higher in women (28%) than men (18%; Anderson et al., 2001). The higher prevalence in women than men has also been demonstrated in other studies (Gucciardi, Wang, DeMelo, Amaral, & Stewart, 2008; McCollum et al., 2005).

Another meta-analysis of depression and T2D indicated that depression increased the risk for T2D by 60%, but diabetes did not increase the risk for depression (Mezuk, Eaton, Albrecht, & Golden, 2008). The causative factors for the higher risk for T2D with diagnosed depression have been linked to the inflammatory process of central abdominal obesity and insulin resistance (Everson-Rose et al., 2009; Whittemore, Melkus, & Grey, 2004), which have been associated with a lack of physical activity. Depressive symptoms have been negatively correlated to physical activity in several observational studies (Brown et al., 2005; Collins-McNeil et al., 2009; Delahanty et al., 2006; Morrato et al., 2007). Because of the increased prevalence of depression associated with diabetes, especially in women with diabetes (Anderson et al., 2001; McCollum et al., 2005), this study examined the association of depressive symptom severity and physical activity in middle-aged women both with and without diabetes.

Smoking. Smoking was negatively associated with physical activity in 61% of the studies

analyzed in a systematic review and especially in women (Kaczynski et al., 2008). In observational studies, smoking has been negatively associated with physical activity both in adults in general (Salmon et al., 2000) and those with diabetes (Grace, Barry-Bianchi, Stewart, Rukholm, & Nolan, 2007; Plotnikoff et al., 2006). Plotnikoff et al. (2006) noted that smoking in adults with T1D, but not T2D, was associated with increased physical activity. The association between smoking and physical activity has mixed results when using accelerometry (Strath et al., 2008). While smokers demonstrated more total mean minutes per day of MVPA than nonsmokers (97.1 versus 87.7, respectively), they had shorter mean time in 10-min consecutive bouts (13.2 min/day) versus nonsmokers (15.5 min/day) by accelerometry (Strath et al., 2008).

Discussion of clinical factors. Clinical factors expected to have a negative influence on physical activity in middle-aged women included diabetes, BMI, comorbidity index, depressive symptom severity, and smoking. The duration and type of diabetes were expected to have a moderating effect for diabetes on physical activity. Differences between women with and without diabetes were expected in BMI, comorbidity index, and depressive symptom severity. Lower scores for the clinical factors were expected in those without diabetes.

The majority of studies analyzing clinical factors related to physical activity have used self-report methods, with the exception of two studies that analyzed BMI (Harris et al., 2009; Strath et al., 2008) and one that analyzed smoking (Strath et al., 2008). The study by Strath et al. included some analysis of middle-aged adults. Clinical factors included in the present study design were diabetes, BMI, comorbidity index, depressive symptom severity, and smoking. These clinical factors were used in the assessment of physical activity by both self-report and accelerometry in middle-aged women with and without diabetes. The next section discusses the social-cognitive factors that have been associated with physical activity.

Social–cognitive factors. Four social–cognitive factors associated with physical activity included perceived attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, and social support for physical activity. The first social–cognitive factor reviewed was attitudes toward physical activity (Armitage, 2005; Conn, Tripp-Reimer, et al., 2003; Harris et al., 2009; Hunt & Gross, 2009; Plotnikoff et al., 2009; Rhodes, Fiala et al., 2009). Physical activity self-efficacy or the perceived confidence to perform the physical activity despite barriers has been associated with physical activity in adults with and without diabetes (Allen, 2004; Amireault et al., 2008; Armitage, 2005; Blanchard, Courneya, Rodgers, Daub, & Knapik, 2002; Blanchard et al., 2007; Conn, Tripp-Reimer, et al., 2003; Delahanty et al., 2006; Dutton et al., 2009; Fraser & Rodgers, 2010; Gleeson-Kreig, 2006; Harris et al., 2009; Hunt & Gross, 2009; Marquez et al., 2004; Murrock & Madigan, 2008; Nelson, McFarland, & Reiber, 2007; O’Hea et al., 2004; Perkins et al., 2008; Young & Stewart, 2006).

Benefits of physical activity have also demonstrated associations to physical activity (Kim et al., 2009; Moore et al., 2003; Plotnikoff, Lippke, et al., 2010; Plotnikoff et al., 2008; Resnick, Orwig, Magaziner, & Wynne, 2002; Resnick et al., 2006). The final social–cognitive factor associated with physical activity and reviewed in this chapter was social support for physical activity (Keller & Fleury, 2006; Thompson, Wolfe, Wilson, Pardilla, & Perez, 2003). Further discussion provides an analysis of each of the social–cognitive factors based on a synthesis of current data.

Attitudes toward physical activity. The review of the literature focused on attitudes toward physical activity and not attitudes toward diabetes (Cox et al., 2004) or attitudes toward physical activity settings or environment (Bailis, Fleming, & Segall, 2005). Attitudes toward physical activity for the present study were defined as “the degree to which a person has a

favorable or unfavorable evaluation or appraisal” of performing the minutes of MVPA (Ajzen, 2001, p. 188; Rhodes, Fiala et al., 2009).

A meta-analysis of 102 studies, 82 non-experimental and 20 experimental, noted an association between positive attitudes and higher levels of physical activity (Rhodes, Fiala et al., 2009). In observational studies, attitudes have been shown to be associated with physical activity in adults, in general (Blue, Wilbur, & Marston-Scott, 2001), with chronic conditions (Armitage, 2005; Hunt & Gross, 2009), and with diabetes (Plotnikoff, Lippke, et al., 2010; Plotnikoff et al., 2008). Other qualitative and quantitative studies have found that adults who exercised the least had the lowest score for attitudes toward physical activity (Berry & Carson, 2010), and physically active occupational work carried over to greater participation in leisure-time physical activity (Wu, 2000). Attitudes toward physical activity have also been a significant predictor of physical activity behavior in adults with T2D (Boudreau & Godin, 2009).

Meta-analysis noted that many intervention studies of attitudes and physical activity did not mention use of a theoretical model (Rhodes, Fiala et al., 2009). However, some studies of attitudes toward physical activity have used the TPB as the conceptual framework (Armitage, 2005; Conn, Tripp-Reimer et al., 2003; Hunt & Gross, 2009). Conflicting findings were also noted by a lack of change in attitudes for physical activity reported in one study (Hardeman et al., 2008), while other studies reported positive changes in attitudes through intervention (Nakagawa, Inomata, Nakazawa, & Sakamoto, 2007; Plotnikoff, Lippke, et al., 2010).

Physical activity self-efficacy. Studies reviewed included both perceived control and self-efficacy because the measure of perceived control includes both self-efficacy (confidence) and how much personal control one has over the activity (Rhodes & Courneya, 2003b). Physical activity self-efficacy is defined as “beliefs in one’s capabilities to organize and execute the

course of action required to produce” minutes per day of MVPA despite the barriers (Bandura, 1997, p. 3). Numerous studies have reported on the associations between physical activity and self-efficacy (Cox & Williams, 2008) or perceived control (Allen et al., 2008; Amireault et al., 2008; Armitage, 2005; Clark & Dodge, 1999; Conn, Burks, et al., 2003; Cox et al., 2004; Delahanty et al., 2006; Dutton et al., 2009; Fisher et al., 2000; Gleeson-Kreig, 2006; Harris et al., 2009; Kim et al., 2009; Marquez et al., 2004; Moore et al., 2003; O’Hea et al., 2004; Perkins et al., 2008; Plotnikoff et al., 2003, 2008; Williams-Piehotta et al., 2009; Young & Stewart, 2006). However, no meta-analyses, one integrative review (Allen, 2004), and one systematic review (Marquez et al., 2004) analyzing the association between self-efficacy and physical activity were found by the investigator.

Allen (2004) indicated that self-efficacy was a strong predictor of physical activity in adults with diabetes despite locating only three intervention studies and having difficulty matching physical activity measures. All studies used self-report and various physical activity measurement such as minutes per week, energy expenditure, treatment adherence, self-care scale, and self-monitoring activity log, making meta-analysis impossible (Allen, 2004). The systematic review noted a positive association between self-efficacy and physical activity in Hispanic women (Marquez et al., 2004).

The lack of meta-analyses may also be the result of the numerous tools used to measure self-efficacy. These tools varied greatly; some were general, while others were specific for diabetes (Nelson et al., 2002), physical activity (Resnick & Jenkins, 2000) or physical activity in adults with diabetes (Plotnikoff et al., 2003). Moreover, self-efficacy tools varied in number of items from five (O’Hea et al., 2004) to 13 (Plotnikoff et al., 2003), making item comparison difficult.

In several randomized controlled trials, higher self-efficacy was associated with increased physical activity in adults in general (Amireault et al., 2008), adults recently experiencing a CVD event (Blanchard et al., 2002), African American women of all ages (Young & Stewart, 2006), and adults with T2D (Dutton et al., 2009). In contrast, no mediating effect of self-efficacy between the intervention and the physical activity was noted in a study of culturally specific dance in African American women (Murrock & Madigan, 2008).

Individual cross-sectional studies have indicated that physical activity self-efficacy has been positively associated with physical activity in adults in general (Armitage, 2005; Blanchard et al., 2007; Hunt & Gross, 2009; Perkins et al., 2008), adults with diabetes (Delahanty et al., 2006; Gleeson-Kreig, 2006; Kim et al., 2009; King et al., 2010; Nelson et al., 2002; Plotnikoff, Pickering, McCargar, Loucaides, & Hugo, 2010; Williams-Piehota et al., 2009), and in women without diabetes (Hankonen, Absetz, Ghisletta, Renner, & Uutela, 2010). More self-efficacy barriers were noted in T1D than in T2D (Plotnikoff et al., 2009).

Comparative studies of adults with diabetes to those without diabetes were few for self-efficacy and physical activity (Grace et al., 2007; Plotnikoff et al., 2003), and neither of these was specific to middle-aged women. However, some evidence suggested that middle-aged women with diabetes may have lower physical activity self-efficacy than those without the disease (Grace et al., 2007; Plotnikoff et al., 2003). These findings indicate that interventions to increase self-efficacy would be potentially beneficial in middle-aged women and especially for those with diabetes. The importance of including self-efficacy as a factor in the study design for this research is indicated by the strong research support for the association between self-efficacy and physical activity, together with an inability to find comparative studies of middle-aged women with and without diabetes.

Benefits of physical activity. Benefits of physical activity include risk factor reduction for CVD and diabetes (Allen, 2004), lower depressive symptom severity (Conroy et al., 2007), weight management (Conroy et al., 2007; Dacey, Baltzell, & Zaichkowsky, 2008; Inzitari, Greenlee, Hess, Perera, & Studenski, 2009), stress management (Dacey et al., 2008), and enjoyment and increased coordination (Inzitari et al., 2009). Benefits of physical activity are defined as the perceived positive consequences of performing the minutes of MVPA (Bandura, 1997). Since benefits are the positive expectations of outcomes, the literature review for benefits associated with physical activity included studies referring to both benefits and outcomes expectancy. In a meta-analysis of adults with T1D and physical activity interventions, researchers found that interventions to increase outcomes expectancy did not increase physical activity (Conn, Hafdahl, LeMaster, et al., 2008). In a systematic review of social–cognitive variables and diabetes self-management behaviors including physical activity, findings were mixed, with only two studies actually evaluating benefits of physical activity (Allen, 2004).

Benefits of physical activity have mostly been measured in older adults and have been positively associated with physical activity (Resnick, 2002; Resnick et al., 2006). In contrast, another study indicated that outcomes expectancy (benefits) did not predict physical activity in older adults (Perkins et al., 2008). In a short 5-week study with a small sample, benefits of physical activity were increased by intervention (Daley et al., 2009). In certain studies, outcomes expectancy (benefits) predicted physical activity for women (Clark & Dodge, 1999; Kim et al., 2010; Moore et al., 2003) and adults with diabetes, with some differences in benefits of physical activity by type (Plotnikoff et al., 2008). Comparative studies of the benefits of physical activity between adults with diabetes and those without diabetes were not found. In response to the lack of studies of the association between benefits and physical activity and the conflicting findings,

the investigator included this factor in the study design.

Social support for physical activity. Social support for physical activity was defined as a person's perception of what important others do or say to either encourage or discourage performing physical activity (Ajzen, 1991). Studies of the effect of social support on physical activity were limited. However, several studies evaluated the effect of social support on outcomes other than physical activity, such as glycemic control for adults with diabetes (Conn, Hafdahl, LeMaster, et al., 2008; Whittemore, Melkus, & Grey, 2005). In a review of the literature, social support was associated with physical activity in women with T2D (Kirk & Leese, 2009). Social support was positively associated with physical activity in female adults of multiple races and ethnicities (Eyler et al., 1999; Keller & Fleury, 2006; Marquez et al., 2004; Moore et al., 2003; Thompson et al., 2003; Wilcox et al., 2001) and middle-aged women with diabetes (Fisher et al., 2000; Glasgow et al., 2006; Gleeson-Kreig, 2006; Grinslade, 2005; Gucciardi, Vogt, Demelo, & Stewart, 2009; Kirk & Leese, 2009; Plotnikoff et al., 2008). Social support predicted exercise frequency and maintenance over time for women in cardiac rehabilitation (Moore et al., 2003).

Findings of differences in social support by sex such that men perceived more social support for physical activity were reported in observational studies (Titler et al., 2009) and interventional studies (Hankonen et al., 2010). These findings indicate that social support may be an important factor for women, especially those with diabetes, to increase physical activity. Further study was needed in middle-aged women with and without diabetes to examine whether social support was a significant factor associated with physical activity in these two groups.

Discussion of social–cognitive factors. As noted in the review of literature and by several researchers, there was a lack of comparative studies between adults with diabetes and

those without, especially in the social–cognitive factors (Bazata, Robinson, Fox, & Grandy, 2008; Plotnikoff et al., 2009; Rhodes & Blanchard, 2008). This lack of comparative studies prompted the investigator to include the social–cognitive factors associated with physical activity in middle-aged women with and without diabetes in the study design. Another limitation of studies analyzing social–cognitive factors was a lack of objective measures of physical activity, except for one study of adults older than 65 years of age (Harris et al., 2009). In response, this study used two physical activity measures, self-report and accelerometry, to assess the influence of social–cognitive factors.

The social–cognitive factors of attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, and social support for physical activity are potentially modifiable by nursing-sensitive interventions. Therefore, the social–cognitive factors were important to the exploration of factors associated with minutes per day of MVPA in middle-aged women with and without diabetes. Findings from one study indicated self-efficacy for physical activity was the lowest of diabetes self-care activities of diet, exercise and blood glucose monitoring, despite being the highest for outcomes expectancy (benefits) to health (Williams & Bond, 2002). These study findings demonstrated the discrepancy between perceived confidence to do the physical activity and the perceived benefits of the activity. Because much of the research demonstrating an association between the social–cognitive factors and physical activity has been conducted with samples without diabetes, the study design incorporated middle-aged women with diabetes as well as those without the disease.

Summary

Middle-aged adults and especially women may be at significant risk for lower levels of physical activity, which increases the risk for CVD and diabetes during a time in life when T2D

greatly increases in incidence. The study design of including only middle-aged women with and without diabetes allows for comparison between these two groups to evaluate factors influencing physical activity.

The beneficial effects of physical activity have been demonstrated for all adults regardless of age, sex, or diabetes. Yet the benefits of physical activity were not being realized by middle-aged women and especially those with diabetes, a subgroup of the population that has been reported to be the least active. This lack of physical activity may be contributing to the high prevalence of CVD in middle-aged women. A better understanding of the demographic, clinical, and social–cognitive factors influencing physical activity was needed to design appropriate interventions for middle-aged women.

The review of the literature provided an understanding of several gaps in knowledge related to the key demographic, clinical, and social–cognitive factors associated with physical activity in middle-aged women with and without diabetes. These gaps include a lack of studies that involve objective measures of physical activity as compared with self-report and a lack of comparative studies of adults with and without diabetes, especially in middle-aged women who were at high risk for the development of diabetes and CVD. In response to the critical lack of research on MVPA in middle-aged women with and without diabetes, this study focused on the key factors associated with MVPA as measured by self-report and accelerometer.

The significance of the study was to expand knowledge of the demographic, clinical, and social–cognitive factors associated with MVPA in middle-aged women with and without diabetes for the design of future interventions.

Chapter Four is a discussion of the design of the study, the specific tools used for the study, analyses of the data, and the methods used for recruitment and data gathering.

Chapter Four

Design and Methods

The primary purpose of the study was to explore the demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA in middle-aged women with and without diabetes and to compare the two groups on these factors and their MVPA. A secondary purpose was to determine the degree of agreement between self-report and accelerometry for measuring minutes per day of MVPA in middle-aged women with and without diabetes. The following sections describe the design, research questions, study factors and measures, setting, samples, data collection, data analysis, and human subjects’ protection plan that were used for the study.

A comparative exploratory cross-sectional design was employed. After consenting to participate in the study during an initial clinic or home visit with the investigator, middle-aged women with and without diabetes completed a self-administered paper-and-pencil survey that elicited information about their demographic, clinical, and social–cognitive factors. Height and weight were obtained. Charts were audited to confirm clinical factors of diabetes and comorbidities.

To measure MVPA, an accelerometer was provided, and each woman was instructed to wear it for the next consecutive seven days for at least 10 hr per day. To obtain additional data on MVPA, two self-report measures were used: (a) a daily log completed concurrently with the accelerometer and (b) the IPAQ short form (Craig et al., 2003). The daily log was used only for context of the MVPA being performed while the women were wearing the accelerometer. The IPAQ short form was completed during a second clinic or home visit scheduled as soon as possible after the conclusion of the accelerometer wear-time. The purpose of the IPAQ short

form was to obtain a retrospective report of MVPA during the previous seven days and to compare it to the accelerometer data.

Research Questions

Based on the literature presented in Chapter Three, the investigator hypothesized that certain demographic, clinical, and social–cognitive factors would be associated with MVPA in middle-aged women and that some of the factors would differ between women with diabetes and those without diabetes. Measurement of MVPA by accelerometer allowed for continuous data gathering during daily living of middle-aged women and comparison of the measured data with one of the self-report measures. The three research questions addressed in the study were as follows.

Research question one. What were the differences between middle-aged women with and without diabetes in their minutes per day of MVPA as measured by the two physical activity measures and their associated demographic, clinical, and social–cognitive factors?

Research question two. What was the degree of agreement in minutes per day of MVPA between the IPAQ short form and the accelerometer?

Research question three. Which demographic, clinical and social–cognitive factors of middle-aged women with and without diabetes were associated with minutes per day of MVPA as measured by the (a) IPAQ short form, and (b) accelerometer?

Study Factors and Measures.

The study included explanatory factors and a response variable. By using labels such as explanatory and response, the investigator assumed certain relationships between the variables. One assumption was that explanatory factors were antecedent to the response variable of minutes per day of MVPA (Tamhane & Dunlop, 2000).

Explanatory factors. While causation was not assumed in this cross-sectional study, the strength of the associations between the explanatory factors and the response variable was explored (Ott & Longnecker, 2010). The study explored the association of the demographic, clinical, and social–cognitive factors to the response variable of minutes per day of MVPA. (See Table 4 for a description of the factors and their respective psychometric properties.)

Demographic factors. The demographic factors included (a) age, (b) race and ethnicity, (c) marital status, (d) educational level, (e) annual household income, and (f) employment status. Data concerning the demographic factors were collected via a self-administered paper-and-pencil survey. The survey was developed by the investigator and adapted from the well-validated BRFSS (CDC, 2011a), especially for the complex factors of race and ethnicity, marital status, and educational level. (See Appendix A for the self-administered paper-and-pencil survey.)

Age. Age was treated as a continuous variable.

Race and ethnicity. Race and ethnicity were treated as categorical variables. The paper-and-pencil survey included the following response choices: (a) African American or Black, (b) American Indian/Alaskan Native, (c) Asian, (d) Hispanic/Latino, (e) non-Hispanic/Latino, (f) native Hawaiian/Pacific Islander, (g) Multi-racial (having parents of different races), (h) White, and (i) don't know. Women were permitted to select more than one response choice as needed to adequately describe their race and ethnicity.

Marital status. Marital status was considered as a categorical factor. Women were asked to choose one of the following response choices to describe their marital status at the current time: (a) married/partnered, (b) widowed, (c) divorced/separated, or (d) never married/unpartnered.

Table 4

Study Variables, Type, Measurement, Number of Items, and Time to Complete

Variable	Type	Measurement (No. of Items)	Time to Complete
Explanatory			
<i>Demographic Factors</i>			<u>4 min</u>
Age	Continuous	Self-report (1)	
Race and ethnicity	Categorical	Self-report (1)	
Marital status	Categorical	Self-report (1)	
Educational level	Categorical	Self-report (1)	
Annual household income	Categorical	Self-report (1)	
Employment status	Categorical	Self-report (1)	
<i>Clinical Factors</i>			<u>10 min</u>
Diabetes (with or without)	Categorical	Self-report/chart audit (5)	
Duration	Continuous	Self-report (1)	
Type	Categorical	Self-report/chart audit (4)	
BMI	Continuous	Measured (3)	
Comorbidity index	Continuous	Self-report (13)	
Depressive symptom severity	Continuous	Self-report (9)	
Smoking status	Categorical	Self-report (1)	
<i>Social–Cognitive Factors</i>			<u>6 min</u>
Attitudes toward physical activity	Continuous	Self-report (6)	
Physical activity self-efficacy	Continuous	Self-report (10)	
Benefits of physical activity	Continuous	Self-report (9)	
Social support for physical activity	Continuous	Self-report (13)	
Response			
Min/day of MVPA	Continuous	Self-report (7)	5 min
	Continuous	Measured	20 min
Total		(87)	<u>45 min</u>

Educational level. Educational level was treated as a categorical variable with four response choices: (a) some high school education, (b) high school graduate, (c) some college or

technical school, or (d) college graduate. Women were asked to choose one of the four choices.

Annual household income. Annual household income was treated as a categorical variable having eight response choices: (a) less than \$15,000, (b) \$15,000 to less than \$25,000, (c) \$25,000 to less than \$35,000, (d) \$35,000 to less than \$45,000, (e) \$45,000 to less than \$55,000, (f) \$55,000 to less than \$65,000, (g) \$65,000 to less than \$75,000, or (h) equal to or more than \$75,000. Women were asked to choose one of the eight choices.

Employment status. Employment status was treated as a categorical variable. Women were asked to choose one of the following response choices to describe their employment status at the current time: (a) employed full-time, (b) employed part-time, (c) retired, (d) unemployed, or (e) unable to work.

Clinical factors. The study included the clinical factors of (a) diabetes, (b) BMI, (c) comorbidity index, (d) depressive symptom severity, and (e) smoking status. Clinical factors were assessed by self-administered paper-and-pencil survey (Appendix A), measurement of height and weight, and chart audit (Appendix B).

Diabetes. Diabetes was treated as a categorical variable. The three categories included (a) with diabetes, (b) without diabetes, and (c) unknown. Diabetes was defined as being diagnosed and/or treated by a health care provider and was determined by four questions on the self-administered paper-and-pencil survey. *With diabetes* was identified initially by the woman's self-reported response of "Yes" to a question of "Other than during pregnancy, have you ever been told by a doctor, nurse, or other health professional that you have diabetes?" or a positive response to either "Are you currently taking pills for diabetes?" or "Are you currently taking insulin for diabetes?" Further verification of diabetes was obtained by documentation on the medical record problem list and/or treatment by oral anti-diabetic medication or insulin on the

medication record during chart audit by the investigator. (See Appendix B for chart audit form.)

Without diabetes was identified by chart audit on the basis of a lack of documented diagnosed diabetes and/or a lack of treatment for diabetes by anti-diabetic medication or insulin. Duration and type of diabetes were included in the analysis of the association of minutes per day of MVPA in women with diabetes.

Diabetes duration in years was treated as a continuous factor. Women with diabetes responded to one question on the self-administered paper-and-pencil survey about the duration of disease in number of years. For women with less than one year of diabetes duration, the months of duration were divided by 12 to determine fraction of the year. For women without diabetes, diabetes duration was entered as 0 years into the study data record.

Type of diabetes was treated as a categorical variable with three levels: T1D, T2D, or unknown. Type of diabetes was based on the criteria established by research and listed by the National Institutes for Health in the NDIC (2009; Tuomi, 2005). Type of diabetes was assessed by the women's self-reported answer to one question ("What type of diabetes do you have?") along with answers about diabetes duration and medication use. Women were considered to have T1D if they affirmatively responded to a single question of "Have you always treated your diabetes with insulin?" Verification of T1D also occurred by chart audit of the medical record problem list and/or treatment by insulin on the medication record. Diabetes duration was another way to verify type since T1D generally has an onset before age 30 years (Sharp, Brown, & Qureshi, 2008).

Determination of T2D was made by self-reported diagnosis of T2D, use of oral medications and/or diet and exercise treatment, and onset occurring after age 30 years (Sharp et al., 2008). If self-report and chart audit were in agreement for type of diabetes, no further audit

was conducted. If a type of diabetes was not listed on the survey, then the investigator audited the problem list and medication record of the woman's chart. If any oral diabetes medications were being used, the investigator considered the woman to have T2D. If only insulin was used, the investigator considered the woman to have T1D. If type differed between self-report and chart audit, the investigator assessed the medication record for diabetes medications.

BMI. BMI was treated as a continuous factor. Self-reported BMI has been shown to be significantly different from measured BMI based on age and gender, with older adults overestimating height and women underestimating weight (Prentice & Jebb, 2001). Therefore, BMI was measured directly by the investigator or research assistant to increase reliability.

The investigator calculated each enrolled woman's BMI by using the CDC (2009a) adult BMI height and weight calculation method of weight in kilograms divided by height in meters squared. Prior to the collection of weight and height data from each woman, the investigator received specialized instruction that involved two 8-hr days of training and testing with Dr. Robert McMurray from the University of North Carolina. Dr. McMurray trained the investigator in accurate measurements of weight and height in a study on physical activity in middle school-aged girls funded by the National Heart, Lung, and Blood and Institute (Robbins, PI). The reliability and validity of the investigator's measurements were evaluated by comparison with measurements made by a previously trained researcher, Dr. Karin Pfeiffer. The investigator followed the procedures used in this training and testing to measure weight and height in the study women. Both weight and height measurements were taken by the investigator at one of the study clinics or at the woman's home using portable equipment in a private setting.

The Profit LifeSource Precision Scale (Milpitas, CA) was used to measure each enrolled woman's weight. This scale has U.S. Federal Drug Administration approval for use with adults

within a 0.5-kg difference between measurements and the ability to weigh subjects up to 150 kg (350 lb). If the woman's weight was greater than 350 lb as indicated by a "high" reading on the scale, the investigator used the Tanika scale (Arlington Heights, IL) at the clinic; this scale measured weights up to 440 lb. To assess the validity of the weight measurement, the investigator used a 50-lb weight at the YMCA. The scale measured the 50-lb weight with precise accuracy when assessed twice. To increase reliability of measurement, the investigator measured a woman's weight at least twice consecutively. If there was a difference in measurements of 0.5-kg or more, measurements were repeated until two measurements were within the 0.5-kg difference. The final two weight measurements were averaged for analysis.

Height was measured using the SECA Stadiometer (Hamburg, Germany), which measures adult height up to 210 cm (6 ft 11 in.) This maximum height accommodated the height measures of the sample of middle-aged women. Height was measured by the investigator consecutively and at least twice. If the two height measurements differed by 1-cm or more, then additional measurements were taken by the investigator. When two measurements were within the 1-cm difference, then these two were averaged for analysis. To determine meters for BMI calculation, centimeters were divided by 100.

Comorbidity index. Comorbidities were measured using the Katz version (Katz, Chang, Sangha, Fossel, & Bates, 1996) of the Charlson Comorbidity Index (CCI; Charlson et al., 1987). This tool scores a variety of comorbid conditions based on the severity of the disease. The CCI (Charlson et al., 1987) was initially used to measure the 1-year post-hospitalization mortality of 559 adults by weighting the severity of 19 comorbidities. In the Katz version, the CCI has been shortened to 17 comorbidities by not differentiating between mild and severe tumors and liver disease.

The Katz version (1996) of the CCI (Charlson et al., 1987) has been used for measuring comorbidities in acute and chronic diseases including diabetes in adults with and without diabetes (Corser et al., 2008; Rockwell & Riegel, 2001). Greater rates of diabetes identification from the Katz version compared with the CCI have been noted in a study of 525 adults with and without diabetes (Corser et al., 2008). Therefore, an implication of using the Katz version of the CCI for this study was potentially higher identification of women with diabetes by self-reports as compared to chart audit.

The Katz version of the CCI has demonstrated good test–retest reliability with alpha of .91 (O'Connor et al., 2005). Spearman correlation between the self-reported Katz version and the chart audit form of the CCI have been between 0.63 and 0.70 (O'Connor et al., 2005; Katz et al., 1996; Rockwell & Riegel, 2001). Because the Spearman correlation was a measure of the relationship between these two ordinal composite comorbidity indices, values between 0.63 and 0.70 indicated a fairly positive association (Tamhane & Dunlop, 2000).

The Katz version (1996) of the CCI (Charlson et al., 1987) was scored using an online version of Microsoft Excel Macro software program developed by Hall, Ramachandran, Narayan, Jani, and Vijayakumar (2004). The online software program utilizes the weighting of the 17 comorbidities from 1 to 6 and determines a composite comorbidity score based on age by adding 1 point for each decade after 50 years. The composite comorbidity score was treated as a continuous factor ranging from 0 to 43 which is the upper limit of the age-adjusted score (Hall et al., 2004).

Depressive symptom severity. Depressive symptom severity was a continuous factor with a potential range from 0 to 27. Depressive symptom severity was measured using the nine-item Primary Care Evaluation of Mental Disorders Patient Health Questionnaire-9 (PHQ-9; Spitzer,

Kroenke, Williams, & the Patient Health Questionnaire Primary Care Study Group, 1999). Permission for use of the tool was granted to the investigator by the company owning the copyright. Items were scored based on the woman's response to how often over the past two weeks she was bothered by depressive symptoms such as feeling down, depressed, or hopeless. Responses included (a) *not at all*, (b) *several days*, (c) *more than half of the days*, and (d) *nearly every day* and were scored from zero to three, respectively. One item, thoughts that you would be better off dead or of hurting yourself in some way, was scored at 15 as suggested by the creators of the tool (Kroenke et al., 2001).

Cut-point scores for depressive symptom severity were (a) 0 to 4 for minimal, (b) 5 to 9 for mild, (c) 10 to 14 for moderate, (d) 15 to 19 for moderately severe, and (e) 20 to 27 for severe (Kroenke et al., 2001). The PHQ-9 has been used with 6,000 adults in primary care with good reliability as indicated by Cronbach's alpha of .80, 75% sensitivity, and 90% specificity (Spitzer et al., 1999). The PHQ-9 has been used in studies of adults with diabetes and in primary care settings with Cronbach's alpha of .89 and sensitivity and specificity of 88% to screen for major depression when scores were greater than 10 compared with mental health professional diagnosis (Grandy, Chapman, & Fox, 2008).

Women whose scores were 10 or greater, indicating moderate to severe depression, may be at higher risk for depression and need intervention (Grandy et al., 2008). For scores of 10 or greater, the investigator utilized the phone protocol of the Depressive Symptom Severity Policy in Appendix C. The investigator developed the protocol based on a similar one developed by Holmes-Rovner et al. (2008) for telephone follow-up with cardiovascular patients following discharge from the hospital. The goal of the Depressive Symptom Severity Policy was to encourage women to follow-up with their primary care provider and to document contact by the

investigator with each woman at risk for depression and in need of follow-up. A letter given to the woman provided documentation of the investigator's contact with her and also contacts information for local mental health community agencies. (See Appendix D for the letter.)

Smoking status. The self-administered paper-and-pencil survey included a single question, "Do you currently smoke tobacco?" to assess smoking status. Women self-reported current smoking status using a categorical response of "Yes" or "No."

Social-cognitive factors. Social-cognitive factors in the study included (a) attitudes toward physical activity, (b) physical activity self-efficacy, (c) benefits of physical activity, and (c) social support for physical activity as perceived by the women. Each of the social-cognitive factors was measured using a consistent 7-point Likert scale except for social support for physical activity, for which the seventh scale number response was *does not apply*. All social-cognitive factors were treated as continuous factors. (See Appendix A for the self-administered paper-and-pencil survey.)

Attitudes toward physical activity. Attitudes toward physical activity were measured by item responses using a 7-point Likert scale as suggested by Armitage (2005) and Courneya, Conner, and Rhodes (2006). The six item responses measured attitudes toward physical activity on a continuum between opposing feelings such as *harmful* versus *beneficial*, *useless* versus *useful*, *unimportant* versus *important*, *unenjoyable* versus *enjoyable*, *boring* versus *fun*, and *painful* versus *pleasurable*. The mean of the six item responses on the attitudes toward physical activity scale was used for analysis, with scores ranging from 1 to 7. (See Appendix A page 160 for the attitudes toward physical activity portion of the self-administered paper-and-pencil survey). Higher scores indicated a more positive attitudes for physical activity. Reliability of the attitudes toward physical activity measure has been found to be moderate to high with alphas

between .78 and .96 (Armitage; Courneya et al.).

Physical activity self-efficacy. Bandura (2001) and Ajzen (2001) have suggested that the measurement of self-efficacy should be specific to the type of behavior being explored. For this reason, the study measured physical activity self-efficacy defined in minutes per day of MVPA. Some researchers have suggested the inclusion of barriers to physical activity to increase the ability of the physical activity tool to measure intention as well as confidence (Rodgers, Wilson, Hall, Fraser, & Murray, 2008). In response, the investigator used the Self-Efficacy for Exercise Scale (SEE), which utilizes barriers associated with physical activity (McAuley et al., 1999; Resnick & Jenkins, 2000).

The SEE for the present study included statements about how 10 situations might affect the middle-aged woman's current confidence to participate in physical activity. The 10 situations or items included (a) if the weather was bothering you, (b) if you were bored by the program or activity, (c) if you felt pain when exercising, (d) if you had to exercise alone, (e) if you did not enjoy it, (f) if you were too busy with other activities, (g) if you felt tired, (h) if you felt stressed, and (i) if you felt depressed. The final item, if you were incontinent (bowel or bladder), was included in the survey by the investigator with permission from the creator of the tool (B. Resnick, personal communication, January 27, 2010) because incontinence has been shown to be a potential barrier for physical activity specific to middle-aged women with diabetes (Belza, 2004). (See Appendix A page 161 for the SEE portion of the self-administered paper-and-pencil survey). The SEE used a 7-point Likert scale from *not very confident* to *very confident* for item responses. The mean of the 10 item responses provided a range from 1 to 7. Higher scores indicated higher physical activity self-efficacy.

The SEE has been used in research with older adults (Resnick, 2002; Resnick & Jenkins,

2000; Resnick et al., 2006, 2007; Resnick, Wehren, & Orwig, 2003), for physical activity intervention studies of adults of all ages with diabetes (Gleeson-Kreig, 2006) and without diabetes (Trost et al., 2002), and with African American women (Murrock & Madigan, 2008). In the previous versions of the SEE, the measure has demonstrated excellent reliability, with alpha of .92 and confirmatory factor analysis loadings of greater than .50 for samples of older multiracial and multiethnic adults (Resnick & Jenkins, 2000; Resnick, Luisi, Vogel, & Junaleepa, 2004; Resnick, Magaziner, Orwig, & Zimmerman, 2002). The SEE used for this study was modified by another study (Gleeson-Kreig, 2006) to include the most recent ACSM recommendations for physical activity (Haskell et al., 2007a, 2007b).

Benefits of physical activity. Benefits of physical activity were measured using the Outcomes Expectancies for Exercise Scale (OEE; Resnick et al., 2000). Responding to nine OEE statements, enrolled women rated the effects of physical activity on their mood, sense of personal accomplishment, and physical and mental functioning. Responses to the OEE statements were *strongly disagree* to *strongly agree* on a 7-point Likert scale. (See Appendix A page 162 for the OEE portion of the self-administered paper-and-pencil survey). The mean response to the nine items obtained a composite score ranging from 1 to 7. Higher scores indicated higher perceived benefits of physical activity.

The OEE has been shown to be reliable, with alphas between .72 and .93 in older adults (Resnick, 2000; Resnick et al., 2000, 2003, 2006, 2007; Resnick, Zimmerman, Orwig, Furstenberg, & Magaziner, 2001). A systematic review noted OEE alphas ranging from .54 to .85 across five studies (Allen, 2004).

Social support for physical activity. Social support for physical activity was measured using the Social Support for Exercise Habits Scale (SSE; Sallis, Grossman, Pinski, Patterson, &

Nader, 1987). The SSE tested the *past three months* of support from *someone important* to the middle-aged woman. While the original SSE divides responses by family and friends, the self-administered paper-and-pencil survey for this study provided the women with only one broader option of *someone important to me* to allow for measurement of social support from anyone rather than a specific type of person such as husband, family member, or friend. This change by the investigator was in response to a cross-sectional study indicating a lack of difference in social support for physical activity by family versus by friends in middle-aged and older women (Eyler et al., 1999).

The self-administered paper-and-pencil survey, as noted in Appendix A page 163 for the SSE portion, sought responses to statements about how frequently the woman received positive or negative support for physical activity behavior by asking if the supporting individual (a) did physical activity with me, (b) offered to do physical activity with me, (c) gave me helpful reminders to do physical activity, (d) gave me encouragement to stick with my physical activity, (e) changed their schedule so we could be physically active together, (f) discussed physical activity with me, (g) complained about the time I spend being physically active, (h) criticized me or made fun of me for being physically active, (i) gave me rewards for physical activity, (j) planned for physical activity on recreational outings, (k) helped plan activities around my physical activities, (l) asked me for ideas on how they can get more physical activity, and (m) talked about how much they like to do physical activity.

Responses for the SSE ranged from *never* to *very often* on a 6-point Likert scale. A seventh additional response, *does not apply*, was provided for middle-aged women who were not involved in any physical activity. Scoring of the SSE for this study included recoding the seventh response of *does not apply* to a score of 1 as described by Sallis et al. (1987). While the original

tool (Sallis et al.) divides the support by family and friends and analyzes these separately, the investigator chose to sum the 13 items for analysis. Values of the SSE ranged from 13 to 78 after scores of the two negatively worded items were reverse-scored, such as from 6 to 1 and 2 to 5. Higher scores on the SSE indicated higher social support for physical activity (Sallis et al., 1987).

The SSE has been used in studies including a physical activity intervention with older adults (Resnick, 2002; Resnick et al., 2006) and samples of women from various racial and ethnic backgrounds (Janisse, Nedd, Escamilla, & Nies, 2004; Murrock & Madigan, 2008; Young & Stewart, 2006). The reliability of the SSE has been tested with alphas between .55 to .79 (Sallis et al., 1987), indicating moderate to strong consistency of measuring social support as scores greater than .70 indicate strong internal consistency (Miller & Salkind, 2002; Vogt, 2005).

Response variable. The response variable in the study was minutes per day of MVPA. Minutes per day of MVPA as assessed by two measures was treated as a continuous factor. A continuous response variable has utility for the study of factors associated with physical activity in middle-aged women by allowing for a wider range of values and greater distribution of intensity levels than a categorical variable (Ott & Longnecker, 2010).

Two measures of MVPA were self-reported, but only the second was used for analyses. The first self-reported measure of MVPA was used concurrently with the accelerometer, and the second was completed directly after the accelerometer wear-time. The third measure of MVPA was the accelerometer. These three measures were assessed separately. The protocols for the three measures are described below.

Self-report protocol. Both self-report measures reported minutes per day of MVPA and included written instructions as part of the paper-and-pencil study survey.

Daily log. The first self-reported measure of MVPA was a daily log similar to one used in another study of physical activity in adults with diabetes (Gleeson-Kreig, 2006). The women were asked to complete the daily log during the same seven days of accelerometer wear-time. Women were asked to log duration in min, type, and intensity of physical activity. (See Appendix E for the daily log.) Examples of various contexts of physical activity were provided on the daily log. Examples on the daily log included contexts such as walking, housework, lawn and garden, childcare and biking. Intensity of physical activity was based on Borg's (1982) Perceived Exertion Scale. Borg's scale uses numbers from 6 to 20 to rate the intensity of the physical activity, with 6 being *no exertion at all* to 20 being *maximal exertion*. Numbers on the Perceived Exertion Scale have been shown to correspond to heart rate during physical activity (Noble, Borg, Jacobs, Ceci, & Kaiser, 1983).

The daily log was returned to the investigator at a second study clinic appointment along with the accelerometer. The daily log has not been tested for validity or reliability and therefore was used only for contextual information in this study.

IPAQ short form. The second measure of MVPA was the IPAQ short form (Craig et al., 2003; Johnson-Kozlow, Sallis, Gilpin, Rock, & Pierce, 2006). The IPAQ short form has been designed for use with young and middle-aged adults and has been used with Swedish adults aged 20 through 69 years with 77% specificity and 45% sensitivity when compared with accelerometry (Ekelund et al., 2006). (See Appendix F for the IPAQ.)

The IPAQ short form was completed by the women during the second home or clinic visit with the investigator and without referring to the daily log. Scoring of the IPAQ short form followed the recommendations described in the Guidelines for Data Processing and Analysis of the IPAQ – Short and Long Forms: Protocol for IPAQ Short Form (2005). Cleaning of data

included truncation as described in the Guidelines (2005) in which vigorous, moderate and walking minutes per day exceeding 3 hr were truncated to 180 min. This allowed for a maximum of 21 hr per week of MVPA while controlling for outliers. As described in the Guidelines (2005), outliers of more than 960 min per week were excluded from study.

Because the IPAQ short form was completed by the women shortly after the accelerometer wear-time, results in minutes per day of MVPA should correlate highly with the accelerometry measurements. However, overestimation of self-reported physical activity behavior has occurred when compared with accelerometer data (Johnson-Kozlow et al., 2006), and Banda et al. (2010) indicated a poor correlation between measurements by self-report and accelerometry. Therefore, for the present study, the degree of agreement between the IPAQ short form and the accelerometer data were compared to explore congruence for future studies.

Accelerometry. Minutes per day of MVPA were measured by the ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL), a small, lightweight accelerometer worn on an elastic belt at the right hip (Swartz et al., 2000). The ActiGraph GT1M generated data on duration, intensity, and frequency of physical activity by measuring and recording physical activity movement intensity. The ActiGraph GT1M featured a rechargeable battery with 14 days of capacity. Accelerometers have been used to measure MVPA with adults in general (Berlin, Storti, & Brach, 2006; Bonomi et al., 2009) and in those with diabetes (Allen et al., 2009).

Psychometrics of ActiGraph GT1M. The ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL) has been validated using oxygen consumption with a correlation coefficient of .64 for treadmill walking and .74 for stair walking (Slootmaker, Chin A Paw, Schuit, van Mechelen, & Koppes, 2009). Sensitivity of the ActiGraph GT1M ranges between 45.9% and 63.5% compared with direct observation of physical activity (Rothney, Apker, Song, & Chen, 2008). Specificity

of the ActiGraph GT1M has ranged from 77% to 90.6%, and Kappa coefficients ranged from .38 to .40 with 95% *CI* [0.26, 0.53] (Freedson et al., 1998).

Testing of various accelerometers indicated that the ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL) had the least amount of variance between devices and trials (Welk, Scheben, & Morrow, 2004). The investigator strictly adhered to the ActiLife5 manual directions. Careful instruction for placement of the ActiGraph GT1M on the right hip of the women with the front of the monitor facing forward was important since the accelerometer measures in the vertical plane (Welk, 2005). A yellow dot placed on the top of the accelerometer was an indicator of which side to place upright. The elastic belts on which the ActiGraph GT1M was worn varied in size for comfort around the woman's waist.

Accelerometer protocol. The investigator provided each enrolled woman with oral and printed instructions about the purpose and correct use and placement of the accelerometer (see Appendix B: Accelerometer Instruction Sheet: Activity Monitor Instructions). Instructions by the investigator for accelerometer wearing included (a) while awake except during water activities such as showering or swimming since it was not water resistant, (b) on the elastic belt with the device facing forward (yellow dot facing up), (c) placed at the right hip, and d) for seven consecutive days with at least 10 hr of wear time.

The ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL) featured a direct universal serial bus connection that allowed the accelerometer data to be downloaded into the ActiLife 5 Data Analysis Software (ActiGraph LLC, Fort Walton Beach, FL) that was used to configure the ActiGraph GT1M for data collection and to download, view, and process the collected ActiGraph GT1M data.

At the time of enrollment, the ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach,

FL) was initialized, which prepared the accelerometer to collect data by allowing the investigator to set the date, time, and data collection intervals. The ActiGraph GT1M was set for 1-min data collection intervals by the investigator and data were collected over seven consecutive days. The recommended wear-time of the accelerometer was 10 to 13 hr per day (Herrmann, Barreira, Kang, & Ainsworth, 2010). Data collection began immediately upon initiation of the ActiGraph GT1M. Sufficient data collection was considered to be 4 days with at least 10 hr of wear time per day and at least one day being a weekend day (Trost et al., 2005).

Enrolled women were counseled by the investigator to continue their overall prestudy physical activity during the week of accelerometer wear-time. The investigator asked whether the scheduled week of accelerometer wear-time was, in the woman's perception, a typical week of physical activity. If the woman perceived that the scheduled week was atypical, such as a week of planned vacation, then an upcoming week that was planned to be more typical was scheduled for wear-time.

The investigator telephoned each enrolled woman twice, usually on the second and fifth day of accelerometer wear-time. The main objectives of the telephone calls were (a) to remind women to wear the accelerometer, (b) to complete and return the paper-and-pencil survey and MVPA measures by return appointment to the study clinic, (c) to assess for problems with study measures such as accelerometer battery failure or incorrect use, (d) to allow women to seek answers to potential questions about the study activities or measures, and (e) to restate the investigator's cell phone contact information for questions or concerns related to the study activities.

Upon return of the ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL), the investigator downloaded the data into the same ActiLife5 Data Analysis Software (ActiGraph

Table 5

Physical Activity Intensity Level Cut-Points in Counts per Minute by Researcher's Method of Measurement

Physical activity intensity level cut-points (counts/min)	Freedson et al., 1998	Hendelman et al., 2000	Swartz et al., 2003	Matthews, 2005
Sedentary	<499	DNP	DNP	0–259
Light	500–1,951	0–190	0–573	260–759
Moderate	1,952–5,724	191–7,525	574–4,944	760–5,724
Vigorous	>5,725	>7,526	>4,945	>5,725

Note. DNP = data not provided.

LLC, Fort Walton Beach, FL) used for initializing. The data were assessed immediately by the investigator using the ActiLife5 Data Analysis Software for reliability of at least four days of 10 hr of wear-time each day. If data were not captured by the accelerometer, the investigator asked the woman to wear the accelerometer for another seven days. The investigator reviewed the accelerometer data output graph of daily wear with each woman at the second home or clinic appointment using the daily log for contextual information.

Cut-points for intensity levels of physical activity were determined by the investigator before beginning the study. To determine the cut-points for intensity levels of physical activity, researchers have used regression equations based on oxygen consumption (the gold standard) and accelerometer data (Ainsworth et al., 2000). Several cut-points for physical activity intensity levels for adults are listed in Table 5 (Banda et al., 2010; Matthews, 2005).

The investigator chose the cut-points of Swartz et al. (2003) for the study because these were developed during daily living of middle-aged adults as compared with during treadmill

testing in a laboratory setting (Freedson et al., 1998). The Swartz method was the closest to actual oxygen consumption in a study comparing five adult accelerometer cut-point methods, indicating the validity of these cut-points for this study (Strath, Bassett, Ham, & Swartz, 2003; Strath et al., 2008). Swartz et al. used mostly moderate activity in calculating the regression equation (Matthews, 2005), which was potentially the most common type of activity performed by middle-aged women (Chen, 2009), and thus most closely matched the study design sample based on the setting, type, and intensity of physical activity. Swartz et al. do not indicate a specific cut-point for sedentary behavior. However, other research has suggested 0–99 counts/min, especially for middle-aged women who were overweight or obese (Herrmann et al., 2010).

For this study, the cut-points used for intensity level of physical activity were (a) sedentary (0–99 counts/min), (b) light (100–573 counts/min), (c) moderate (574– 4,945 counts/min), and (d) vigorous (>4,945 counts /min) (Swartz et al., 2000). The MeterPlusTM (Version 4.2) software program (Santech, San Diego, CA) was used to analyze the accelerometry data to obtain minutes per hour of MVPA. MeterPlusTM converts the data from counts to minutes of activity at light, moderate, and vigorous, and sedentary behavior per hour. The average minutes of MVPA per hour was multiplied by the number of hours worn and then divided by the number of days worn to determine minutes per day.

Setting

Subjects were recruited from four study clinics located in an urban setting. These four study clinics were part of a primary care system serving the health care needs of the community, including underserved adults. The four study clinics were associated with a larger community organization that was part of a nationwide health care system. While there were 21 clinics within

Table 6

Targeted and Actual Enrollment of 100 Women Based on U.S. Census Data for Kent County, MI (2008)

Category	Enrollment	
	Targeted	Actual
<i>Ethnic</i>		
Hispanic or Latino	9	6
Non-Hispanic or non-Latino	91	103
Total	100	109
<i>Racial</i>		
American Indian/Alaska Native	1	0
Asian	2	0
Native Hawaiian or other Pacific Islander	0	0
Black or African American	9	25
Multiracial	0	3
White	88	82
Total	100	109

Note. Totals for ethnic category and racial category must be equal.

the community organization, the four clinics for this study were all in the downtown urban area. Three of the sites were within a block of each other, and the fourth was less than 5 miles from the other sites. The close proximity of the four sites allowed the investigator to be present at the study clinics for maximal direct face-to-face recruitment.

In 2007, the numbers of patients with diabetes were estimated from preliminary reports at the four clinic sites to be 646, 376, 774, and 226. If approximately half of the patients were women, then on average 83 women with diabetes were evaluated per month at the four clinics. With recruitment potential of about 10% of these women, the estimated time for recruitment was approximately 6 months. Actual time for recruitment lasted 7 months. (See Table 6 for targeted and actual enrollment.) Recruitment of 100 women was planned with a goal of recruiting at least

50 middle-aged women with diabetes and 50 middle-aged women without diabetes.

Sample

The convenience sampling of middle-aged women used a rolling enrollment design. Women were included in the study if they (a) were between 45 and 64 years of age, (b) were able to comprehend, read, and speak English, (c) had access to a home or cellular phone, (d) were able to ambulate for at least 10 minutes as indicated by a response of “yes” to the question of “Are you able to walk independently for at least 10 minutes during an activity such as grocery shopping?”, and e) were not pregnant. Pregnancy is a confounding factor for physical activity (Kramer & McDonald, 2010).

Recruitment. Recruitment began after approval was obtained from the Institutional Board Review (IRB) of the agency associated with the clinics and reciprocally approved by the Michigan State University (MSU) IRB through protection of human subjects (MSU, 2009). Effective recruitment procedures have included print media, simplified and repeated study explanations, assurance of confidentiality protection, investigator’s statement of the importance of each woman’s contribution to the study, personal communication and networking between the investigator and recruitment site staff, colorful flyers, and personal and phone contact by the investigator with participants (Brown, Long, & Milliken, 2002; Clark et al., 2007). Recruitment methods used for this study included colorful recruitment flyers, personal communication and networking between the investigator and recruitment site staff, and personal and phone contact by the investigator with participants.

Subjects self-identified at the four clinic sites in response to (a) recruitment flyers posted in waiting rooms and at the reception desk and check-out area, (b) posters, recruitment flyers and investigator’s business cards located in examination rooms, or (c) available Permission to

Contact forms that they were able to sign and leave with the clinic staff. Women either called the investigator directly using the cell phone number listed on the poster and recruitment flyer or signed a Permission to Contact form stapled to the recruitment flyer. Signed Permission to Contact forms included name, date, phone number, and best days and times to contact with a signature giving the investigator permission to contact the respondent. Permission to Contact forms were detached from the recruitment flyer by each respondent and given to clinic staff to store in a confidential file at each clinic site for the investigator to retrieve.

Business cards included the investigator's name, cell phone number, and MSU address and phone number. Recruitment flyers and posters included the name of the study, participant criteria for recruitment, the collaborating institutions, the name and contact information of the investigator, and the estimated amount of time required by the study. Estimated time included (a) approximately 20 minutes for completing the survey; (b) an additional 25 minutes for measuring height and weight, initiating the accelerometer, and instructing the women about the accelerometer; (c) one week of accelerometer wear-time; (d) 5 minutes per day to complete the daily log; and (e) a 20-minute return appointment to download the accelerometer data, review the data graphing, and complete the IPAQ short form.

The investigator met with each of the site lead physicians, then the practice leaders, and finally with the staff to discuss the study. At a scheduled staff meeting with each individual clinic, the investigator explained the study and need for assistance in identifying patients. After the staff meeting, the investigator observed the flow of patients through the clinic and then began recruitment during the following five weekdays. Each week the process began again with a staff meeting at the next site until all four clinics were identifying patients for recruitment. The investigator encouraged the staff to offer suggestions about where to place posters, recruitment

flyers, and business cards and how best to identify patients for the study. Staff suggested locations to store the confidential file for collected Permission to Contact forms.

The investigator made introductions to staff and physicians, explained the study, and passed out business cards with the inclusion and exclusion criteria printed on the reverse side. The investigator also spoke to each physician individually about the study. The investigator made weekday rounds to each study clinic and was stationed at each site on a rotating schedule one day of each week to meet with potential recruits. The investigator was available by cell phone to answer questions that women had about the study and to recruit women who expressed interest in the study during their clinic appointments. The practice leader at each clinic site provided the investigator with a locked file for data storage and a private space to meet with interested women to explain the study, obtain informed consent, offer the self-administered paper-and-pencil study survey, explain the daily log and the accelerometer, and collect data such as height and weight.

Recruitment challenges included difficulty identifying participants as a result of conflicting time commitments, busy primary care practices, and new procedures such as electronic medical records and in-room check-out of patients. Measures taken to deal with recruitment challenges included being present at each clinic for one week after the start-up staff meeting and interacting with staff and physicians to remind them about the study and offer positive encouragement for progress on identifying women who met the study criteria. Other recruitment issues included women not keeping scheduled appointments with the investigator and recruitment of fewer women with diabetes.

Two women, who were unable to continue the study due to illness, were sent letters to assess further participation (see Appendix I for Letter of Continued Participation for Women

who had Stopped Participation). Further measures to recruit middle-aged women with diabetes were taken. The investigator received IRB permission to contact a list of 16 women with diabetes by letter. The list of names was received from one physician's practice by the staff nurse, who addressed envelopes and edited the letter of recruitment (see Appendix J for Letter of Recruitment for Women with Diabetes). Letters were sent to women who were then asked to contact the investigator.

Informed consent. During the initial phone call, the investigator asked the women to confirm their criteria eligibility and to set an appointment time to meet with the investigator at one of the study clinics. Women who did not meet the study criteria were thanked for their willingness to participate and excluded from the study. At the initial appointment, women who verbalized an interest in the study received a folder containing (a) an Informed Consent/Health Insurance Portability and Accountability (HIPAA) Authorization form (Appendix H), (b) the self-administered paper-and-pencil survey (Appendix A), (c) the daily log (Appendix F), and (d) two accelerometer information sheets (Appendix B). After signing, a copy of the signed Informed Consent/HIPAA Authorization form was given to each enrolled woman, and the original copy was kept by the investigator in a confidential locked file at one of the clinic sites.

Data Collection

Data collection for each woman began after completion of the Informed Consent/HIPAA Authorization form (see Appendix H). All data collection materials were coded by the investigator to a study identification (ID) number to protect the privacy of each woman. The self-administered paper-and-pencil study survey, except for the IPAQ short form (Craig et al., 2003; Johnson-Kozlow et al., 2006), was completed by the woman at the study clinic site during the initial visit with the investigator. The investigator encouraged completion of the

surveys at the initial clinic visit but did allow for location flexibility of survey completion at home if requested. The investigator offered to answer any questions the women had about the self-administered paper-and-pencil study survey. The investigator asked each woman if she would be willing to receive a phone call on approximately the second and fifth days of the week of wearing the accelerometer. Refusals to accept such calls were noted in the log of the study.

Surveys were assessed within the first 24 to 48 hr for scores over 10 on the PHQ-9 and follow-up by the investigator using the Depressive Symptom Severity Policy (see Appendix D for Depressive Symptom Severity Policy). Missing data on the self-administered paper-and-pencil survey were tabbed with a brightly colored note as a reminder to the investigator to ask the woman to review the survey and answer any unanswered questions if desired.

During the second visit with the investigator at the clinic site or the woman's home, women completed the IPAQ short form (Craig et al., 2003; Johnson-Kozlow et al., 2006) and returned the accelerometer as described above in the accelerometer protocol. A graph of the downloaded accelerometer data were reviewed with the women by the investigator using the daily log for contextual information. Each woman was given an incentive of a \$10 store card for the safe return of the accelerometer. If the accelerometer was not returned within two weeks of initiation, the investigator telephoned the woman to ask to retrieve the accelerometer by making a home visit. If further missing data on the self-administered paper-and-pencil survey were noted during data entry, women were called for a response; if they preferred no response or were unable to be contacted the items were left blank or recorded as no response.

Data Management

To maintain each woman's study information and data confidentiality three separate records were kept. These three records were the study roster key, the study data files, and the

computer program (see Appendix K for the data management plan of the study roster key, study data file, and computer program).

Study roster key. The study roster key contained any and all of each woman's identifying information such as names, addresses, phone numbers, study ID number, and accelerometer number. The study roster key was the direct link between the subject name and the subject ID number. The study roster key was housed on an encrypted flashdrive (# 1) and was used at the clinic sites only by the investigator and only when necessary to connect the subject name to the study data file for the return visit, for potential follow-up phone calls, or for chart audits. The study roster key was backed up weekly to an external hard drive. Both the encrypted flashdrive (# 1) and the external hard drive were locked in a file cabinet in the investigator's home office. The home is protected by a security system in use when no one is home and during the night.

Study data files. Signed Research Participant Information and Consent/HIPAA Authorization forms were all housed in one locked file cabinet at one clinic location in a file separate from the study data files. The study data files included de-identified participant folders kept in a locked file in each of the clinic sites separate from the study roster key to maintain the confidentiality of the enrolled women. Each folder contained de-identified information using an ID number based in part on the accelerometer number. The study ID number was determined by the last three digits of the accelerometer worn for data collection along with a three-digit number assigned at random. Each clinic site was assigned a specific color, and folders were color-coded to reflect the four clinic sites.

The study data file for each woman housed the self-administered paper-and-pencil survey that included the demographic factors, clinical factors, and social–cognitive factors and the IPAQ

short version. Information about the \$10 store card number given to the participant and date was also included in the file along with notes written inside the front file cover for data entry dates, dates of letters sent to patient, or issues noted with data.

Deidentified data from the study data file were entered into the Statistical Package for the Social Sciences (SPSS; Version 19) software program on an MSU computer by the investigator or research assistant and rechecked for quality control by the person who did not enter the data. The SPSS (Version 19) file housed all study data file information as well as data from the accelerometers once these had been analyzed using MeterPlusTM (Version 4.2; Santech, San Diego, CA). Deidentified study data were loaded onto an encrypted flash-drive (# 2) for transfer between clinics. This capability was especially important for use in clinics without Internet access. The SPSS (Version 19) file was backed up weekly to the network drive.

Data Analyses

Data files for the study were computer generated through SPSS (Version 19) by entering data from the paper-and-pencil study survey, daily log, and IPAQ short form into the system. The research assistant entered the data, which were then double-checked by the investigator. Data files included separate files for each of the demographic, clinical, and social–cognitive factors. Data files were merged into one master file when the study was completed. The ActiGraph GT1M (ActiGraph LLC, Fort Walton Beach, FL) data were first analyzed using the specialized MeterPlusTM (Version 4.2; Santech, San Diego, CA) to compute minutes per day of MVPA.

Data were analyzed using the SPSS (Version 19). A significance level was set at .05 for these analyses, which were one-tailed. Analyses included descriptive and inferential statistics, correlations, and linear regression. As an initial step for the exploratory factors, basic descriptive

statistics were computed for the continuous and categorical variables. Descriptive analysis of the continuous variables included measures of central tendency and variation such as means, ranges, and standard deviations, and measures of normality, such as skewness and kurtosis (Tamhane & Dunlop, 2000).

Continuous variables included age, BMI, comorbidity index, depressive symptom severity, attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, social support for physical activity, and minutes per day of MVPA as noted in Table 4 on page 67. For continuous variables that did not meet the assumptions of normality, a nonparametric test was used for analysis (Tamhane & Dunlop, 2000).

For analysis of the categorical variables, frequency distributions and percentages were calculated (Tamhane & Dunlop, 2000). Categorical variables included race and ethnicity, marital status, educational level, annual household income, employment status, diabetes, and smoking status as noted in Table 4 on page 67.

After assessing for normality of the data, correlations were analyzed between each of the exploratory factors and then between the exploratory factors and the response variable of minutes per day of MVPA. According to Miller and Salkind (2002), the correlation coefficients indicate the usefulness of the association between the factors, with a response of 0.00–0.20 indicating little or no relationship, 0.02–0.40 indicating some slight relationship, 0.40–0.60 indicating a substantial relationship, 0.60–0.80 indicating a strong useful relationship, and 0.80–1.00 indicating a strong relationship.

Missing data. Missing data were assessed for random versus nonrandom effect and use of appropriate imputation. Missing data were evaluated to assess for patterns of variables that were missing. Consistent patterns indicate that a nonrandom effect had occurred and should be

assessed for further reasons for this missing effect. One method for handling missing data is to use imputation (McKnight, McKnight, Sidani, & Fidueredo, 2007). However, certain factors such as the demographic, clinical, and social–cognitive factors were not appropriate to impute for this study. The investigator assessed the accelerometer output for missing data. Missing data could cause the estimated minutes per day of MVPA to be much lower than the actual number of minutes. To prevent bias and promote power and efficiency of data analysis, missing data for the accelerometers were handled by asking women to re-wear the accelerometer if the computer indicated a lack of valid data.

Research question one. *What were the differences between middle-aged women with and without diabetes in their minutes per day of MVPA as measured by the two physical activity measures and their associated demographic, clinical, and social–cognitive factors?*

Comparison of the two groups of middle-aged women, those with and those without diabetes, was conducted by comparing the means of the continuous factors using parametric *t* tests if assumptions for normality were met. The investigator used nonparametric Wilcoxon rank sum tests if assumptions were not met (Munro, 2005). For the categorical variables, data were compared by chi-square tests with cross tabulations (Ott & Longnecker, 2010). Another method of comparison was to use analysis of variance or multivariate analysis of variance, in which the null hypothesis was that there was no difference in the key demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA between women with diabetes and those without (Tamhane & Dunlop, 2000).

Research question two. *What was the degree of agreement in minutes per day of MVPA between the IPAQ short form and the accelerometer?*

Self-reported measures have been shown to overestimate MVPA (Bryan & Katzmarzyk,

2009) and underestimate light and sedentary behaviors (Adams et al., 2005). To analyze differences in minutes per day of MVPA measured by the IPAQ short form and the accelerometer, the degree of agreement was used. The degree of agreement was best used to evaluate non-independent groups such as repeated measures from the same individual (Bland & Altman, 1986), and thus was the appropriate method to analyze the two physical activity measures for this study. Mean differences were calculated by subtracting minutes per day of MVPA computed the IPAQ short version data from the accelerometer data. The Bland and Altman method (1986) allows for calculation of bias and limits of agreement, which were two standard deviations from the difference between two measures (Vanhelst et al., 2009). The method can only be used for two measurement comparisons at one time. Other investigators have used the Bland and Altman method to compare the self-reported IPAQ short form to accelerometer-measured physical activity (Ekelund et al., 2006; Hagströmer, Oja, & Sjöström, 2006; McKay et al., 2009).

Research question three. *Which demographic, clinical, and social–cognitive factors of middle-aged women with and without diabetes were associated with minutes per day of MVPA as measured by the (a) IPAQ short form and (b) accelerometer?*

For specific analyses of research question three, correlation tables and multiple linear regressions were used to assess which of the demographic, clinical, and social–cognitive factors have significant associations with minutes per day of MVPA (Kutner, Nachsheim, Neter, & Li, 2004). Pearson correlations were calculated among continuous factors, and Spearman correlation was calculated for the categorical factors (Miller & Salkind, 2002). Regression analyses were used to test the primary hypothesis that certain key demographic, clinical, and social–cognitive factors were associated with minutes per day of MVPA in middle-aged women with and without

diabetes.

Since correlation of independent factors often occurs in the social sciences, multicollinearity was also assessed (von Eye & Schuster, 1998). Assessing for multicollinearity was important since factors such as social support for physical activity and depressive symptom severity may not be independent of each other causing greater standard error (Collins-McNeil et al., 2009; Hagger, Chatzisarantis, & Biddle, 2002). Multicollinearity was assessed using variance inflation factors. Values equal to or greater than 10 indicate multicollinearity (von Eye & Schuster, 1998; Tamhane & Dunlop, 2000). Other methods used to diagnose multicollinearity include whether the sign of the estimated coefficient was opposite from what was expected. An example would be if self-efficacy were negatively associated with minutes per day of MVPA. If factors were highly correlated and affected the usefulness of the model, then the investigator had the option to drop the factor that contributed little to the model (von Eye & Schuster, 1998). A number of regression models were assessed for the best model fit. The coefficients of determination were used to identify the amount of variance in minutes per day of MVPA accounted for by the variance in the explanatory factors (Tamhane & Dunlop, 2000).

For nominal categorical factors such as race and ethnicity, educational level, annual household income, marital status, employment status, and diabetes, dummy coding or effect coding was used (von Eye & von Clogg, 1996). Dummy coding was used for dichotomous factors such as race and ethnicity, marital status, employment status, and diabetes (von Eye & von Clogg). Effect coding was used for categorical data having more than two categories, such as educational level and annual household income (von Eye & Schuster, 1998).

Multiple linear regressions were used to assess which demographic, clinical, and social-cognitive factors were associated with the response variable of minutes per day of MVPA

(Kutner et al., 2004). For skewed distributions, which were highly likely in a sample of middle-aged women with and without diabetes, appropriate transformations of continuous factors were performed (von Eye & Schuster, 1998). A potential model was attempted around each of the physical activity measures data of the IPAQ short form and accelerometer. The modeling equation was similar to the following: minutes per day of MVPA = $b_0 + b_1(\text{age}) + b_2(\text{race and ethnicity}) + b_3(\text{marital status}) + b_4(\text{educational status}) + b_5(\text{annual household income}) + b_6(\text{employment status}) + b_7(\text{diabetes}) + b_8(\text{BMI}) + b_9(\text{comorbidity index}) + b_{10}(\text{depressive symptom severity}) + b_{11}(\text{smoking status}) + b_{12}(\text{attitudes for physical activity}) + b_{13}(\text{physical activity self-efficacy}) + b_{14}(\text{benefits of physical activity}) + b_{15}(\text{social support for physical activity}) + \varepsilon$.

Research has indicated that most adults have difficulty performing the recommended physical activity and therefore the sample may be quite sedentary. Despite this hypothesis, the use of a continuous physical activity measure by minutes and intensity potentially increases the variability of the distribution so that more rigorous comparisons could be made between women who were most active and those who were least active. The centering of the data or transformation by logarithmic calculations also provides benefits to analyses for skewed data (Tamhane & Dunlop, 2000). By comparing the factors associated with the continuum of physical activity, the study design provided a more comprehensive examination of the factors contributing to the minutes per day of MVPA in middle-aged women with and without diabetes.

Power analysis. A priori power analysis using Statistical Analytic Software (SAS; 2011 SAS Institute Inc., Cary, NC) indicated that a sample size of 72 was sufficient for analyses with 15 variables. The investigator recruited 100 women because of the high probability of missing data caused by events such as non-completion of surveys or forgetting to wear the accelerometer.

Attrition has been close to 25% in some studies (Jilcott et al., 2007; Rhodes, Plotnikoff, & Courneya, 2008). Sample size determination was based on a .05 significance level and 80% power. Assuming that physical activity self-efficacy accounts for 25% of the variability in MVPA (Gleeson-Kreig, 2006; Resnick & Jenkins, 2000; Resnick et al., 2004), a 10% increase in the coefficient of determination, R^2 , with the addition of the other social–cognitive, demographic, and clinical factors was calculated to be statistically significant with a total sample size of 72 middle-aged women, 36 with and 36 without diabetes. Earlier cross-sectional studies exploring the social–cognitive factors’ prediction of physical activity have used sample sizes of 94 (Hunt & Gross, 2009), 108 (Perkins et al., 2008), and 106 (Blue, 2007).

Protection of Human Subjects

As noted above, this study was approved by both the agency associated with the clinics and by the MSU IRB (MSU, 2009) before any subject information was collected. Informed Consent/HIPAA Authorization forms were presented to prospective eligible women by the investigator at the initial home or clinic visit. Upon receipt of the signed Informed Consent/HIPAA Authorization form, the investigator considered the woman to be enrolled in the study until the IRB expired or the woman withdrew from the study.

Risks to human subjects and protection against risks. The middle-aged women in the study were not expected to be placed at any anticipated physical, psychological, or financial risk by their participation in the study. During enrollment and the midweek phone call, each woman was asked to continue her typical level of physical activity during the study time period. The women also received instructions from the investigator during enrollment and the midweek phone calls that they may choose to withdraw from participation at any time during the study. The women were informed that whether they chose to participate or withdraw would be held in

confidence with no changes in their health care access or provision. To prevent potential risk from the stress of wearing a new device, a printed information sheet of accelerometer instructions was given to the enrolled women during the initial visit.

Women having moderately severe or greater depressive symptom severity, as indicated by a score of 10 or greater on the PHQ-9, were identified by the investigator who reviewed data after the initial clinic appointment. The investigator contacted all appropriate women within the week of initial contact. Findings of moderately severe or greater depressive symptom severity were discussed by the investigator with the women at their second clinic appointment. A letter (see Appendix E) stating the findings and providing a list of mental health agencies with their contacts information was given to the women. If a second clinic appointment was delayed, the investigator contacted women by phone and mailed a letter to the woman.

There might have been some potential risk for stress related to the time needed to complete the initial visit. The investigator minimized the risk of time involvement by developing a 20-minute self-administered paper-and-pencil survey and keeping the height and weight measurement and accelerometer protocol to approximately 25 min, so the initial visit took approximately 45 minutes to complete. The second visit, which involved downloading and reviewing the accelerometer data and completing the IPAQ short version, took approximately 20 min. Recruitment and informed consent procedures for this study were discussed previously.

Potential benefits. It was not likely that the enrolled middle-aged women directly benefitted from their participation in the study. Benefits to the women were generally limited to the information received from the investigator about their individual physical activity by reviewing a graphic computer display of their downloaded accelerometer data. It was anticipated that information obtained during the study would serve to guide development and testing of

physical activity interventions within primary care for middle-aged women with and without diabetes.

Women and Minority Inclusion in Clinical Research

Recruitment of women was appropriate for this study because the study design called for the inclusion of only middle-aged women with and without diabetes. Men and children were excluded from the study by design. Recruitment included all racial and ethnic groups found within the socio-demographic profile of Michigan except for Asian decent as noted in Table 6 on page 85 since multi-racial included three women with American Indian decent (U.S. Census Bureau, 2008). The demographic characteristics of the final study sample are presented in Chapter Five and were reported only in grouped and collective terms, not by individual, in order to protect the privacy of individual women.

Data Security and Management

All members of the research team, which included the investigator, her advisor, a research assistant, and the statistician, have completed yearly mandatory agency and MSU IRB training related to patient consent, confidentiality, quality assurance, and data safety and security. Access to de-identified subject-level study data record was only provided to members of the research team. (See Appendix K for the data management plan used in this study.)

Quality control and data management procedures completed by the investigator included (a) developing a procedural manual for recruitment, enrollment, consent, use and administration of study instruments and forms, and data analysis and management; (b) creating a confidential study roster key of enrolled women's names, phone numbers, and study ID numbers; (c) collecting the raw data; (d) developing a study codebook linking the study factors to names in SPSS (Version 19); (e) entering the data into the computer program; (f) creating a study data file

with individual folders to store paper-and-pencil study surveys, daily logs, and IPAQ short forms; and (g) discussing any recruitment issues with advisor, committee and clinic site personnel. The research assistant helped with data management by entering weight and height on the paper forms, calculating kilograms from pounds, entering data into the computer program, and storing the study data. The research assistant also performed an integrity double check of the investigator's data entries, and the investigator reciprocated by double-checking the research assistant's data entries. Entries that did not match were revised by the investigator after assessing the raw data.

Summary

This chapter reviews the research questions, study factors and measures, setting, sample, data collection and analyses, and human subject protection plan. The purpose of this research was to explore the demographic, clinical, and social–cognitive factors associated with MVPA in middle-aged women with and without diabetes. The exploratory cross-sectional design used a self-administered paper-and-pencil survey and two measures of MVPA, the IPAQ short version and accelerometry. Few studies have analyzed the differences in factors associated with MVPA in middle-aged women and compared the differences between women with and without diabetes. This exploratory comparative study provided important baseline data for future interventions with similar samples of middle-aged women with and without diabetes. Future interventions are needed in this population of women due to their pervasive lack of MVPA and the associated high risk for development of diabetes and CVD and the mortality related to CVD. In Chapter Five, results of the analyses for each of the three research question are discussed.

Chapter Five

Results

The primary purpose of the study was to explore the demographic, clinical, and social–cognitive factors associated with minutes per day of MVPA in middle-aged women with and without diabetes and to compare the two groups on these factors and their MVPA. A secondary purpose was to determine the degree of agreement between self-report and accelerometry for measuring minutes per day of MVPA. This chapter begins with a CONSORT diagram depicting the flow of recruitment and enrollment. Results from statistical analyses related to each research question are discussed and the reliability coefficient for each of the study instruments is presented where appropriate.

As indicated by Figure 2 of the CONSORT diagram of recruitment and enrollment, 662 women received recruitment flyers and Permission to Contact Forms at the clinics, 225 (34.0%) signed the Permission to Contact Forms, seven women called the investigator directly (1.1%), and one emailed the investigator (1.1%).

After more than 50 women without diabetes had been recruited into the study, the investigator began to recruit only women with diabetes. This change was advised by the investigator’s dissertation committee. After IRB approval was granted for the change in recruitment, the investigator mailed 16 letters to women with diabetes from the practice of one clinic provider.

Of the 249 women recruited to participate, 35 (14.1%) declined to participate, 17 (6.8%) were not eligible (six were from clinics not in the study sites, two were older than 64 years, four were younger than 45 years, and five were unable to walk for 10 minutes during an activity such as grocery shopping), 44 (17.7%) were not available by phone call after at least three attempts,

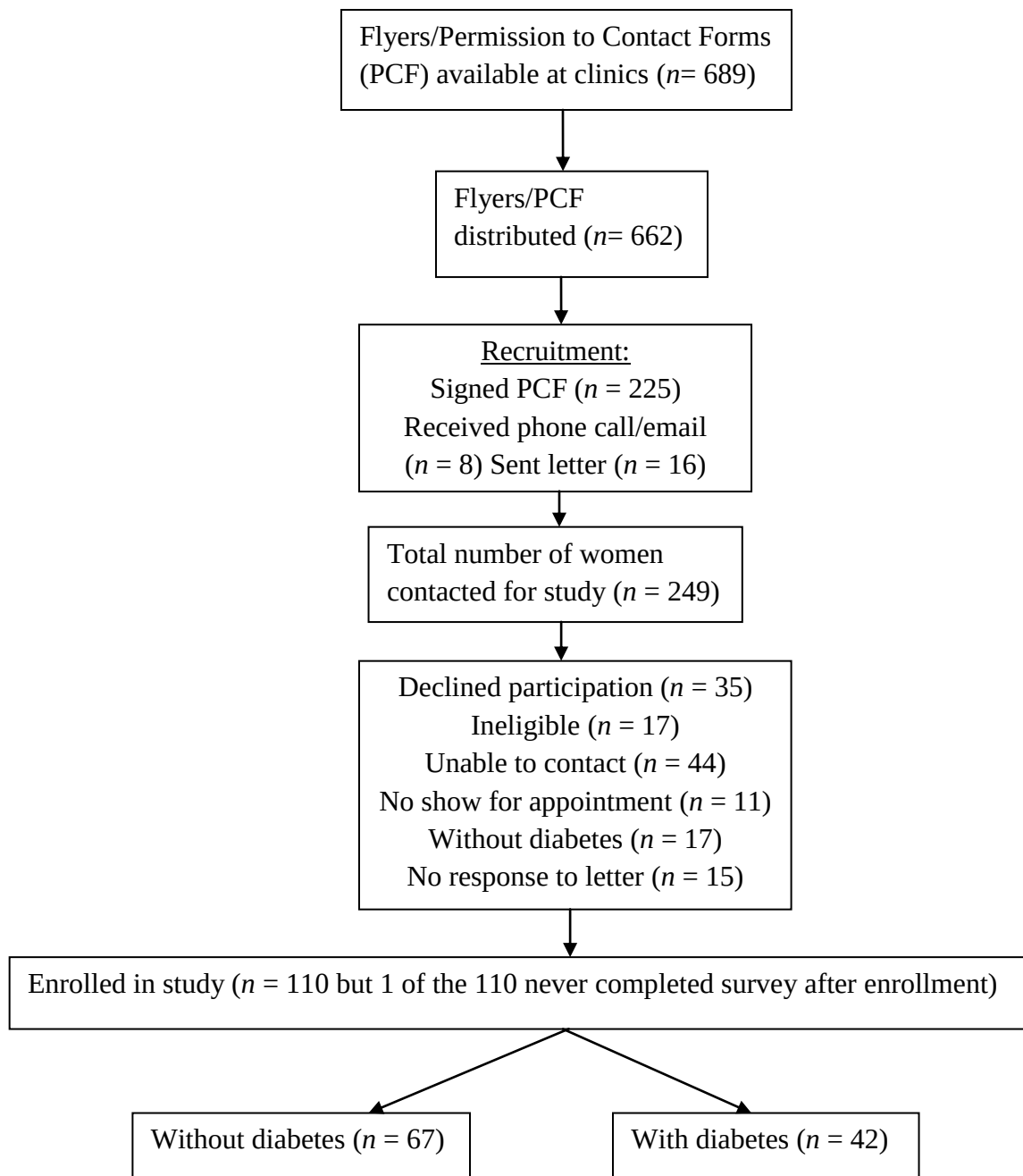


Figure 2. Consort diagram of study flow by recruitment and enrollment of women.

11 (4.4%) did not keep appointment(s) with the investigator, and 17 (6.8%) lacked a self-reported diagnosis of diabetes during the final phase of recruitment. Of the 16 women with diabetes who were sent letters, 15 did not respond (6.0%). Final enrollment included 110

(44.2%) women in the study. One enrolled woman was not able to complete any survey information and therefore had no data for study. The final sample size was 109 (43.8%) participants ($n = 42$ with diabetes; $n = 67$ without diabetes).

Analysis of Research Question Results

Research question one. *What were the differences between middle-aged women with and without diabetes in their minutes per day of MVPA as measured by the two physical activity measures and their associated demographic, clinical, and social–cognitive factors?* To analyze the data obtained from answers to research question one, the investigator used independent *t*-tests to compare the means of continuous demographic, clinical, and social–cognitive factors between women with and without diabetes. Continuous factors included age, BMI, scores for comorbidities, depression symptom severity, attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, and social support for physical activity. Cross-tabulations and chi-square tests were used to analyze the between-group differences in categorical factors, such as race and ethnicity, marital status, educational level, annual household income, employment status, and smoking status. Comparisons were made between the 42 women with diabetes and the 67 women without diabetes.

Demographic factors. Table 7 compares the women with and without diabetes on demographic factors.

Age. The total sample of 109 women had a mean age of 54.1 years with a median of 54.0. No significant difference by age was noted between women with and without diabetes ($t = -0.9$ [107], $p = .37$).

Race and ethnicity. Women were able to choose more than one response for the race and ethnicity item. However, to increase the number of women in each category being compared in

Table 7

Descriptive Statistics for Demographic Factors of the Total Sample of Women and Comparison of Those with and Without Diabetes

Demographic Factors	Mean (Standard Deviation)			t (df)
	Total Sample $N = 109$	With Diabetes $n = 42$	Without Diabetes $n = 67$	
Age, years	54.1 (5.1)	54.6 (5.1)	53.7 (5.2)	-0.90 (107)
	N (%)	n (%)	n (%)	χ^2 (df)
Race and ethnicity				4.3* (1)
White	75 (68.8)	24 (57.1)	51 (76.1)	
Non-White	34 (31.2)	18 (42.9)	16 (23.9)	
Marital status				0.1 (1)
Not married/unpartnered	44 (40.4)	18 (42.9)	26 (38.8)	
Married/partnered	63 (57.8)	24 (57.1)	39 (58.2)	
Missing	2 (1.8)		2 (3.0)	
Education level				0.3 (2)
High school graduate or less	24 (22.0)	10 (23.8)	14 (20.9)	
Some college or technical school	51 (46.8)	20 (47.6)	31 (46.3)	
College graduate	32 (29.4)	11 (26.2)	21 (31.3)	
Missing	2 (1.8)	1 (2.4)	1 (1.5)	
Annual household income				0.8 (2)
<\$25,000	45 (41.3)	19 (45.2)	26 (38.8)	
\$25,000 to < \$65,000	34 (31.2)	11 (26.2)	23 (34.3)	
\$65,000 to $\geq$ \$75,000	30 (27.5)	12 (28.6)	18 (26.9)	
Employment status				2.7 (1)
Employed	62 (56.9)	20 (47.6)	42 (62.7)	
Not employed	46 (42.2)	22 (52.4)	24 (35.8)	
Missing	1 (0.9)		1 (1.5)	

* $p < .05$.

the analysis, women selecting a race other than White or more than one race were combined to create a non-White group. Findings showed more women with diabetes identifying themselves as non-White compared with those without the disease ($\chi^2 = 4.3$ [1], $p = .04$).

Marital status. Marital status was analyzed by using two categories, *married/partnered* and *not married/unpartnered*. The latter category was formed by combining the following three response choices: *widowed*, *divorced/separated*, and *never married/unpartnered*. Results showed that women with and without diabetes were not significantly different by marital status ($\chi^2 = 0.1$ [1], $p = .77$).

Educational level. Education levels were categorized by *high school graduate or less* (category formed by combining two response choices: *some high school* and *high school graduate*), *some college or technical school*, and *college graduate*. No significant differences in educational levels were noted between women with and without diabetes ($\chi^2 = 0.3$ [2], $p = .84$). Of the 107 women who responded to this item, almost half ($n = 51$, 47.7%) reported having some college or technical school education, and approximately a third of the women ($n = 32$, 29.9%) reported being college graduates.

Annual household income. Three categories were used to analyze annual household income: *less than \$25,000*, *between \$25,000 and less than \$65,000*, and *greater than or equal to \$65,000*. Of the 109 women responding to the item, 45 (41.3%) reported making *less than \$25,000*. No significant association was noted between women with or without diabetes and annual household income ($\chi^2 = 0.8$ [2], $p = .66$). When study participants were dichotomized by those making *less than \$25,000* versus those making *\$25,000 or more*, there was no significant difference noted between women with and without diabetes ($\chi^2 = 1.1$ [1], $p = .30$).

Employment status. Employment status was categorized as *employed* (full-time and part-time response choices combined) versus *not employed* (category formed by combining three response choices: *retired*, *unemployed*, and *unable to work*). No significant difference was noted between women with diabetes and those without diabetes in employment status ($\chi^2 = 2.7$ [1], $p = .10$). Of the 62 women who were employed, 45 (41.7%) were employed full-time.

Clinical factors. Middle-aged women were compared on the following clinical factors: with or without diabetes, BMI, comorbidities, depressive symptom severity, and smoking status (see Table 8 for clinical factors related to the total sample and to women with and without diabetes).

Diabetes. Of the 109 women who responded to the paper-and-pencil survey, 41 (37.3%) reported having diabetes, and 68 (61.8%) indicated they did not. Chart audits indicated that 42 (38.2%) of the 109 women were diagnosed with and/or treated for diabetes, and 67 (60.9%) were without diabetes. One woman reported having diabetes without chart audit indicating a diagnosis and/or treatment. Two women reported not having diabetes, but chart audit indicated diagnosed diabetes. Thus, 42 women with diabetes were accounted for by chart audit, and their results were used for further analysis.

Of the 42 women with diabetes, duration of the disease ranged from 0.08 to 63 years. The mean duration of diabetes was 5.6 ($SD = 11.2$) years. Thirty-one (72.1%) women reported having T2D, eight (18.6%) reported having T1D, and four (9.3%) did not know the type of diabetes. Several discrepancies were noted by chart audit: (a) only five (14.3%) women had T1D compared to the eight by self-report, (b) 37 (85.7%) had T2D compared to the 31 by self-report, and (c) all four of the women who did not know type were diagnosed and/or treated for T2D. Due to the discrepancies between self-report and chart audit on type of diabetes, chart audit data

Table 8

Descriptive Statistics for Clinical Factors of the Total Sample of Women and Comparison of Those with and Without Diabetes

Clinical Factor	N	Mean (Standard Deviation)			Range	t (df)
		Total Sample N = 109	With Diabetes n = 42	Without Diabetes n = 67		
BMI, kg/m ²	108	32.0 (8.2)	35.9 (9.1)	29.6 (6.6)	10.8–55.8	4.1**(106)
Comorbidity index ^a	109	1.9 (2.1)	3.3 (1.9)	1.1 (1.7)	0–7	6.3** (107)
Depressive symptom severity ^b	109	4.8 (4.6)	5.8 (5.0)	4.2 (4.2)	0–20	1.7 (107)
	n (%)		n (%)	n (%)		χ^2 (df)
Smoking status	108					0.5 (1)
Yes	16 (14.8)		5 (4.6)	11 (10.2)		
No	92 (85.2)		37 (34.3)	55 (50.9)		

Note. ^a Measured via Katz CCI. ^b Measured via PHQ-9.

** $p < .001$.

for diagnosis and type were used for analysis. As a result, 37 (88.1%) of the 42 women with diabetes were categorized as being diagnosed with and/or treated for T2D and five (11.9%) women for T1D.

Twenty-nine (67.4%) women with diabetes reported currently taking anti-diabetes oral medication, and 22 (51.2%) reported taking insulin. These results indicated that 13 women with T2D were taking insulin along with oral anti-diabetic medication to treat their diabetes. Thirty-

eight (88.4%) of the women with diabetes reported not always having treated their diabetes with insulin. Independent *t*-test and chi-square analysis indicated no significant difference between women with T1D and those with T2D by age ($t = 1.5$ [40], $p = .14$), marital status ($\chi^2 = 1.5$ [2], $p = .47$), educational level ($\chi^2 = 1.1$ [2], $p = .59$), annual household income ($\chi^2 = 3.0$ [2], $p = .56$) or employment status ($\chi^2 = 2.6$ [2], $p = .28$).

Comparisons by type were not possible for categorical factors because there were only five women with T1D. However all women with T1D were of White race and ethnicity. Longer duration of diabetes was expected and noted for women with T1D compared to those with T2D ($t = 5.5$ [4.21], $p = .01$, 95% CI [29.0, 43.6]). BMI was higher in women with T2D ($M = 25.1$ [8.5]) compared to those with T1D ($M = 37.4$ [8.2], $t = 3.1$ [39], $p < .01$, 95% CI [4.3, 20.2]). Women with T2D had lower scores for physical activity self-efficacy ($M = 4.1$ [1.2]) compared to those with T1D ($M = 5.6$ [1.3], $t = -2.5$ [39], $p = .02$, 95% CI [-2.6, -0.3]). Therefore, in consideration of the difference noted between types of diabetes, the 37 women with only T2D (excluding the five women with T1D) were compared with those without diabetes on all factors.

Table 9 lists the descriptive statistics for the demographic factors of the total sample of women and compares those with T2D and without diabetes. Comparison of the demographic factors between women with T2D and without diabetes indicates that the only demographic factor that differed significantly was race and ethnicity; there were more non-White women with T2D ($\chi^2 = 6.7$ [1], $p = .01$) than non-White women without diabetes.

BMI. The mean BMI of 32.0 ($SD = 8.2$) indicates that a majority of the women in the study were overweight or obese. The CDC (2010) categorizes weight as (a) *underweight* for a BMI below 18.5 kg/m², (b) *healthy weight* for a BMI between 18.5 and 24.9 kg/m²,

Table 9

Descriptive Statistics for Demographic Factors of the Total Sample of Women and Comparison of Those with T2D and Without Diabetes

Demographic Factor	Mean (Standard Deviation)			<i>t</i> (df)
	Total Sample <i>N</i> = 104	With T2D <i>n</i> = 37	Without Diabetes <i>n</i> = 67	
Age, years	53.9 (5.1)	54.2 (5.0)	53.7 (5.2)	0.5(102)
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	χ^2 (df)
Race and ethnicity				6.7* (1)
White	70 (67.3)	19 (51.4)	51 (76.1)	
Non-White	34 (32.7)	18 (48.6)	16 (23.9)	
Marital status				0.3 (1)
Not married/unpartnered	43 (41.3)	17 (45.9)	26 (38.8)	
Married/partnered	59 (56.7)	20 (54.1)	39 (58.2)	
Missing	2 (2.0)		2 (3.0)	
Education level				0.2 (2)
High school graduate or less	22 (21.1)	8 (21.6)	14 (20.9)	
Some college	49 (47.1)	18 (48.7)	31 (46.3)	
College graduate	31 (29.8)	10 (27.0)	21 (31.3)	
Missing	2 (2.0)	1 (2.7)	1 (1.5)	
Annual income				0.8 (2)
<\$25,000	45 (41.3)	18 (48.6)	26 (38.8)	
\$25,000 to <\$65,000	34 (31.2)	9 (24.3)	23 (34.3)	
\$65,000 to ≥\$75,000	30 (27.5)	10 (27.0)	18 (26.9)	
Employment status				3.0 (1)
Employed	59 (56.7)	17 (45.9)	42 (62.7)	
Not employed	44 (42.3)	20 (54.1)	24 (35.8)	
Missing	1 (1.0)		1 (1.5)	

**p* = .01.

(c) *overweight* for a BMI between 25 and 29.9 kg/m², and (d) *obese* for a BMI of equal to or greater than 30.0 kg/m². Based on the CDC categorization, of the 108 women measured, one (0.9%) was underweight, 14 (13.0%) were healthy weight, 27 (25.0%) were overweight, and 66 (61.1%) were obese. Thus, 93 (86.1%) of the women were either overweight or obese. As noted in Table 8, women with diabetes had higher average BMI than those without diabetes ($t = 4.12$ [106], $p < .001$, 95% CI [3.23, 9.23]). Table 10 lists the descriptive statistics for the clinical factors of the total sample of women and compares those with T2D and without diabetes. As noted in Table 10, women with T2D also had higher average BMI than those without diabetes ($t = 5.2$ [101], $p < .001$, 95% CI [4.8, 10.7]).

Comorbidity index. Of the 109 women who responded to the Katz version of the CCI items, the mean index score was 1.94 ($SD = 2.05$). The comorbidity index varied based on number and severity of comorbid conditions and the age of the woman. As noted in Table 8, women with diabetes had significantly higher comorbidity index scores on the Katz version of the CCI than those without diabetes ($t = 6.32$ [107], $p < .001$, 95% CI [1.50, 2.87]). As noted in Table 10, women with T2D had higher comorbidity index scores on the Katz version of the CCI than those without diabetes ($t = 5.8$ [102], $p < .001$, 95% CI [1.4, 2.8]). The mean scores for this study indicate that women with diabetes had on average two comorbid conditions more than women without diabetes. Cronbach's alpha for the 14 items on the Katz CCI was .55, indicating fair internal consistency reliability of the tool because values above .7 indicate that the items are measuring the same concept (Miller & Salkind, 2002; Vogt, 2005).

Depressive symptom severity. Depressive symptom severity as measured by the PHQ-9 was not statistically different between women with diabetes and those without diabetes ($t = 1.72$

Table 10

Descriptive Statistics for Clinical Factors of the Total Sample of Women and Comparison of Those with T2D and Without Diabetes

Clinical Factor	N	Mean (Standard Deviation)			Range	t (df)
		Total Sample N = 104(SD)	With T2D n = 37	Without Diabetes n = 67		
BMI, kg/m ²	102	32.3 (8.1)	37.4 (8.2)	29.6 (6.6)	17.7–55.8	5.2 **(101)
Comorbidity index ^a	104	1.8 (2.0)	3.2 (1.9)	1.1 (1.7)	0–7	5.5 **(101)
Depressive symptom severity ^b	104	4.9 (4.7)	6.1 (5.2)	4.2(4.2)	0–20	2.0 (102)
N (%)		n (%)		n (%)	χ^2 (df)	
Smoking status	103				0.2 (1)	
Yes	16 (15.5)	5 (13.5)		11 (10.2)		
No	87 (84.5)	32 (86.5)		55 (50.9)		

Note. ^a Measured via Katz CCI. ^b Measured via PHQ-9.

** $p < .001$.

[107], $p = .09$). For the 109 women who responded to the nine items on the PHQ-9, the mean score was 4.82 ($SD = 4.60$) with a range of 0 to 20. Scores over 10 were indicative of moderate to severe depressive symptom severity. Sixteen women had scores greater than 10 and were either mailed or given a letter at their second clinic appointment encouraging them to discuss the

results with their primary care provider and seek help for symptoms. The letter included a list of mental health community agencies and contact information (see Appendix E for the letter). One of the 16 women was unable to be reached by phone call and did not return for her second appointment; mail was returned to sender undelivered. As noted in Table 10, women with T2D approached significant difference in depressive symptom severity compared with those without diabetes ($t = 2.0$ [102], $p = .05$). For this study, Cronbach's alpha related to the nine items on the PHQ-9 was .80, indicating very good internal consistency reliability.

Smoking status. As noted in Table 8, the difference between women with diabetes and those without diabetes regarding smoking status approached statistical significance ($\chi^2 = 0.46$ [1], $p = .50$). Of the 108 women who responded to the question about smoking status, 92 (85.2%) reported not smoking. Of the 16 (14.8%) women who reported smoking, five (31.3%) were diagnosed with and/or treated for diabetes. As noted in Table 10, women with T2D did not significantly differ from those without diabetes in smoking status ($\chi^2 = 0.18$ [1], $p = .67$).

Social–cognitive factors. Table 11 lists the descriptive statistics for the sample of women and compares middle-aged women with and without diabetes on the following social–cognitive factors: attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, and social support for physical activity. Table 12 lists the descriptive statistics for the sample of women and compares those with T2D and those without diabetes on the social–cognitive factors.

Attitudes toward physical activity. Attitudes toward physical activity were assessed using a rating scale for six items. As noted in Table 11, women with diabetes were not statistically different from those without diabetes in their response to items assessing attitudes toward physical activity ($t = -1.12$ [106], $p = .26$). As noted in Table 12, women with T2D also did not

Table 11

Descriptive Statistics for Social–Cognitive Factors of the Total Sample of Women and Comparison of Those with and Without Diabetes

Social– Cognitive Factor	Mean (Standard Deviation)			Range	<i>t</i> (<i>df</i>)
	Total Sample <i>N</i> = 108	With Diabetes <i>n</i> = 42	Without Diabetes <i>n</i> = 67		
Attitudes toward physical activity	5.8 (0.9)	5.6 (1.1)	5.8 (0.9)	2.7–7.0	–1.1 (106)
Physical activity self- efficacy	4.6 (1.3)	4.3 (1.3)	4.8 (1.2)	1.6–7.0	–1.9* (109)
Benefits of physical activity	6.0 (1.0)	5.7 (1.2)	6.1 (0.8)	1.3–7.0	–2.1* (61.1)
Social support for physical activity	41.4 (13.4)	39.1 (14.7)	43.4 (12.9)	13–72	–1.6 (106)

* $p < .05$.

significantly differ in their responses to items assessing attitudes toward physical activity compared with those without diabetes ($t = -0.8$ [101], $p = .46$). The mean score of 5.8 with a range of 2.7 through 7.0 indicates the positive attitudes toward physical activity held by women with and without diabetes. For this study, Cronbach’s alpha for the six items of the attitudes scale was .81, which indicated strong internal consistency reliability.

Physical activity self-efficacy. Ten items on the Self-Efficacy for Exercise Scale (SEE) were used to measure physical activity self-efficacy. As noted in Table 11, women with diabetes differed significantly from those without diabetes in their responses to items about physical activity self-efficacy ($t = -2.05$ [106], $p = .03$, 95% CI [-0.82, -0.05]). As noted in Table 12,

Table 12

Descriptive Statistics for Social–Cognitive Factors of the Total Sample of Women and Comparison of Those with T2D and Without Diabetes

Social– Cognitive Factor	Mean (Standard Deviation)			Range	t-test (df)
	Total Sample N = 103	With T2D n = 36	Without Diabetes n = 67		
Attitudes toward physical activity	5.8 (0.9)	5.7 (0.9)	5.8 (0.9)	2.7 – 7.0	–0.7 (101)
Physical activity self-efficacy	4.6 (1.3)	4.1 (1.2)	4.8 (1.2)	1.6 – 7.0	–2.6* (101)
Benefits of physical activity	6.0 (1.0)	5.6 (1.2)	6.1 (0.8)	1.3 – 7.0	–2.4*(51.0)
Social support for physical activity	41.4 (13.4)	38.4 (14.4)	43.4 (12.9)	13.0–72.0	–1.8 (101)

* $p \leq .01$.

women with T2D reported lower physical activity self-efficacy than those without diabetes ($t = -2.6 [101]$, $p = .01$, 95% CI [-1.2, -0.10]). Therefore, findings for women with and without diabetes were similar to those for women with T2D and without diabetes when comparing the results between Table 11 and Table 12. For this study, Cronbach's alpha for the 10 items of the SEE was .90, indicating very strong internal consistency reliability.

Benefits of physical activity. The nine statements on the Outcomes Expectancies for Exercise Scale (OEE; Resnick et al., 2000) were used to measure benefits of physical activity. As noted in Table 11, women with diabetes reported fewer benefits of physical activity than women

without diabetes ($t = -2.05$, [61.50], $p = .045$, 95% CI [-0.01, -0.86]). As noted in Table 12, women with T2D reported fewer benefits of physical activity than women without diabetes ($t = -2.4$, [51.0], $p = .02$, 95% CI [-0.100, -0.10]). For this study, Cronbach's alpha for the nine items of the SEE was .91, indicating strong internal consistency reliability.

Social support for physical activity. Social Support for Exercise Habits Scale (SSE; Sallis et al., 1987) was used to measure social support for physical activity. As noted in Table 11, women with and without diabetes did not significantly differ in their responses to items on the SSE ($t = -1.60$ [106], $p = .11$). As noted in Table 12, women with T2D and those without diabetes also did not significantly differ in their responses to items on the SSE ($t = -1.8$ [101], $p = .07$). While the developers of the SSE suggest that the tool be scored differently for friends and family (Sallis et al., 1987), this study utilized one tool with very acceptable reliability (see page 78 of Chapter Four for rationale). For this study, Cronbach's alpha for the 13 items of the SSE was .86, which indicated strong internal consistency reliability.

Response variable. The daily log provided contextual content for the types of physical activity that the women engaged in during their week of accelerometer wear. The response variable of minutes per day of MVPA is described by the IPAQ short form and accelerometry.

Daily log. The daily log was used by the investigator to provide contextual feedback to the women when reviewing the graphing of accelerometer data. During the second clinic appointment, the investigator shared a graph of her downloaded accelerometer data with each woman. When noting times of MVPA on the graph, the investigator would ask the woman what the context was for the activity and refer to the daily log for assistance. Contextual information for the physical activity performed by the women throughout the week included activities such as walking; yoga; household duties such as cooking, cleaning, and laundry; lawn and garden work;

swimming; childcare; occupational work; and grocery shopping.

Certain activities, such as yoga, biking and swimming, either were not visually apparent or were not apparent as MVPA on the accelerometer graphing when reviewed with the women. Activities such as yard work, walking for exercise, dancing, exercise class/health club, walking the dog, and shopping were frequently noted to be in the moderate physical activity range or between 574 and 4,944 counts (Swartz et al., 2003) on the graphing. Many of the women expressed surprise that they were capable of MVPA in their everyday lives.

IPAQ short form. Scoring of the IPAQ short form followed the Guidelines for Data Processing and Analysis of the IPAQ (2005) for calculating minutes per day of MVPA. The IPAQ short form differs from accelerometry by calculations that include walking activity along with vigorous and moderate physical activity during a 7-day week. Walking is considered to be a moderate physical activity. Therefore, all minutes of vigorous and moderate physical activity were summed with minutes of walking time to create MVPA for the IPAQ short form. Minutes of MVPA per 7-day week were calculated first and then divided by 7 to score the minutes per day of MVPA as measured by the IPAQ short form.

Of the 109 women in the study, 101 had complete data for the IPAQ short form. Six women were missing all data, and two were missing partial data. These eight women were excluded from the analysis. Of the 101 IPAQ short form surveys with complete data, 40 were truncated for excess time (greater than 180 min) in at least one physical activity category. As explained in the Guidelines for the IPAQ short form, data exceeding 180 minutes per day of time spent in any one of the categories of vigorous or moderate physical activity or walking is recoded or truncated to equal 180 min. This recoding is an attempt to normalize the distribution of the activity data while still allowing for up to 21 hr per week of combined activity. Fifteen women

Table 13

Descriptive Statistics for Response Variable in Minutes per Day for the Total Sample of Women and Comparison of Those with and Without Diabetes

Response Variable	Mean (Standard Deviation)			<i>t</i> -test (<i>df</i>)
	Total Sample	With diabetes	Without diabetes	
IPAQ	<i>N</i> = 101	<i>n</i> = 38	<i>n</i> = 63	
M VPA	115.8(103.4)	93.4 (79.7)	129.4(113.9)	−1.9 (96.7)
Vigorous	23.2 (35.9)	19.0 (34.6)	25.7 (36.7)	−0.9 (99)
Moderate	36.5 (49.4)	20.8 (26.6)	46.0 (57.2)	−3.0* (94.1)
Walking	56.1 (58.8)	53.6 (57.5)	57.7 (60.0)	0.3 (99)
Sedentary	574.8(668.4)	360.8(168.8)	709.4 (816.7)	−3.3* (69.1)
Accelerometer	<i>N</i> = 99	<i>n</i> = 40	<i>n</i> = 59	
MVPA	137.1 (55.3)	130.6 (47.2)	141.6 (60.1)	−1.0 (97)
Vigorous	2.1 (4.7)	0.4 (1.3)	3.3 (5.7)	−3.8**(66.8)
Moderate	135.0 (53.2)	130.2 (47.1)	138.3 (57.2)	−0.7 (97)
Light	186.9 (48.1)	191.2 (54.4)	183.9 (43.5)	0.7 (97)
Sedentary	508.0 (109.3)	511.7(127.6)	505.4 (96.0)	0.3 (97)

p* < .01. *p* < .001.

reported more than 960 minutes per week (137 minutes per day) of MVPA. Although the scoring guidelines suggest exclusion from the study for excess time, data were not excluded because the accelerometer data indicated that 41 women had more than 137 minutes per day of MVPA.

As noted in Table 13, there was no significant difference between women with diabetes and those without diabetes in minutes per day of MVPA, minutes per day of vigorous physical activity, or minutes per day of walking reported on the IPAQ short form. However, women with diabetes reported significantly fewer minutes per day of moderate physical activity compared with women without diabetes ($t = -3.0$ [94.1], $p = .003$, 95% CI [-41.9, -8.6]). Interestingly, women with diabetes also reported significantly fewer minutes per day of sedentary behavior than women without diabetes on the IPAQ short form ($t = -3.3$ [69.1], $p = .002$, 95% CI [-562.4, -134.8]).

As noted in Table 14, there was no significant difference between women with T2D and those without diabetes in minutes per day of MVPA, minutes per day of vigorous, or minutes per day of walking reported on the IPAQ short form. However, women with T2D reported significantly fewer minutes per day of moderate physical activity compared to women without diabetes ($t = -3.0$ [92.7], $p = .004$, 95% CI [-42.4, -8.5]). Women with T2D also reported significantly fewer minutes per day of sedentary behavior than women without diabetes on the IPAQ short form ($t = -3.3$ [69.3], $p = .001$, 95% CI [-572.3, -144.1]).

Accelerometry. Accelerometry data were cleaned to assess for valid data. The investigator defined valid data as at least four days of greater than or equal to 10 hours of wear time with at least one being a weekend day as suggested by Trost et al. (2005). If more than seven days of data were recorded by the accelerometer only the first seven valid days were kept for analysis. Mean wear time per day for the middle-aged women was 15.2 ($SD = 1.6$) valid hours. No significant difference in average wear time was noted between women with diabetes ($M = 15.3$ [2.1]) and those without diabetes ($M = 15.1$ [1.2], $t = 0.5$ [56.0], $p = .63$). Mean wear time for the women with T2D and without diabetes was 15.2 (1.6) valid hours. No significant

Table 14

Descriptive Statistics for Response Variable in Minutes per Day for the Total Sample of Women and Comparison of Those with T2D and Without Diabetes

Response Variable	Mean (Standard Deviation)			<i>t</i> -test (<i>df</i>)
	Total Sample	With T2D	Without Diabetes	
IPAQ	<i>N</i> = 96	<i>n</i> = 33	<i>n</i> = 63	
MVPA	117.5 (105.0)	94.6 (82.3)	129.4 (113.9)	−1.7 (84.5)
Vigorous	24.2 (36.5)	21.3 (36.5)	25.7 (36.7)	−0.6 (94)
Moderate	37.3 (50.1)	20.6 (26.1)	46.0 (57.2)	−3.0* (92.7)
Walking	56.0 (58.7)	52.7 (56.9)	57.7 (60.0)	−0.4 (94)
Sedentary	582.5 (683.3)	351.2(160.7)	709.4 (816.7)	−3.3**(69.3)
Accelerometer	<i>N</i> = 94	<i>n</i> = 35	<i>n</i> = 59	
MVPA	136.5 (56.6)	127.8 (49.7)	141.6 (60.2)	−1.2 (92)
Vigorous	2.2 (4.8)	0.4 (1.4)	3.3 (5.7)	−3.8**(69.2)
Moderate	134.3 (54.5)	127.4 (49.5)	138.3 (57.2)	−0.9 (92)
Light	185.7 (48.6)	188.7 (56.8)	183.9 (43.5)	0.5 (92)
Sedentary	510.1(107.2)	517.9(125.1)	505.4 (96.0)	0.5 (92)

p* < .01. *p* ≤ .001.

difference in average wear time was noted between women with T2D (*M* = 15.4[2.1]) and those without diabetes (*M* = 15.1[1.2], *t* = 0.6 [47.3], *p* = .55).

For the outcome response of minutes per day of MVPA as measured by the accelerometer and noted in Table 13, no significant difference was noted between women with and without

diabetes ($t = -1.0$ [97], $p = .33$). Women with diabetes had fewer minutes per day of vigorous physical activity than those without the disease ($t = -3.8$ [66.8], $p < .001$, 95% CI [-4.5, -1.4]). However, less than 1 to slightly over 3 minutes per day as noted in Tables 13 and 14 is a very short amount of time spent in vigorous physical activity. There was also a lack of significant difference between women with and without diabetes in minutes per day of light and moderate physical activity ($t = 0.7$ [97], $p = .33$, and $t = -0.7$ [97], $p = .46$, respectively). Minutes per day of sedentary time did not differ significantly between women with and those without diabetes ($t = 0.3$ [97], $p = .78$). These findings were similar to results for the outcomes of MVPA; vigorous, moderate, and light physical activity; and sedentary time between women with T2D and those without diabetes as noted in Table 14. Further analysis of the response variables is addressed in research question two.

Research question two. *What was the degree of agreement in minutes per day of MVPA between the IPAQ short form and accelerometer?* The investigator used descriptive comparative analyses to analyze the differences between the IPAQ data and the accelerometer data. From the sample of 109 women, 97 contributed complete data for both the IPAQ short form and the accelerometer. As noted in Table 13, for the total sample of middle-aged women with and without diabetes, mean minutes per day of MVPA was 115.8 ($SD = 103.4$) for the IPAQ short form and 137.1 ($SD = 55.3$) for accelerometry. As noted in Table 14, for the total sample of middle-aged women with T2D and without diabetes, mean minutes per day of MVPA was 117.5 ($SD = 105.0$) for the IPAQ short form and 136.5 ($SD = 56.6$) for accelerometry. To further assess the relationship between the IPAQ and the accelerometer, the investigator used the Bland and Altman (1986) method of agreement.

Figure 3, a scatter plot of the relationship between the IPAQ short form and the

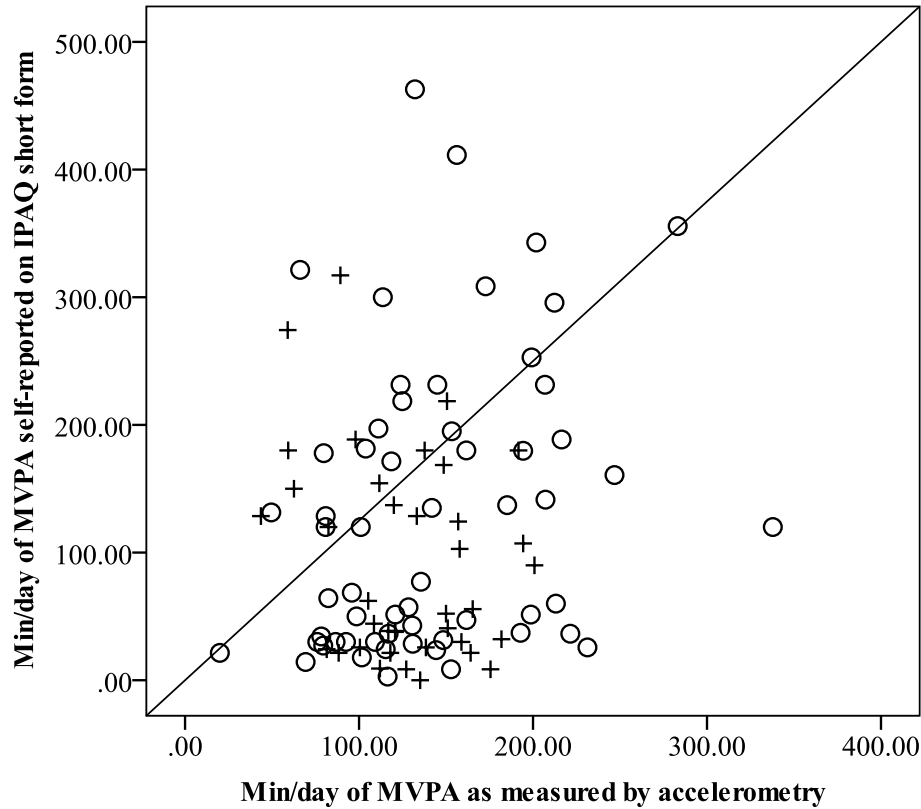


Figure 3. Scatter plot of relationship between minutes per day of MVPA as measured by accelerometry and self-reported IPAQ short form labeled by middle-aged women with diabetes (plus symbol) and without diabetes (circle symbol).

accelerometer data by individual women, indicates the lack of a strong linear relationship between the two measures. Data points that fall near the line indicate a close match between the IPAQ short form and the accelerometer data. The nearer the data points are to the line, the closer the match between the two measurements. Five (5.2%) women approximated their self-reported measurement of MVPA closely to the accelerometer results, but the majority ($n = 92$, 94.8%) either under-reported or over-reported their MVPA.

Provided that physical activity measured via accelerometry is accurate, data points under the line would indicate under-reported minutes per day of MVPA. The cluster of data points in the lower left part of the Figure 3 scatter plot indicates that 27 (27.8%) middle-aged women with

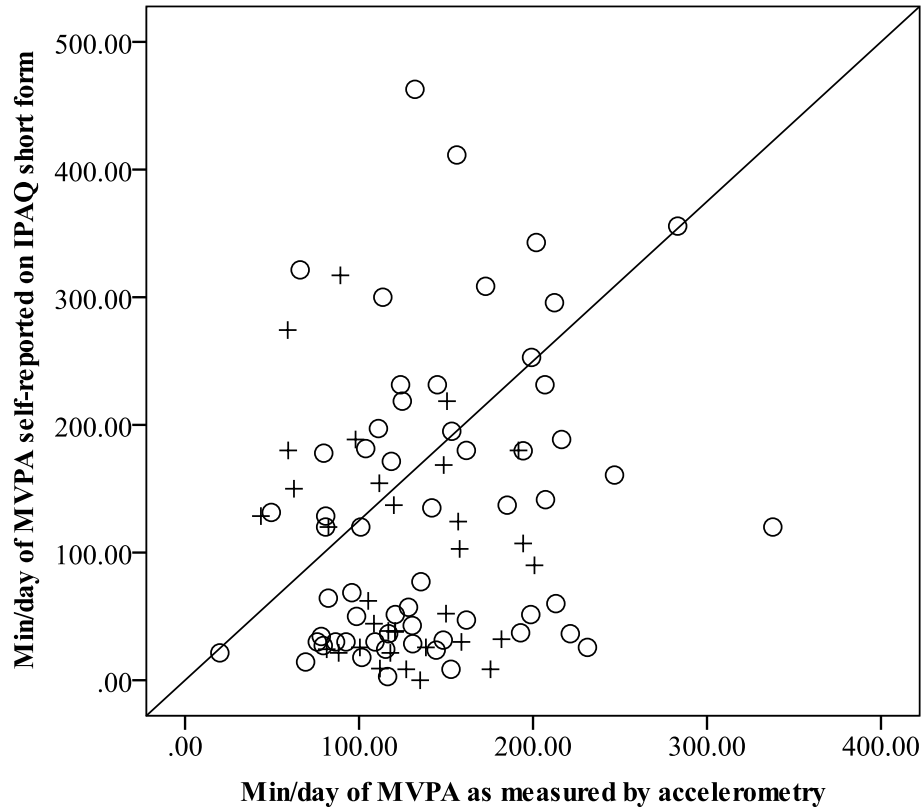


Figure 4. Scatter plot of relationship between minutes per day of MVPA as measured by accelerometry and self-reported IPAQ short form labeled by middle-aged women with T2D (plus symbol) and without diabetes (circle symbol).

diabetes and 38 (39.2%) without diabetes under-reported their daily minutes of MVPA. Data points above the line indicate over-reported minutes per day of MVPA. Ten (10.3%) middle-aged women with diabetes and 17 (17.5%) of those without diabetes overestimated their minutes per day of MVPA. The pattern of under-reporting and over-reporting is similar between women with and without diabetes.

Excluding the five women with T1D, 92 middle-aged women contributed complete data for both the IPAQ short form and the accelerometer. The scatter plot in Figure 4 indicates that five (5.4%) women without diabetes estimated very close to the accelerometer data as their data points fell on the line. Twenty-three (25.0%) middle-aged women with T2D and 38 (41.3%)

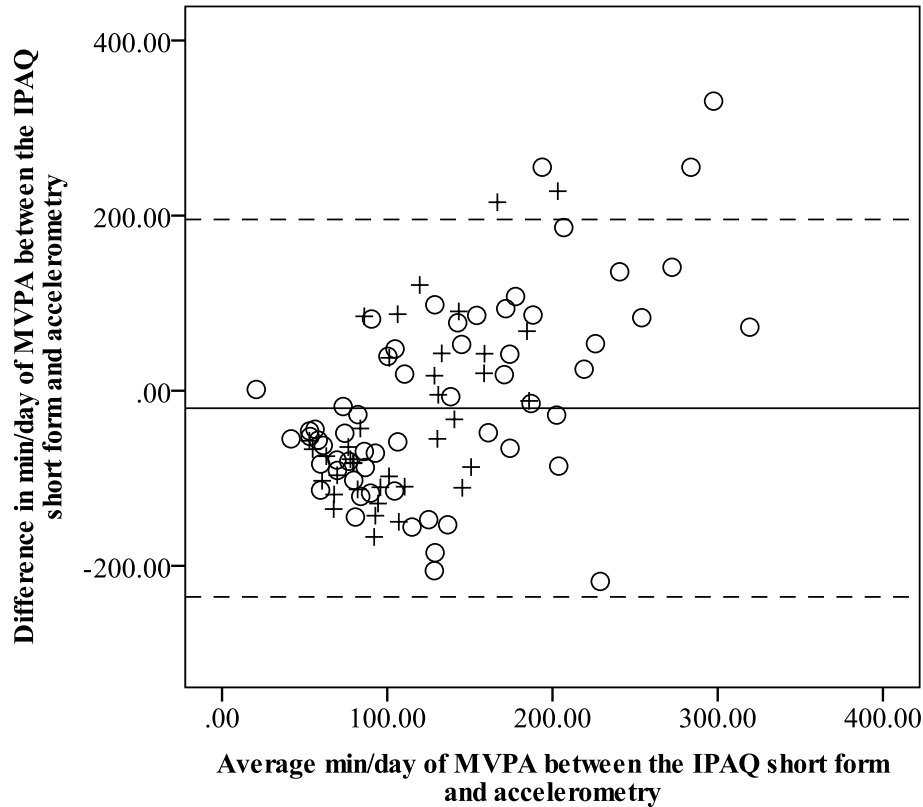


Figure 5. Bland and Altman degree of agreement of min/day of MVPA between the IPAQ short form and accelerometry in middle-aged women with diabetes (plus symbol) and without diabetes (circle symbol).

women without diabetes under-reported their daily minutes of MVPA. Nine (9.8%) middle-aged women with T2D and 17 (18.5%) of those without diabetes overestimated their minutes per day of MVPA.

Bland and Altman (1986) suggest using the difference between the two measures graphed in relationship to the average between the two as a method of comparison, as shown in Figures 5 and 6. The x-axis demonstrates the average found by adding the IPAQ short form data to the accelerometry data and dividing by two. The y-axis demonstrates the difference found by subtracting the accelerometry data from the IPAQ short form data.

Descriptive statistics were used to calculate the mean difference (solid black line), which

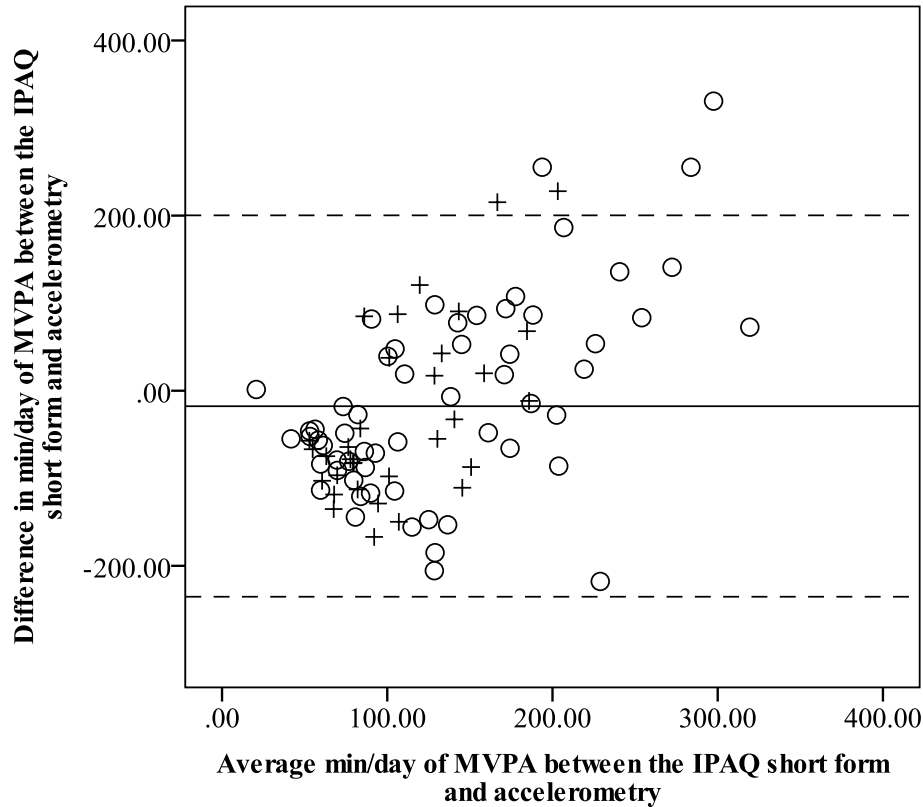


Figure 6. Bland and Altman degree of agreement between the IPAQ short form and accelerometry in middle-aged women with T2D (plus symbol) and without diabetes (circle symbol).

is the overall mean of the average between the IPAQ short version and the accelerometry data. The calculated standard deviation was multiplied by two and added and subtracted from the mean difference to find two standard deviations from the mean difference (dotted black line).

In Figure 5, the majority of the scatter plot data points fall within two standard deviations (-235.5, 195.6) from the mean difference (-20.0). As indicated by Figure 6, for middle-aged women with T2D and those without diabetes, the majority (94.8%) of the scatter plot data points fall within two standard deviations (-235.3, 200.3) from the mean difference (-17.5). Of the five data points that are outside the degree of agreement, two represent women with diabetes and three without diabetes.

The pattern of the scatter plot indicates that women with lower MVPA tended to under-report, and those with higher MVPA tended to over-report. Note also that as minutes per day of MVPA increased the variability between the IPAQ short form and accelerometry data also increased.

Research question three. *Which demographic, clinical, and social–cognitive factors of middle-aged women with and without diabetes were associated with minutes per day of MVPA as measured by the (a) International Physical Activity Questionnaire (IPAQ) short form, and (b) accelerometer?* For specific analyses of research question three, correlation tables and multiple linear regressions were used to assess which of the demographic, clinical, and social–cognitive factors have significant associations with minutes per day of MVPA (Kutner et al., 2004) in middle-aged women with and without diabetes. Correlations of the demographic, clinical and social–cognitive factors with minutes per day of MVPA as measured by the IPAQ and the accelerometer are described in Tables 15 through and 18. Pearson correlations were calculated among continuous factors (see Tables 15 and 17), and a Spearman correlation was calculated for the ordinal factors (see Table 16 and 18; Miller & Salkind, 2002).

Correlations to MVPA. As noted in Table 15, minutes per day of MVPA as measured by the IPAQ short form was not significantly correlated with any of the continuous factors, including age, diabetes duration, BMI, comorbidity index, depressive symptom severity, attitudes toward physical activity, physical activity self-efficacy, benefits of physical activity, or social support for physical activity. As measured by accelerometry, minutes per day of MVPA was correlated by a weak association to depressive symptom severity ($r = -.21, p = .03, n = 99$), attitudes toward physical activity ($r = .21, p = .04, n = 99$), and benefits of physical activity ($r = .20, p < .05, n = 99$). As depressive symptom severity increased, minutes per day of MVPA

decreased. As attitudes toward physical activity became more positive, minutes per day of MVPA increased. A greater perception of the benefits of physical activity was associated with more minutes per day of MVPA.

Table 16 indicates that minutes per day of MVPA as measured by the IPAQ short form were correlated by a weak association to one categorical factor, educational level ($r = -.27$, $p = .01$, $n = 101$). As educational level increased from less than a high school education to college graduate, minutes per day of MVPA declined. None of the categorical factors were significantly associated with minutes per day of MVPA as measured by accelerometry. A moderately strong positive association was noted between attitudes toward physical activity and both physical activity self-efficacy ($r = .40$, $p < .001$, $n = 108$) and benefits of physical activity ($r = .47$, $p < .001$, $n = 108$). Physical activity self-efficacy also had a moderately positive association with benefits of physical activity ($r = .44$, $p < .001$, $n = 108$) and a moderately negative association with BMI ($r = -.33$, $p = .001$, $n = 107$).

For the sample of middle-aged women with T2D and those without diabetes, some differing associations were found when compared to the total sample as noted in Tables 17 and 18. Minutes per day of MVPA as measured by the IPAQ short form were still moderately correlated with educational level for women with T2D and those without the disease. However, minutes per day of MVPA as measured by accelerometry was no longer associated with benefits of physical activity but continued to be associated with depressive symptom severity and attitudes toward physical activity.

Multiple linear regression. For the linear regression analysis, the investigator loaded all demographic, clinical, and social–cognitive factors into the model. A number of regression models were assessed for the best model fit by analyzing the significance of each factor and

Table 15

Pearson Correlations (r) Between Continuous Factors and MVPA as Measured by IPAQ Short Form and Accelerometer

		1	2	3	4	5	6	7	8	9	10	11
1. MVPA by IPAQ	<i>r</i>	1	.168	-.039	-.121	-.019	.054	.123	-.077	.080	.077	.061
	<i>n</i>		97	101	101	101	101	101	101	101	101	100
2. MVPA by accelerometer	<i>r</i>		1	.067	-.017	-.192	-.089	-.214*	.208*	.144	.199*	.088
	<i>n</i>			99	99	99	99	99	99	99	99	98
3. Age	<i>r</i>			1	.188	-.066	.177	-.088	-.164	.052	-.020	-.183
	<i>n</i>				109	108	109	109	108	108	108	108
4. Diabetes duration	<i>r</i>				1	.092	.464**	.023	-.194*	.004	-.109	-.132
	<i>n</i>					108	109	109	108	108	108	108
5. BMI	<i>r</i>					1	.172	.250**	-.192*	-.325**	-.252**	-.079
	<i>n</i>						108	108	107	107	107	107
6. Comorbidity index	<i>r</i>						1	.275**	-.098	-.242*	.281**	-.178
	<i>n</i>							109	108	108	108	108
7. Depressive symptom severity	<i>r</i>							1	-.114	-.189	-.326**	-.059
	<i>n</i>								108	108	108	108
8. Attitudes toward physical activity	<i>r</i>								1	.402**	.466**	.083
	<i>n</i>									108	108	107
9. Physical activity self-efficacy	<i>r</i>									1	.435**	.202*
	<i>n</i>										108	107
10. Benefits of physical activity	<i>r</i>										1	.183
	<i>n</i>											107
11. Social support for physical activity	<i>r</i>											1
	<i>n</i>											

* $p < .05$. ** $p < .01$.

Table 16

Spearman Correlations (r) Between Categorical Factors and MVPA as Measured by IPAQ Short Form and Accelerometer

		1	2	3	4	5	6	7	8	9
1. MVPA by IPAQ	<i>r</i>	1	.160	-.016	.111	-.267**	-.154	-.139	-.147	.103
	<i>n</i>		97	101	100	101	101	101	101	101
2. MVPA by accelerometer	<i>r</i>		1	.140	.007	.028	.018	.191	-.066	-.015
	<i>n</i>			99	98	99	99	99	99	99
3. Race/ethnicity	<i>r</i>			1	.059	.197*	.343**	.201*	-.199*	-.006
	<i>n</i>				107	107	109	108	109	108
4. Marital status	<i>r</i>				1	.062	.504**	-.058	-.028	-.100
	<i>n</i>					106	107	107	107	107
5. Educational level	<i>r</i>					1	.371**	.197*	-.063	-.148
	<i>n</i>						107	107	107	107
6. Annual household income	<i>r</i>						1	.315**	.002	-.173
	<i>n</i>							108	109	108
7. Employment status	<i>r</i>							1	-.158	-.115
	<i>n</i>								108	108
8. Diabetes	<i>r</i>								1	-.065
	<i>n</i>									108
9. Smoking status	<i>r</i>									1
	<i>n</i>									

* $p < .05$. ** $p < .01$.

Table 17

Pearson Correlations (r) Between Continuous Factors and MVPA Measured by the IPAQ Short Form and Accelerometer for Women with T2D and Those Without Diabetes

		1	2	3	4	5	6	7	8	9	10	11
1. MVPA by IPAQ	<i>r</i>	1	.181	-.025	-.123	-.031	.081	.112	-.086	.074	.087	.056
	<i>n</i>		92	96	96	96	96	96	96	96	96	95
2. MVPA by Accelerometer	<i>r</i>		1	.056	-.112	-.187	-.109	-.208*	.222*	.148	.197	.096
	<i>n</i>			94	94	94	94	94	94	94	94	93
3. Age	<i>r</i>			1	.068	-.036	.120	-.065	-.202*	.028	-.035	-.166
	<i>n</i>				104	103	104	104	103	103	103	103
4. Diabetes duration	<i>r</i>				1	.388**	.443**	.168	-.178	.220*	-.419**	-.254**
	<i>n</i>					103	104	104	103	103	103	103
5. BMI	<i>r</i>					1	.220*	.249*	-.214*	-.296**	-.254*	-.068
	<i>n</i>						103	103	102	102	102	102
6. Comorbidity index	<i>r</i>						1	.321**	-.098	-.298*	-.331**	-.169
	<i>n</i>							104	103	103	103	103
7. Depressive symptom severity	<i>r</i>							1	-.093	-.204*	-.328**	-.090
	<i>n</i>								103	103	103	103
8. Attitudes toward physical activity	<i>r</i>								1	.482**	.546**	.172
	<i>n</i>									103	103	102
9. Physical activity self-efficacy	<i>r</i>									1	.437**	.185
	<i>n</i>										103	102
10. Benefits of physical activity	<i>r</i>										1	.177
	<i>n</i>											102
11. Social support for physical activity	<i>r</i>											1
	<i>n</i>											

* $p < .05$. ** $p < .01$.

Table 18

Spearman Correlations (r) Between Categorical Factors and MVPA Measured by the IPAQ Short Form and Accelerometer for Women with T2D and Those Without Diabetes

		1	2	3	4	5	6	7	8	9
1. MVPA by IPAQ	<i>r</i>	1	.177	-.009	.094	-.301**	-.144	-.139	-.144	.102
	<i>n</i>		92	96	95	96	96	96	96	96
2. MVPA by Accelerometer	<i>r</i>		1	.123	.004	.038	.009	.199	-.105	-.005
	<i>n</i>			94	93	94	94	94	94	94
3. Race/Ethnicity	<i>r</i>			1	.046	.201*	.341*	.206*	-.253**	-.007
	<i>n</i>				102	102	104	103	104	103
4. Marital status	<i>r</i>				1	.063	.540**	-.045	-.058	-.094
	<i>n</i>					101	102	102	102	102
5. Educational level	<i>r</i>					1	.364**	.164	-.035	-.164
	<i>n</i>						102	102	102	102
6. Annual Household Income	<i>r</i>						1	.302**	-.026	-.173
	<i>n</i>							103	104	103
7. Employment status	<i>r</i>							1	-.172	-.117
	<i>n</i>								103	103
8. Diabetes	<i>r</i>								1	-.042
	<i>n</i>									103
9. Smoking status	<i>r</i>									1
	<i>n</i>									

* $p < .05$. ** $p < .01$

dropping the factor that contributed the least to the model as suggested by von Eye and Schuster (1998). No linear regression equation was found that modeled the association between the predictor variables and the response variable of minutes per day of MVPA as measured either by the IPAQ short form or accelerometry.

Missing data. The investigator analyzed the extent of missing data by using the IBM SPSS Statistics (Version 19) software program for Missing Value Analysis. Missing data for the demographic, clinical, and social–cognitive factors was 2.7% for marital status and educational level, 1.8% for employment status and smoking, and less than 1% for age, race, and duration of diabetes. Social–cognitive variables were complete in data entry. IPAQ short form and accelerometer data were complete for those matched for analysis. No imputations were necessary.

Power analysis. A post hoc analysis utilized G*Power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) to determine the effect size and power of this study. Effect size is a measure of the observed association or difference between groups and factors of interest, in this study, the women with diabetes and those without the disease for the continuous demographic, clinical, and social–cognitive factors and minutes per day of MVPA. The effect size indicates to what extent the null hypothesis is false (Vogt, 2005). Statistical power is the probability of rejecting the null hypothesis when it is false. Power values range from 0 to 1.0. An acceptable level of power is .80, with lower values indicating that significant mean differences could potentially be missed (Vogt, 2005).

The analysis was run for all independent *t*-tests comparing the women with diabetes to women without diabetes on the clinical, social–cognitive, and outcome variables of minutes per day of MVPA. As noted in Table 19, the effect size (power) for each of the clinical factors was 0.78 (0.98) for BMI, 1.23 (1.00) for comorbidity index and 0.33 (0.38) for depressive symptom

Table 19

Power Analysis for Explanatory Factors and Response Variable

Explanatory Factor	<i>N</i>	With Diabetes <i>n</i>	Without Diabetes <i>n</i>	Effect size	Power
<u>Clinical</u>					
BMI	108	41	67	0.78	0.98
Comorbidity index	109	42	67	1.23	1.00
Depressive symptom severity	109	42	67	0.33	0.38
<u>Social–Cognitive</u>					
Attitudes toward physical activity	108	41	67	0.21	0.19
Physical activity self- efficacy	108	41	67	0.38	0.47
Benefits of physical activity	108	41	67	0.42	0.55
Social support for physical activity	108	42	66	0.32	0.36
Response Variable	<i>N</i>	<i>n</i>	<i>n</i>	Effect size	Power
<u>IPAQ</u>					
MVPA	101	38	63	0.37	0.42
Vigorous	101	38	63	0.20	0.17
Moderate	101	38	63	0.57	0.78
Walking	101	38	63	0.12	0.09
Sedentary	101	38	63	0.60	0.80
<u>Accelerometer</u>					
MVPA	99	40	59	0.17	0.09
Vigorous	99	40	59	0.69	0.90
Moderate	99	40	59	0.03	0.05
Light	99	40	59	0.14	0.10
Sedentary	99	40	59	0.24	0.19

severity. The effect size (power) for each of the social–cognitive factors was 0.21 (0.19) for attitudes toward physical activity; 0.38 (0.47) for physical activity self-efficacy; 0.42 (0.55) for benefits of physical activity and 0.32 (0.36) for social support for physical activity.

For the response variable of minutes by the IPAQ short form, the effect size (power) was 0.37 (0.42) for MVPA, 0.20 (0.17) for vigorous, 0.57 (0.78) for moderate, 0.12 (0.09) for walking, and 0.60 (0.80) for sedentary time. For the response variable of minutes per day of light, moderate, and vigorous physical activity, MVPA, and sedentary time by the accelerometer, the effect size (power) was 0.17 (0.09) for MVPA, 0.69 (0.90) for vigorous, 0.03 (0.05) for moderate, 0.14 (0.10) for light, and 0.24 (0.19) for sedentary. Cohen’s guidelines for effect size indicate that 0.2 is small, 0.5 is moderate, and 0.8 is large (Munro, 2005). Thus, factors with a medium effect size included benefits of physical activity, and moderate physical activity and sedentary time as measured by the IPAQ short form. Large effect sizes were noted for BMI, comorbidity.

Summary of Findings for Research Question One

Despite the differences between women with T1D and those with T2D (the T1D group had lower BMI, longer duration of diabetes, and greater perceived physical activity self-efficacy), the same demographic, clinical, and social–cognitive factors and outcome variable were significantly different whether or not the middle-aged women with T1D were included in the analytic sample. Differences in demographic factors between middle-aged women with diabetes compared with those without included only race and ethnicity. Significantly more non-White women had diabetes in the sample than White women.

Differences in clinical factors between middle-aged women with and without diabetes included higher BMI and comorbidity index. While depressive symptom severity was not

significantly different in either group, the sample of middle-aged women with T2D and without diabetes approached significance on this factor. Differences in social–cognitive factors between middle-aged women with and without diabetes included physical activity self-efficacy and benefits of physical activity. Middle-aged women with diabetes perceived significantly lower physical activity self-efficacy and benefits of physical activity.

For the outcome variable of minutes per day of MVPA, no significant differences were noted between middle-aged women with diabetes and those without the disease as measured by the IPAQ short version or accelerometry. Differences between middle-aged women with diabetes and those without were noted in moderate physical activity and sedentary time by the IPAQ short form. Middle-aged women with diabetes reported fewer minutes per day of moderate physical activity and also time spent in sedentary behavior. Middle-aged women with diabetes had fewer minutes per day of vigorous physical activity than those without diabetes as measured by accelerometry.

Summary of Findings for Research Question Two

As indicated by the scatter plots, the majority of data points fall within the limits of the degree of agreement. Five women estimated their MVPA to exactly match the accelerometer data. Five women estimated their MVPA over the limits of agreement. However, the pattern of the scatter plot indicates that women with lower MVPA tended to under-report and those with higher MVPA tended to over-report their physical activity.

Summary of Findings for Research Question Three

Minutes per day of MVPA as measured by the IPAQ short form were negatively associated with educational level in middle-aged women with and without diabetes. As educational level increased, minutes per day of MVPA decreased. Minutes per day of MVPA as

measured by accelerometry were negatively associated with depressive symptom severity in middle-aged women with and without diabetes. As depressive symptom severity increased, minutes per day of MVPA decreased. Minutes per day of MVPA as measured by accelerometry were positively associated with attitudes toward physical activity and benefits of physical activity in middle-aged women with and without diabetes. As attitudes toward physical activity became more positive, minutes per day of MVPA increased. As perceived benefits of physical activity increased, minutes per day of MVPA increased. Minutes per day of MVPA were not significantly associated with age, race and ethnicity, marital status, annual household income, employment status, diabetes, diabetes duration, BMI, comorbidity index, smoking status, physical activity self-efficacy or social support for physical activity as measured by either the IPAQ short form or accelerometry in middle-aged women with and without diabetes. Further discussion and implications of these findings are presented in Chapter Six.

Chapter Six

Discussion and Implications

Discussion and implications of the results described in Chapter Five are presented in this final chapter. Discussion is focused on the interpretation of the findings from each of the three research questions and validation from the current literature. Limitations of the study are also presented. Finally, and of major importance, a discussion of the implications for nursing practice, research, and policy is presented.

Discussion of Research Question One

Differences noted between middle-aged women with diabetes compared with those without diabetes included a greater percentage of non-White race and ethnicity, higher BMI and comorbidity index, lower perception of physical activity self-efficacy and benefits of physical activity, and fewer minutes per day of moderate and vigorous physical activity as measured by different tools. Each of these findings is discussed by demographic, clinical, and social–cognitive factors and outcome variables.

Demographic factors. Differences noted included fewer White and more non-White middle-aged women with diabetes compared with those without diabetes. This finding is in agreement with CDC (2009b) national statistics indicating that age-adjusted incidence (standard error) of diabetes per 1,000 is 8.5 (0.6) in White, 11.7 (2.2) in African American, and 13.1 (1.5) in Hispanic adults. No significant differences were found in the demographic variables of age, marital status, educational level, annual household income, or employment status between women with diabetes and those without the disease. Differences by age have been noted in a national study of diabetes, with increased disease prevalence with age (Cowie et al., 2006). However, the national sample had a much larger age range than this study.

While no significant difference in marital status was noted between women with and without diabetes, the investigator was unable to compare across all marital categories due to the small sample size in some categories. An aged-based study noted differences in marital status; women with diabetes were more likely to be widowed (15.6%), or divorced or separated (19.3%) than women without diabetes (72.2% married and 9.4% divorced or separated; Beckles & Thompson-Reid, 2001).

No significant differences by educational level or annual household income were noted between women with diabetes versus those without diabetes. Research findings differ in regard to educational level and annual household income in middle-aged women with and without diabetes. Some studies have found a greater prevalence of diabetes by lower income, particularly for those with less than a high school education (Robbins, Vaccarino, Zhang, & Kasl, 2001; Tang, Chen, & Krewski, 2003). In contrast, another longitudinal study found a lack of association between diabetes and educational level or income (Maty, Everson-Rose, Haan, Raghunathan, & Kaplan, 2005).

On the whole, the sample was a fairly well-educated group of women, with approximately four-fifths having some formal education beyond high school. Despite their high educational levels, 45 (41.3%) women reported having an annual household income of less than \$25,000, which is close to the 2011 U.S. Poverty Guideline of \$22,350 for a family of four (U.S. DHHS, 2011). Therefore, while educational level was highly correlated with annual household income ($r = .318$ [107], $p = .001$), many of the women had lower socio-economic status. Implications of lower socio-economic status and decreased physical activity have included lack of access, time, social support, importance, and physician advice and increased medical conditions and family responsibilities (Dutton, Johnson, Whitehead, Bodenlos, & Brantley,

2005).

Middle-aged women without diabetes had higher rates of employment (59.9%) than those with diabetes (39.5%) in one study (Beckles & Thompson-Reid, 2001). While the present study did not find significant differences in employment between women with and without diabetes, 32.3% of the women with diabetes were employed compared with 67.7% of women without diabetes. Small sample size may have accounted for this discrepancy in findings.

Clinical factors. Differences in clinical factors between middle-aged women with and without diabetes included BMI and comorbidities. Because there are significant differences between women with T1D and women with T2D, exclusion criteria should be established to prevent one group from influencing the findings. In retrospect, the investigator would include only one type of diabetes to study comparisons of middle-aged women with and without diabetes.

The finding of this study that women with diabetes had higher average BMI was in agreement with national studies (Bays, Chapman, & Grandy, 2007; Shai et al., 2006). Shai et al. found that a five-unit increase in BMI increased the risk of diabetes by 37%% for White women, 84% for Asian women, 44% for Hispanic women, and 38% for Black women. Study findings are in agreement with obesity prevalence as a better predictor of diabetes than socio-economic status as demonstrated by Maty et al. (2005).

Studies have indicated that women with diabetes have a greater number of comorbidities than those without diabetes (Volpato et al., 2002), which is similar to this study's finding. While risk for depression has been demonstrated to be higher in women with diabetes than for those without the disease (Golden et al., 2008), no significant difference was noted in the present study. However, this study did not assess for treatment for depression or provider awareness of

higher prevalence of depression in women with diabetes, which would increase the likelihood of women experiencing less depressive symptom severity. Therefore, depressive symptom severity may have been modified by treatment which would influence the findings.

While smoking has been associated with a dose-related risk for the development of diabetes in a systematic review of 25 cohort studies (Willi, Bodenmann, Ghali, Faris & Cornuz, 2007), this study found no significant difference between the number of women with diabetes who smoked compared with women without diabetes who smoked. The study finding of smoking by 13.5% of women with diabetes was slightly lower than national studies indicating that 15% to 20% of women with diabetes smoke (Karter et al., 2008; Resnick et al., 2006).

Social–cognitive factors. Social–cognitive differences between women with diabetes and those without the disease included physical activity self-efficacy and benefits of physical activity. Neither of the other social–cognitive factors of attitudes toward physical activity nor social support significantly differed between women with diabetes and those without the disease. Differences in some social–cognitive factors between middle-aged women with and those without diabetes have not been established in the literature.

However, Im et al. (2008, 2010, 2011) have qualitatively and systematically studied attitudes toward physical activity of middle-aged women by various races and ethnicities. Attitudes expressed by non-White middle-aged women included a lack of time, health concerns and lack of companionship, family first, and waste of time (Im et al., 2008, 2010). While attitudes toward physical activity did not significantly differ between women with and without diabetes in the present study, the high mean value of 5.78 and ceiling effect may have caused a lack of variability. The high scores also indicate that women with and without diabetes highly value physical activity whether or not they participate in it.

Physical activity self-efficacy has been found to be lower in adults with diabetes than in those without diabetes (Grace et al., 2007; Plotnikoff et al., 2003), which was similar to this study's finding. While more self-efficacy barriers have been reported in adults with T1D than in those with T2D (Plotnikoff et al., 2009), the present study found an opposite effect. The five women with T1D had higher physical activity self-efficacy than those with T2D ($t = 2.28 [39]$, $p = .03$, 95% CI [0.15, 2.54]). Findings of lower physical activity self-efficacy in women with T2D compared with those without the disease is an important finding for future research. Because physical activity self-efficacy is significantly lower in women with T2D compared with those without diabetes, interventions to increase self-efficacy may be an effective method for increasing minutes per day of MVPA in middle-aged women, especially those with T2D.

Women with diabetes also perceived fewer benefits of physical activity than women without diabetes. This finding is similar to studies of Canadian adults with and without diabetes (Plotnikoff et al., 2009). How much health literacy influenced this finding is not known and would be beneficial to establish in future research. The benefits tool used for this study was not specific to a particular health condition such as diabetes. Use of a benefits tool for diabetes or CVD would provide information for study about how women assess the health risks and benefits of physical activity specific to these disease processes. Implications of this finding are that raising awareness of benefits may be a beneficial approach to increasing minutes per day of MVPA in middle-aged women, especially those with diabetes. Health policy to encourage instruction and follow up about physical activity at primary care clinic appointments and media presentations that demonstrate various racial and ethnic and age-related groups of women performing MVPA are potential methods to increase awareness among middle-aged women.

Response variable. Significant differences in minutes per day of MVPA between women

with diabetes compared with those without diabetes were not evident when measured by either the IPAQ short form or accelerometry. Differences in minutes per day were noted for individual measures of moderate physical activity and sedentary time by the IPAQ short form and for vigorous physical activity when measured by accelerometry. The finding of 25 fewer minutes of moderate physical activity on average by the IPAQ short form by women with diabetes compared with those without diabetes would potentially be clinically significant. A 19% reduction in risk for heart disease with a 30 min daily walk has been noted (Zheng et al., 2009). However, both the IPAQ short version and accelerometry indicated that middle-aged women with and without diabetes on average were performing sufficient minutes per day of MVPA. The cut-points for MVPA used for analysis were very lenient, which may have decreased the ability to identify a significant difference. Further study is needed to investigate whether the significant difference in vigorous physical activity between middle-aged women with diabetes and those without the disease is clinically significant.

In comparison to this study's lack of significant difference in MPVA by IPAQ short form and accelerometry, Plotnikoff et al. (2003) found similar results with a lack of significant difference in energy expended with exercise for adults with diabetes compared with those without the disease. While numerous studies have noted the association of inactivity with the development of diabetes (Kriska et al., 2006; Manson et al., 1991), few studies have compared physical activity levels between those with diabetes and those without diabetes (Plotnikoff et al., 2003). Therefore, findings of this study that middle-aged women with diabetes differ from those without diabetes in race and ethnicity, BMI, comorbidities, physical activity self-efficacy and benefits of physical activity are important for the design of interventions to increase minutes per day of MVPA.

Discussion of Research Question Two

The Bland–Altman (1986) test of agreement underscores the issues related to measurement of physical activity. Based on the average of IPAQ short form and accelerometer data, middle-aged women with and without diabetes having lower MVPA tended to under-report and those having higher MVPA tended to over-report. Both over-reporting and under-reporting (De Cocker, De Bourdeaudhuij, & Cardon, 2009) have been demonstrated in use of the IPAQ short form, although over-reporting has been more widely publicized (Ekelund et al., 2006; Johnson-Kozlow et al., 2006; Kaleth, Ang, Chakr, & Tonget, 2010; Rzewnicki, Auweele, & Bourdeaudhuij, 2003). Johnson-Kozlow et al. (2006) reported severe overestimation of reporting on the IPAQ short form. Continued research is warranted to determine if issues related to MVPA measurement by the IPAQ short form are more related to recall bias than to contextual properties such as understanding whether housework is a light or moderate physical activity or whether women can recall whether they did any housework since it is such a common daily occurrence.

Accelerometry has been found to overestimate walking activities and underestimate MVPA due to an inability to assess acceleration in certain activities, such as biking or swimming or any movement above the waist when the accelerometer is worn in that location (Bassett et al., 2000; Bonomi et al., 2009). Therefore, the under-reporting of MVPA, as noted from a number of women in this study, particularly among those with low MVPA levels, deserves further investigation. Another interesting phenomenon needing exploration was that over-reporting occurred more in women with high levels of MVPA. These findings suggest the recall bias of forgetfulness and social desirability that has been associated with physical activity measurement by other researchers (Courneya, Jones, Rhodes, & Blanchard, 2003; Prince et al., 2008). Another reason for under-reporting that needs further investigation is whether women are able to

differentiate light, moderate, and vigorous physical activity appropriately to complete the IPAQ short form. Over-reporting in women with high levels of MVPA may in part be due to participation in activities that are not sensed by accelerometry such as arm movement, yoga, swimming and biking.

Discussion of Research Question Three

The demographic, clinical and social–cognitive factors were chosen by the investigator based on findings from the literature about a potential association with physical activity.

Interestingly, very few of these factors were significantly associated with minutes per day of MVPA in this study. Findings of factors associated with minutes per day of MVPA in the total sample of middle-aged women with and without diabetes included: (a) the demographic factor of educational level when MVPA was measured by the IPAQ short form, (b) the clinical factor of depressive symptom severity when MVPA was measured by accelerometry, and (c) the social–cognitive variables of attitudes toward physical activity and benefits of physical activity when MVPA was measured by accelerometry.

Findings of this study are similar to other research using the IPAQ, which noted a negative relationship with meeting the physical activity recommendations by educational level (Ainsworth et al., 2006). Another study demonstrated greater physical activity in those with at least a high school education but less than a college degree, compared with those with less than a high school education and those with a college degree (Bergman et al., 2008). Opposing results indicating that those with a high school education or less were more inactive than those with more than a high school education have also been reported (Ainsworth et al., 2006). Findings may be related to the non-linear association between educational level and MVPA as indicated by the box plot in Figure 7. One potential cause for declining physical activity among more

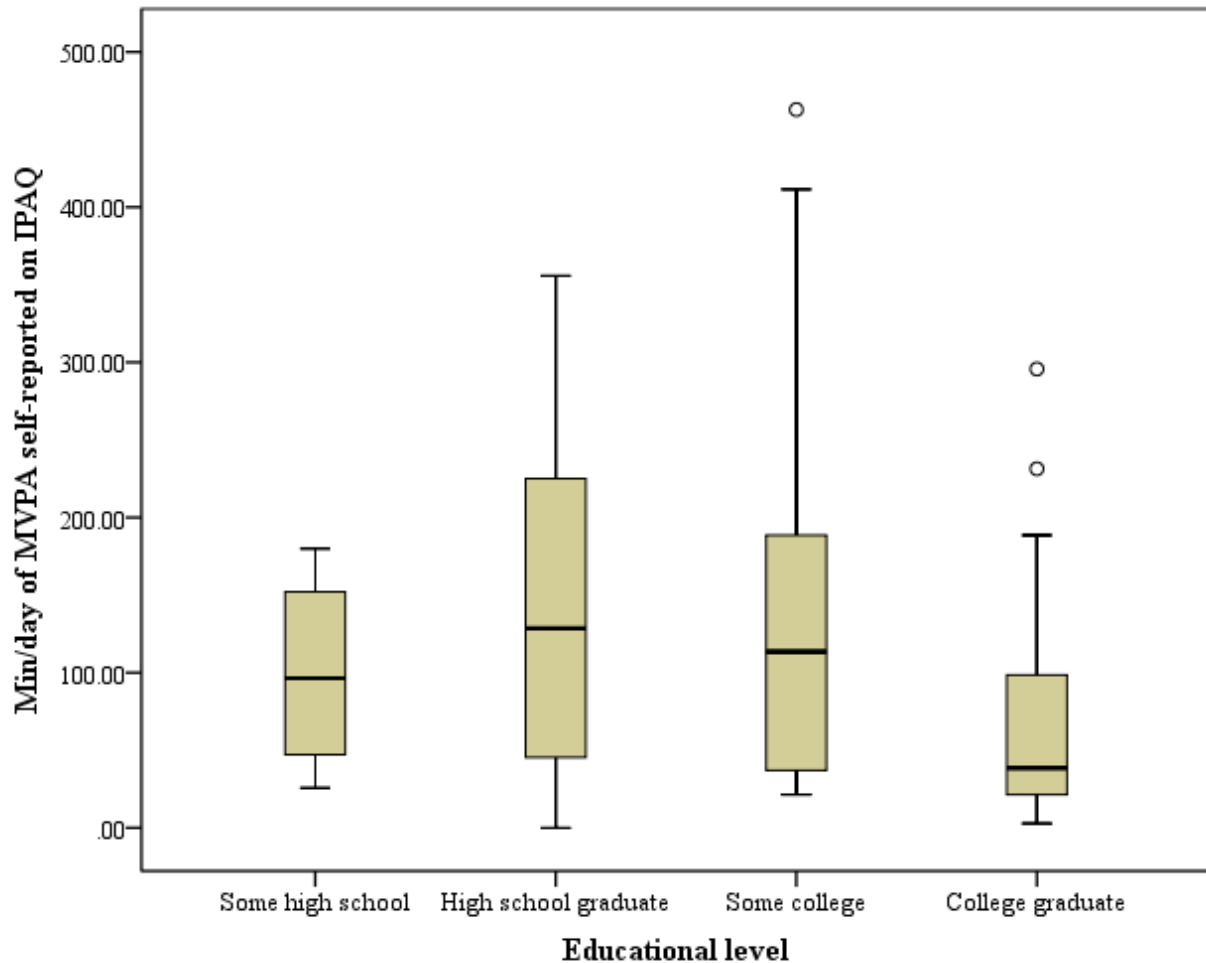


Figure 7. Box plots of minutes per day of MVPA reported by IPAQ short form by educational level in four categories demonstrating the nonlinear association between education level and MVPA. Circles indicate minor outliers.

educated women is their greater sedentary work environment (Church et al., 2011).

The extant literature indicates a negative association between BMI and physical activity, as well as a negative effect of BMI on physical activity, with sedentary behavior as a risk factor for obesity (Bankowski et al., 2011; Frank et al., 2009). Lower BMI is associated with a higher level of physical activity among adults with diabetes (Plotnikoff et al., 2006). Similar to this study, findings from another study of adults with T2D noted a negative association between comorbidities and physical activity in adults with T2D (Plotnikoff et al., 2007). Despite the high

BMI and comorbidity index of the middle-aged women in this study, all were capable of some moderate physical activity. Further study is needed to encourage middle-aged women to increase their MVPA to reduce their overweight and obesity especially in those with diabetes.

Study Limitations

The study has both limitations and strengths. The study was observational and therefore no causal inferences could be made. Limitations of this study include decreased generalizability due to the small sample size and homogeneity of the sample by sex and setting. Selection bias of subjects may have also restricted generalizability as a result of the investigator's decision to conduct the study in only four urban clinics. Because women who chose to participate in the study may differ from those who did not, self-selection bias could occur. Factors that were not evaluated that could be useful in intervention study include measurement of heart rate, blood pressure, lipid levels, and blood glucose level. Both self-report of physical activity and accelerometry have limited measurement accuracy (Courneya et al., 2003; Prince et al., 2008). Reliability of self-reported physical activity is a problem due to bias and forgetfulness. By allowing a few women to complete the self-administered paper-and-pencil survey at home rather than immediately at the clinic, the investigator may also have inadvertently affected the findings by giving them more time to complete the survey. Data gathering also varied by site, either clinic or home visit. Strengths of this study include: (a) the use of an objective measure of physical activity to compare two groups, (b) the ability to measure physical activity during daily living in middle-aged women, and (c) the successful recruitment of middle-aged women from primary care clinics, who had low levels of vigorous physical activity and were primarily overweight or obese and in need of intervention.

Implications for Nursing Practice and Education

The implications of the present findings for nursing practice and education are significant. Nursing practice implications from this study are that women may need information about the intensity and duration of physical activity recommended to achieve health-related benefits. Feedback data from accelerometers can provide duration and intensity information for women about their MVPA. All of the women included in this study were capable of doing at least moderate physical activity. One activity that was done for short periods of time by the women and noted on the accelerometer to be vigorous was stair-climbing during household work. To magnify the positive effect of stair-climbing among employed women, a worksite intervention to promote positive health behavior could be the posting of signs to encourage stair-climbing versus using the elevator. Because women can easily integrate this type of physical activity into their daily lives, those who are capable of engaging in stair-climbing should be encouraged to do so.

Theoretical approaches used to study physical activity in middle-aged women with and without diabetes need to focus on ways to increase their physical activity. A behavioral approach that involves both instruction and feedback may be beneficial. Both SCT and the TPB suggest that physical activity self-efficacy and perceived benefits of physical activity need to be targeted in interventions to increase physical activity in middle-aged women with and without diabetes. Primary care nursing interventions to increase physical activity need to provide specific instruction and feedback on duration and intensity of physical activity and assist women in setting realistic goals to increase physical activity.

Implications for nursing education include effective disease prevention efforts which are the key to ensuring a healthy community. Nurses can serve as role-models of behaviors that

prevent disease and disseminate information about various diseases and ways to prevent them. Dissemination of information is essential if people are to grasp the importance of changing behavior.

Implications for Nursing Research

The National Institute of Nursing Research (2011) will support research that achieves the following objectives: (a) to develop “innovative behavioral interventions to promote health and prevent illness in diverse populations and across the lifespan,” (b) to improve “the understanding of behavioral patterns and the incentive for behavioral change,” (c) to develop and test “models of lifelong preventive care,” and (d) to incorporate “interdisciplinary, community, and other health care partnerships in the design or conduct of health promotion research”. Financial incentives for increased physical activity have been used with some success in decreasing health care costs by insurers and organizations (Lu et al., 2008; Nguyen et al., 2007). One type of non-financial incentive used successfully in physical activity research is positive feedback through self-monitoring (Ingram, Wilbur, McDevitt, & Buchholz, 2011). Because several women commented that having the opportunity to review the feedback from the accelerometer graphing provided the incentive to continue their MVPA, further investigation of the association between incentives and perceived benefits may be productive.

Further nursing research is needed among women with and without diabetes to determine: (a) if any specific beneficial health-related effects, such as an enhanced quality of life, result from increasing light-intensity physical activity; (b) how intensity of physical activity affects perceptions of benefits of physical activity; (c) what interventions promote maintenance of adequate physical activity; and (d) whether certain intensities of physical activity are easier to maintain by this particular population.

Implications for Nursing Policy

Major stake-holders in increasing physical activity in middle-aged women vary from broad (involving community and public health systems) to the personal level (involving the women and their families). At the institutional level, stake-holders include large health care organizations, employers, and insurance providers. At the largest system level, the World Health Organization (WHO, 2011) recognizes that a lack of physical activity is a contributor to diabetes and CVD. By adopting the May 2004 Global Strategy on Diet, Physical Activity and Health, which is published in four languages besides English, the WHO underscored lack of physical activity as a major public health priority and made recommendations to promote regular physical activity in adults aged 18 through 64 years.

The CDC and the President's Council on Fitness, Sports, and Nutrition partnered to develop the Healthy People 2020 (U.S. DHHS, 2011) physical activity guidelines. Part of this effort included findings from the NHANES accelerometer data. Targets for physical activity criteria were set using a 10% relative beneficial change. One new objective for Healthy People 2020 (PA-11) is to monitor provider counseling of patients to promote physical activity (exercise) as a means to prevent or treat disease. A higher need for provider counseling of middle-aged women to increase physical activity, as compared with other groups, is necessary due to their increased risk for diabetes and related CVD problems, such as stroke and heart disease (Towfighi et al., 2007, 2009). Research indicates that women do not perceive their high risk for CVD (Liewer, Mains, Lyken, & Rene, 2007). Therefore, middle-aged women, especially those with diabetes might also not realize the potential benefits of physical activity. Findings of the low benefits of physical activity by women with diabetes in this study demonstrate the current disconnect between perceived health benefits and physical activity. The increased cost of

health care for diabetes and job-related days of work loss due to diabetes are other reasons to seriously consider recommendations for increasing physical activity in middle-aged women with and without diabetes.

During middle-age, many women are at the prime of their careers, yet they may also feel overburdened by the responsibilities of family. As the main family caregiver in many instances, women often prioritize their family's needs over their own. While this culture of care-giving is important to the structure of the family, women also need to be made aware of the benefits that result from taking care of themselves. These benefits include the prevention of diabetes and cardiovascular disease and increased longevity and quality of life. Because what these women do is noticed by their children and grandchildren, benefits also include the role-modeling of healthy behavior for future generations. Therefore, to increase the quality of women's lives while increasing their productivity and decreasing the personal social burden of health care costs, regular engagement in healthy behaviors, such as physical activity, is advised.

Methods to increase physical activity in middle-aged women that need to be evaluated in primary care practices include increasing women's awareness of the health benefits of physical activity and enhancing physical activity self-efficacy by assessing and affirming what women are currently doing that is physically active in their daily lives and gently encouraging greater duration and intensity of these activities. In order for health care professionals to be successful in helping women to achieve recommendations for physical activity, they must first assist women to understand the important attributes of duration and intensity. Feedback on current physical activity, such as allowing women to view graphs depicting their accelerometer data, may enhance women's understanding of exactly what moderate to vigorous physical activity is and motivate them to explore ways to fit this type of activity into their daily lives.

Summary

Findings from this study that women with diabetes have higher BMI and comorbidities than those without diabetes indicate a need for preventive, evidenced-based nursing interventions. Empirically tested approaches found to be effective can affect decisions related to policy development. Social–cognitive factors that differ between women with and without diabetes can provide a starting point or framework for the design of interventions. The importance of MVPA was not fully comprehended by many of the women with diabetes in this study, despite their positive attitudes toward physical activity. While women with diabetes are advised to be physically active as part of their disease management and to reduce weight, the majority of the middle-aged women in this study were either overweight or obese. All of these women were capable of doing the recommended minutes per day of at least moderate physical activity but are still in urgent need of interventions to decrease overweight and obesity which may be related to increased intensity and frequency of MVPA throughout the day.

APPENDICES

APPENDIX A

Self-administered Paper-and-Pencil Survey

LETTERHEAD OF AGENCY

Subject ID _____

Date _____

I am interested in factors that might affect physical activity in middle-aged women. The questionnaire has 7 parts and will take about 20 minutes to complete. This group of questions will provide me with important information about middle-aged women. Please read each question carefully and give your answer.

1. What is your age? _____ Years
2. Other than during pregnancy, have you ever been told by a doctor, nurse, or other health professional that you have diabetes? YES NO

If you answered No to question # 2, skip to question # 8 on next page.

3. How many years have you had diabetes? _____ Years

Please circle one answer for the following questions.

4. What type of diabetes do you have?

Type 1 diabetes Type 2 diabetes Don't know

5. Are you currently taking pills for diabetes? YES NO
6. Are you currently taking insulin for diabetes? YES NO
7. Have you always treated your diabetes with insulin? YES NO

Continued from question # 2.

8. Do you currently smoke tobacco? YES NO

9. What is your current marital status? Please fill in one circle.

- ☐ Married/Partnered
- ☐ Widowed
- ☐ Divorced/Separated
- ☐ Never Married/Unpartnered

10. What is the highest grade of school you completed? Please fill in one circle.

- ☐ Grades 9 through 11 (Some high school)
- ☐ Grade 12 or GED (High school graduate)
- ☐ College 1 year to 3 years (Some college or technical school)
- ☐ College 4 years or more (College graduate)

11. Currently are you: Please fill in one circle.

- ☐ Employed Full-time
- ☐ Employed Part-time
- ☐ Retired
- ☐ Unemployed
- ☐ Unable to work

12. What is your current yearly household income from all sources?

Please fill in one circle.

- ☐ Less than \$15,000
- ☐ Between \$15,000 to less than \$25,000
- ☐ Between \$25,000 to less than \$35,000
- ☐ Between \$35,000 to less than \$45,000
- ☐ Between \$45,000 to less than \$55,000
- ☐ Between \$55,000 to less than \$65,000
- ☐ Between \$65,000 to less than \$75,000
- ☐ Equal to or greater than \$75,000

13. What would you say is your race/ethnicity? You may fill in more than one circle.

- ☐ African American or Black
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Hispanic/Latino
- ☐ Non-Hispanic/Latino
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Multi-Racial (having parents of different races)
- ☐ White
- ☐ Don't Know

Health Conditions

Please circle the answer to the question:

Has a doctor ever told you that you have this condition or need to take medication for:

- | | | |
|--|-----|----|
| 1. Heart attack, myocardial infarction, angina | YES | NO |
| 2. Heart failure (short of breath or fluid in lungs or heart not pumping well) | YES | NO |
| 3. Peripheral vascular disease or had an operation to unclog or
bypass the arteries in your legs | YES | NO |
| 4. Cerebrovascular accident (CVA) or stroke or blood clot or bleeding
in the brain, or transient ischemic attack (TIA) | YES | NO |
| 5. Hemiplegia (difficulty moving an arm or leg) because of a stroke (CVA) | YES | NO |
| 6. Chronic obstructive pulmonary disease (COPD) or asthma or
emphysema or chronic bronchitis, or chronic obstructive lung disease | YES | NO |
| 7. Ulcer disease such as stomach ulcers, or peptic ulcers | YES | NO |
| 8. Renal problems (kidneys), or poor kidney function (blood tests show high creatinine) | YES | NO |
| 9. Used dialysis or received a kidney transplantation | YES | NO |
| 10. Connective tissue disease or rheumatoid arthritis or Lupus | YES | NO |
| 11. Dementia or liver disease or leukemia or lymphoma, tumor, metastases,
AIDS, Alzheimer's Disease, Cirrhosis, or serious liver damage, Leukemia
or polycythemia vera or a cancer (other than skin cancer). | YES | NO |

If you answered YES to Question # 11, please Circle the health condition(s) that you have been told that you have.

Please circle the answer to the question:

Has a doctor ever told you that you have this condition or need to take medication for:

12. Diabetes or high blood sugar YES NO

If you answered YES to the last question please continue to the next question.

If you answered NO, skip the next question.

13. If you have diabetes, has the diabetes caused any of the following problems?

Problems with your kidneys (protein in urine, high creatinine) YES NO

Problems with your eyes needing treatment by an ophthalmologist YES NO
(retinopathy, retinal detachment, glaucoma, macular degeneration)

(based on the Katz version (Katz, Chang, Sangha, Fossel, & Bates, 1996) of the Charlson Comorbidity Index (CCI; Charlson et al., 1987)

PHYSICAL ACTIVITY QUESTIONNAIRE

All of the questions in this next section ask about physical activity during your daily life. **Daily life** for this study includes being at home, at work, at school or any place you spend time while you are awake. **Physical activity** for this study is any movement of your body. Exercise is one example of physical activity. Other examples of physical activity are walking, biking, vacuuming, gardening or dancing.

The **recommendation** for middle-aged women is for 30 minutes of moderate physical activity on 5 days of the week or 25 minutes of vigorous activity on 3 days of the week or a combination of both moderate and vigorous.

- ❖ **Moderate** activities take some physical effort and may make you breathe somewhat harder than normal, your heartbeat somewhat harder and faster or your skin to sweat a little.
- ❖ **Vigorous** activities take hard physical effort and make you breathe much harder than normal, your heartbeat harder and faster and your skin to sweat.

Please answer each question on the following pages even if you do not consider yourself a physically active person.

THANK YOU FOR PARTICIPATING.

Attitudes toward Physical Activity

Please circle 1 number for the 6 scales describing opposite attitudes toward physical activity by answering the following sentence:

For me, doing the recommended minutes of moderate to vigorous physical activity would be . . .

Extremely Quite Slightly Neutral Slightly Quite Extremely

Harmful.....Beneficial

1 2 3 4 5 6 7

Useless.....Useful

1 2 3 4 5 6 7

Unimportant.....Important

1 2 3 4 5 6 7

Unenjoyable.....Enjoyable

1 2 3 4 5 6 7

Boring.....Fun

1 2 3 4 5 6 7

Painful.....Pleasurable

1 2 3 4 5 6 7

(Based on Armitage 2005; Courneya, Conner et al. 2006)

Physical Activity Self-Efficacy Measure

These are ten situations that might affect your confidence to do physical activity or exercise. For each situation, use the scale where 1 is *I am Not Confident* and 7 is *I am Very Confident*, to tell me how confident are you right now that you could do the recommended minutes of moderate to vigorous physical activity (e.g., exercise classes, swimming, or walking as an exercise).

Circle one number for each statement.

	I am Not Confident				I am Very Confident		
1. The weather was bothering you	1	2	3	4	5	6	7
2. You were bored by the activity	1	2	3	4	5	6	7
3. You felt pain when participating	1	2	3	4	5	6	7
4. You had to participate alone	1	2	3	4	5	6	7
5. You did not enjoy it	1	2	3	4	5	6	7
6. You were too busy with other activities	1	2	3	4	5	6	7
7. You felt tired	1	2	3	4	5	6	7
8. You felt stressed	1	2	3	4	5	6	7
9. You felt depressed	1	2	3	4	5	6	7
10. You were incontinent (bowel or bladder)	1	2	3	4	5	6	7

(based on Self-efficacy for Exercise Scale, Resnick, Palmer, Jenkins, & Spellbring, 2000)

Benefits of Physical Activity

These are nine different statements about the benefits of doing moderate to vigorous physical activity. Using the scale from 1 to 7, where 1 means you *Strongly Disagree*, and 7 means you *Strongly Agree*, please circle how much you agree or disagree with each statement.

	Strongly Disagree					Strongly Agree
1. Physical activity makes me feel better.	1	2	3	4	5	6 7
2. Physical activity makes my mood better in general.	1	2	3	4	5	6 7
3. Physical activity helps me feel less tired.	1	2	3	4	5	6 7
4. Physical activity makes my muscles stronger.	1	2	3	4	5	6 7
5. Physical activity is an activity I enjoy doing.	1	2	3	4	5	6 7
6. Physical activity gives me a sense of personal accomplishment.	1	2	3	4	5	6 7
7. Physical activity makes me more alert mentally.	1	2	3	4	5	6 7
8. Physical activity improves my endurance in performing my daily activities.	1	2	3	4	5	6 7
9. Physical activity helps to strengthen my bones.	1	2	3	4	5	6 7

(Based on the Outcomes Expectations for Exercise Scale by Resnick, Zimmerman, Orwig, Furstenberg, Magaziner, 2000)

SOCIAL SUPPORT for PHYSICAL ACTIVITY

Below is a list of things people might do or say to someone who is trying to be physically active. If you are not trying to be physically active or exercise, then some of the questions may not apply to you (NA), but please read and give an answer to every question.

Please write one number from the following rating scale in each space:

**never rarely a few times sometimes often very often not apply
(NA)**

During the past three months, someone important to me:

- 1) Did physical activity or exercised with me. _____
- 2) Offered to do physical activity or exercise with me. _____
- 3) Gave me helpful reminders to do physical activity or exercise
(ex. "Are you going to walk tonight?") _____
- 4) Gave me encouragement to stick with my physical activity or exercise. _____
- 5) Changed their schedule so we could be physically active or
exercise together. _____
- 6) Discussed physical activity or exercise with me. _____
- 7) Complained about the time I spend being physically active or exercising. _____
- 8) Criticized me or made fun of me for being physically active or exercising. _____
- 9) Gave me rewards for physical activity or exercising
(bought me something or gave me something I like). _____
- 10) Planned for physical activity or exercise on recreational outings. _____
- 11) Helped plan activities around my physical activities or exercise. _____
- 12) Asked me for ideas on how they can get more physical activity or exercise. _____
- 13) Talked about how much they like to do physical activity or exercise. _____

(Based on Social Support for Exercise Scale, Sallis, 1987)

APPENDIX B

Accelerometer Instruction Sheet: Activity Monitor Instructions

ACTIVITY MONITOR INSTRUCTIONS

Wear the activity monitor

ALL DAY – EVERY DAY

From when you wake up until you go to bed

Take the activity monitor off **only** for:

SWIMMING SHOWERING BATHING SLEEPING

Wear the activity monitor always around **your waist** at the **middle of your right side**

with the colored dot facing **up**.

The ID sticker should face your body.

DO NOT try to take the activity monitor apart!

DO NOT worry about whether the light is blinking or not!

I will call you during the week to see how you are doing.

Your next clinic visit with Melodee is on _____

***Wear your activity monitor to the clinic visit.

Bring the surveys you completed at home!***

If you have any questions, concerns or problems

with the activity monitor, please contact me at

616-308-2353 or vande484@msu.edu.

APPENDIX C

Chart Audit Form

Protected Health Information

Subject ID Number_____

ActiGraph ID Number_____

\$10 Store Gift Card Number_____ **Date**_____

All Listed Medical Diagnoses on Charlson Comorbidity Index (page 2)

Type of Diabetes:_____

Duration of diabetes_____

Medication Use: Oral antidiabetic medication_____

Insulin_____

APPENDIX D

Depressive Symptom Severity Policy

Depressive Symptom Severity Policy

MICHIGAN STATE UNIVERSITY

College of Nursing

SCOPE: The Principal Investigator, Doctoral Candidate

EFFECTIVE DATE: last revised 09/16/10

POLICY: If any study woman's composite PHQ-9 score is 10 or greater, the investigator will confidentially telephone the woman within two weeks of receiving her data. The investigator will inquire as to her current participation in some form of psychiatric, psychological, or counseling assistance. The purpose of the telephone call is to encourage the woman to seek professional evaluation for potential for depression.

PROTOCOL:

1. Each woman in the study will be given a self-administered paper-and-pencil survey including questions from the Patient Health Questionnaire-9 (PHQ-9), which asks a series of nine questions indicating the severity of depressive symptoms. Questions are rated from zero to three. Cut-point scores for severity of depression are five for low, 10 for moderate, 15 for moderately severe, and 20 for severe.
2. For all patients who score ≥ 10 on the PHQ-9, the investigator will initiate the following steps.
3. The investigator will telephone the woman in a strictly confidential manner using one of the telephone numbers that the patient provided earlier.
4. Using the (attached) script, the investigator will advise the woman that her

survey questionnaire responses suggest that she is at risk for depression. The investigator will encourage her to have this potential risk evaluated by a health care professional if she is not currently receiving care from such a professional.

5. Following such a telephone conversation, the investigator will document the date, time and topic of discussion in the data record. The investigator will send a letter of mental health agencies in the Grand Rapids area to each woman called.
6. All written records regarding the investigator's conversations with women will be stored in a locked file cabinet when not being used.

MSU University Committee on Research Involving Human Subjects (UCRIHS) will be provided a periodic report of the number of women who have been identified to be at high possible risk of depression if requested.

Submitted and recorded 06/10/10

Melodee Vanden Bosch, PhD(c), RN

Depression Telephone Call Script

(Italicized words are directions for Follow-up Telephone Call)

“Hello, my name is (name of investigator). May I please speak to (name of consented person)?”

If no then: “Okay, is there a better time that I can reach (name of consented person)?”

Record time.

“Thank you, goodbye.”

If yes then: “Hi, Ms. (name of consented person). This is (name of investigator) calling from the Physical Activity and Middle-aged Women Study at Michigan State University. As a result of a

survey questionnaire that you completed with the project, I wanted to check with you about some of your responses. Do you have five minutes now to discuss your survey questionnaire answers?”

If no then: “When would be a good time for me to call back?”

Record time.

“Thank you, goodbye.”

If yes then: “According to some questions you answered on the survey, your answers suggested that you should speak with your primary care provider (physician, nurse) about being at risk for possible depression if you haven’t already done so. “Have you discussed this possible depression with your doctor?”

If yes, then: “I’m really pleased you did this. It may be important for your recovery.

If “no” (hasn’t called the physician, but is willing), then:

“That’s good. When do you plan to call?”

Complete denial: Ok, Ms. (name of consented person). “I felt it was important that I contact you because I was concerned about your health and any possible impact of depression. Thank you for your time and willingness to speak with me.” *If the woman indicates an immediate pressing need for assistance, then refer her to a local Community Mental Health crisis line.*

APPENDIX E

Letter Associated with Depressive Symptom Severity Policy

LETTERHEAD OF AGENCY

PHYSICAL ACTIVITY in MIDDLE-AGED WOMEN STUDY

Melodee Vanden Bosch, PhD(c), RN

Investigator

Michigan State University

500 West Fee Hall

East Lansing, MI 48824

Dear Ms. (name of consented person),

Thank you for joining the Physical Activity in Middle-aged Women Study, and agreeing to complete a survey questionnaire and wear the accelerometer.

The purpose of this letter is to remind you of the telephone conversation that I had with you concerning your risk of possible depression.

Although I have no access to psychiatrists, psychologists, or counselors for study participants, and will never refer your name to anyone concerning this matter, I strongly encouraged you to speak with your regular provider (doctor, nurse or another of the above listed healthcare professionals) who could speak with you about your risk for possible depression. A list of mental healthcare professionals in the Grand Rapids area and their contact information is listed below:

- Network 180 790 Fuller Avenue NE, Grand Rapids, MI 49503 (616)336-3909 or 1-800-749-7720
- Claystone Clinical Associates 3330 Claystone St SE, Grand Rapids, MI 49546 (616) 949-7460

LETTERHEAD OF AGENCY

- North Kent Guidance Services 5250 Northland Dr NE, Grand Rapids, MI 49525 (616) 361-5001
- Pine Rest Christian Mental Health Services
 - 310 Lafayette Ave SE, Grand Rapids, MI 49503 (616) 913-1400
 - 751 Lafayette Ave NE, Grand Rapids, MI 49503 (616) 742-9942
 - 550 3 Mile Rd NW, Grand Rapids, MI 49544 (616) 222-3724
 - 1700 E Beltline Ave NE, Grand Rapids, MI 49525 » Map (616) 364-6400
- Family Outreach Center 1939 Division Ave S, Grand Rapids, MI 49507 (616) 247-3815
- Psych Resources Pc 115 Luray Ave NW, Grand Rapids, MI 49504 (616) 453-8344
- Grand Rapids Counseling Services 2400 Eastern Ave. SE, Grand Rapids, MI 49507 (616) 617-1559

Thank you again for your participation in the Physical Activity in Middle-aged Women study! Individuals like you who give of their time and effort help to further our understanding of factors influencing physical activity in middle-aged women. If you have any questions, please feel free to call or email me.

Sincerely,

Melodee Vanden Bosch, PhD(c), RN

Investigator

(616) 308-2353

vande484@msu.edu

APPENDIX F

Table 20: Daily Physical Activity Log

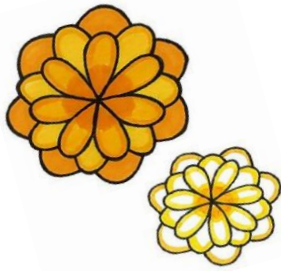


Table 20

Daily Physical Activity Log

For each day of the week, please record the activities that you did for 10 minutes or more: See next page for examples.

Day of Week	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Minutes/ Activity/ Intensity							
Minutes/ Activity/ Intensity							
Minutes/ Activity/ Intensity							
Minutes/ Activity/ Intensity							
Minutes/ Activity/ Intensity							

Note. Used with permission from Gleeson-Kreig, 2010.

Minutes/Activity/Intensity**Examples:** 15 JOG 16

20 LG 13

120 GOLF 10

Activity Codes

WALK = walking, treadmill

SW = swimming

CC = child care

JOG – jogging

HH = household

STEPS = climbing stairs

ROW = rowing machine

LG = lawn, garden

SPORT = (specify which activity)

YOG = yoga,

Pilates OTHER = (specify which activity) STR = stretching exercises

LIFT = lift moderate weight

Intensity Codes: Use Borg's Scale on next page

- While doing physical activity, we want you to rate your perception of exertion. This feeling should reflect how heavy and strenuous the physical activity feels to you, combining all sensations and feelings of physical stress, effort, and fatigue. Do not concern yourself with any one factor such as leg pain or shortness of breath, but try to focus on your total feeling of exertion.
- Look at the rating scale below while you are engaging in a physical activity; it ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Choose the number from below that best describes your level of exertion. This will give you a good idea of the intensity level of your physical activity.
- Try to appraise your feeling of exertion as honestly as possible, without thinking about what the actual physical load is. Your own feeling of effort and exertion is important, not how it compares to other people's. Look at the scales & the expressions & give a number.

Borg's Scale

- 6 No exertion at all
- 7
- Extremely light (7.5)
- 8
- 9 Very light (For a healthy person, it is like walking slowly at his or her own pace for some minutes)
- 10
- 11 Light
- 12
- 13 Somewhat hard, but it still feels OK to continue.
- 14
- 15 Hard (heavy)
- 16
- 17 Very hard (A healthy person can still go on, but he or she really has to push him- or herself. It feels very heavy, and the person is very tired)
- 18
- 19 Extremely hard (For most people this is the most strenuous exercise they have ever experienced)
- 20 Maximal exertion

Borg RPE scale © Gunnar Borg, 1970, 1985, 1994, 1998

APPENDIX G

International Physical Activity Questionnaire, Short Form

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. This is part of a large study being conducted in many countries around the world. Your answers will help us to understand how active we are compared with people in other countries. The questions are about the time you spent being physically active in the last 7 days. They include questions about activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Your answers are important.

Please answer each question even if you do not consider yourself to be an active person.

THANK YOU FOR PARTICIPATING.

In answering the following questions,

*****vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal.

*****moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

1a. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

Think about *only* those physical activities that you did for at least 10 minutes at a time.

_____ **days per week** ☐ ☐ 1b. How much time in total did you usually spend on one of those days doing vigorous physical activities?

none

or

_____ **hours** _____ **minutes**

2a. Again, think *only* about those physical activities that you did for at least 10 minutes at a time.

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

_____ **days per week** ☐ 2b. How much time in total did you usually spend on one of those days doing moderate physical activities?

none

or

_____ **hours** _____ **minutes**

3a. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

_____ **days per week** ☐ 3b. How much time in total did you usually spend walking on one of those days?

none •

or

_____ **hours** _____ **minutes**

The last question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading traveling on a bus or sitting or lying down to watch television.

4. During the last 7 days, how much time in total did you usually spend *sitting* on a week day? _____ **hours** _____ **minutes**

APPENDIX H

Informed Consent and The Health Insurance Portability and Accountability Act (HIPAA)

Authorization Form

LETTERHEAD OF AGENCY

Research Informed Consent Form

Study Title: Physical Activity in Middle-aged Women
with and without Diabetes

Sub-Investigator: Melodee Vanden Bosch, RN, PhD(c)

Principle Investigator: Lorraine Robbins, PhD, RN, FNP-BC

Study Sponsor: College of Nursing, Michigan State University
500 West Fee Hall, East Lansing, MI, 48824
phone (517)432-9159

1. Introduction

You are being asked to participate in a nursing research study. Nursing research is the study of the clinical care of individuals to seek to understand their responses to the effects of acute and chronic illness, to promote healthy behaviors, to prevent or delay disease or disability and to improve the environment of care. In order to decide whether or not you should agree to be part of this research study, you should receive enough information about its risks and benefits to make a judgment. This process is called informed consent.

This consent form gives detailed information about the research study, which will be discussed with you. If you wish to participate in this study you will be asked to sign this form.

2. Purpose of This Research Study

- You are being asked to take part in a research study of middle-aged women and physical activity. The study partners are Saint Mary's Health Care through Advantage Health Physician Network and Michigan State University.
- You have been selected as a possible participant in this study because you are a woman

between the ages of 45 and 64.

- From this study, the researchers hope to learn about factors that influence physical activity in middle-aged women and if these factors are different for middle-aged women with diabetes compared to those without diabetes. Physical activity has been shown to decrease the risk for diabetes and diseases of the blood vessels in the heart and brain. Diabetes and diseases of the blood vessels in the heart and brain increase significantly in middle-aged women who are not physically active. The researchers also want to learn about how to measure physical activity in middle-aged women.

3. Length of Your Participation

- Your participation in the study will occur over a 1 week time period including two visits with the researcher.

4. Where the Study is Being Done and Number of People Participating

- The study is being conducted at the Saint Mary's Health Care clinics of Browning-Claytor, Downtown, Wege Internal Medicine and Wege Family Medicine.
- In the entire study, 100 women are being asked to participate, 50 women with diabetes and 50 women without diabetes.

5. Study Procedures

- At the first clinic visit with the researcher, you will be asked to fill out a 30 minute survey at a clinic visit and have your height and weight measured. This will be conducted in a private exam room.
- You will:
 - Be asked to wear an activity monitor for the next 7 days for 13 hours each day during your daily activities except when showering or swimming.

- receive instructions about how to use the activity monitor and be shown an example of what the activity monitor data looks like on the computer.
- During the week of wearing the activity monitor, you will be asked
 - to continue with your usual level of physical activity.
 - to keep a daily log of your physical activities during the week that you wear the activity monitor.
 - if the researcher can call you twice. The purpose of the calls is to remind you to wear the activity monitor, to ask if you have questions about the survey, activity monitor or daily log, and to schedule a return clinic visit.
- During the return clinic visit, you will be asked
 - to return the surveys, activity monitor, and daily log.
 - to complete a 10-minute physical activity survey.
- While you are completing the final survey, the researcher will review the activity monitor data. If no data has been recorded, you will be asked to re-wear the activity monitor for another 7 days.
- All of the activities listed above are part of the study and will in no way affect the care you receive from your primary provider (doctor, nurse).
- You are being asked to participate because you meet the study inclusion criteria of:
 - Being a woman between 45 and 64 years of age.
 - Having or not having a diagnosis of diabetes
 - Being able to read, write, speak and comprehend English
 - Being able to walk for 10 minutes without stopping
 - Not pregnant

- You do not need to be physically active to participate.
- Having access to a cell or home phone for contact

6. What Will Happen When You Complete the Study

When your participation in the study is completed, you will be done providing information for the research.

7. Possible Risks of Taking Part in this Study

- Minimal risks are associated with taking part in this study.
- There may be some discomfort from wearing the activity monitor belt around your waist and in answering sensitive survey questions.
- If a potential risk for depression is identified during the study, the researcher will call you and discuss having you follow-up with your primary health provider (doctor, nurse or other health professional).

8. Costs for Taking Part In this Study

- *Your involvement in this study will not result in any additional costs to you.*

9. Compensation for Taking Part in this Study

- Procedures such as measurement of height and weight will be provided free of charge.
- You will be compensated for the safe return of the activity monitor after the 7 days of wear time, with a \$10 store card.

10. Possible Benefits to You for Taking Part in the Study

- You will not directly benefit from taking part in this study. However, taking part in this study may contribute to the understanding of factors that influence physical activity in middle-aged women with and without diabetes.

12. About Participating in this Study

- Taking part in this research study is completely voluntary. You have the right to say no.
- You may change your mind at any time and withdraw without penalty or loss of benefits to which you are otherwise entitled.
- To withdraw from the study, contact the researcher by phone or email.
- You may choose not to answer specific questions or to stop taking part at any time.

13. Confidentiality of Study Records and Medical Records

- Information collected for this study is confidential. However, the researcher and her study staff, delegated representatives of Saint Mary's Health Care, Saint Mary's Health Care Institutional Review Board (IRB), and the Michigan State Institutional Review Board will have access to the data.
- To keep data confidential, the data will be coded with an anonymous ID number. The ID number will be used to collect data from your surveys and personal health information.
- The key linking your name and contact information with your ID number will be kept in a locked file cabinet separate from the de-identified data. The de-identified data will be entered into a database on a secured laptop computer and stored in a locked file cabinet.
- Meetings with the researcher will take place in a private room for measuring your height and weight, completing the survey and preparing the activity monitor for you to wear.

14. Release of Personal Information

- The researcher will keep all individual survey data and private conversations confidential to protect your privacy. Information about you will be kept confidential to the maximum extent allowed by law unless there is a danger to yourself or others.
- The results of this study may be published or presented at professional meetings, but your identity will remain anonymous.

15. Financial Conflict of Interest

- The Institutional Review Board at Saint Mary's Health Care has reviewed the possibility of a financial conflict of interest and believes that the possible benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study.

16. Names of Contacts for Questions About the Study

- If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report any problems, please contact the researcher:
 - Melodee Vanden Bosch, PhD(c), RN: 500 West Fee, East Lansing MI 48824, vande484@msu.edu, (517) 432-9159 or cell: 616 308-2353.
- If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact:
 - Brenda Hoffman, Saint Mary's Institutional Review Board (IRB) Chairperson, 200 Jefferson Ave. SE – Grand Rapids, MI 49503
Telephone: 616-685-619

17. HIPAA Authorization

As part of this research study, you are being asked to release your health information. The Health Insurance Portability and Accountability Act (HIPAA) permits a hospital or doctor's office to use or release protected health information (PHI) for the purposes of treatment, payment or health care operations. A HIPAA authorization gives permission from you to use or release PHI for research purposes, and is in addition to your consent to participate in this research study. The researcher will use and share personal health information about you only in collective data

analysis not individually. *This is information about your health that may also include your name, address, telephone number or other facts that could identify the health information as yours.*

This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The researcher will use this information about you to complete this research.

In most cases, the researcher will use your initials and assign a code number to your information and may review or copy your personal health information at the study site. The Saint Mary's Health Care Institutional Review Board or the Michigan State University Institutional Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

By signing this Authorization, you allow the researcher to use your personal health information to carry out and evaluate this study. You also allow the researcher to share your personal health information with:

- Saint Mary's Health Care Institutional Review Board
- Michigan State University Institutional Review Board

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health confidential.

You have the right to see and get a copy of your records related to the study for as long as the researcher has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the researcher in writing. Send your written withdrawal notice to **(Melodee Vanden Bosch, PhD(c), RN: 500 West Fee, East Lansing MI 48824)**. If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical records may be reviewed.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

If you do not sign this Authorization, you cannot participate in this research study. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

DOCUMENTATION OF INFORMED CONSENT

By signing this consent form and HIPAA authorization and by initialing each page, you certify you have read this form, you have had the opportunity to ask questions about this study and this form, and you have received answers that fully satisfy those questions. You are voluntarily signing this consent form and HIPAA authorization as evidence of your decision to participate in this research study and you are giving authorization for release of all your protected health information relative to this research.

You are aware you may withdraw your consent and HIPAA authorization in writing at any time without harming future medical care or losing any benefits to which you might be otherwise entitled. You have been advised that the researcher in charge of this study may discontinue your participation in this study if it is felt to be in your best interest, if you do not

follow the study requirements or if the study is stopped.

You will receive a signed copy of this Research Informed Consent Form and HIPAA Authorization. By signing this consent form, you have not waived any of your legal rights or released the parties involved in this study from liability for negligence.

_____	_____
Signature of Study Participant	Date

Printed Name of Study Participant	
_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Printed Name of Person Obtaining Consent	Date
_____	_____
Signature of Principal Investigator	Date

APPENDIX I

Letter of Continued Participation for Women who had Stopped Participation

LETTERHEAD OF AGENCY
PHYSICAL ACTIVITY in MIDDLE-AGED WOMEN STUDY

Melodee Vanden Bosch, PhD(c), RN, Investigator

Michigan State University

500 West Fee Hall

East Lansing, MI 48824

Dear Ms. (name of consented person),

Thank you for participating in the Physical Activity in Middle-aged Women Study, completing some of the survey questionnaires and wearing the accelerometer. Although you were unable to complete the study, I am including a store gift card for return of the accelerometer.

If you still wish to complete the study, feel free to call me to set up an appointment for May or early June. My contact information is included at the end of this letter. If you choose not to continue participation, I want you to know that I appreciated your participation in the Physical Activity in Middle-aged Women study!

Sincerely,

Melodee Vanden Bosch, PhD(c), RN, Investigator

(616) 308-2353

vande484@msu.edu

APPENDIX J

Letter of Recruitment for Women with Diabetes

LETTERHEAD OF AGENCY

Melodee Vanden Bosch, PhD(c), RN, Investigator

Michigan State University

500 West Fee Hall

East Lansing, MI 48824

Dear Ms.

You are being invited to participate in a study through your physician's office, (name of clinic). The study is titled, *Physical Activity in Middle-aged Women With and Without Diabetes*. You were identified by (Physician Name) to participate as one of his patients with diabetes. The study involves two visits with Melodee Vanden Bosch, RN, PhD(c), the nurse investigator, to complete survey questionnaires and receive an activity monitor called an accelerometer. This initial visit lasts about 45 minutes. You will be asked to wear the activity monitor for 7 days in a row and for 10-13 hours each day. The second appointment is scheduled for after the 7 days of activity monitor wearing and involves completing 1 more survey questionnaire and looking at the graph of the accelerometer data with the investigator. This second visit lasts about 20 minutes.

Please read the enclosed flyer to determine if you fit the inclusion criteria of the study. If you wish to participate in the study please call me to set up an appointment for August or early September. My contact information is included at the end of this letter and on the flyer.

Sincerely,

Melodee Vanden Bosch, PhD(c), RN, Investigator

(616) 308-2353

vande484@msu.edu

APPENDIX K

Data Management Plan For Confidential Storage of Data

Data Management Plan

There are 6 places used for data storage in this study. These 6 places include: 1) a locked File Cabinet, one at each clinic site 2) N:drive of investigator's office computer; 3) an Encrypted Flashdrive #1; 4) Michigan State University (MSU) laptop computer; 5) an Encrypted Flashdrive # 2 ; 6) External hard-drive.

Data housed at each of these places includes:

- 1) Locked File cabinet, separate from clinic patient data or charts, at each clinic site includes:

Study Data

- Signed Research Participant Information and Consent Form/HIPAA Authorization in a file separate from the Study Data Files.
- Study Data File

A deidentified study data file with the subject's study ID number listed on the outside kept separate from the Study Roster Key. The study data file includes:

- Middle-aged Women and Physical Activity Survey Data:
 - Demographic Information
 - Comorbidities
 - Patient Health Questionnaire (PHQ-9)
 - Attitudes Toward Physical Activity
 - Self-efficacy for Physical Activity
 - Benefits of Physical Activity
 - Social Support for Physical Activity

- Daily Log of Physical Activity
- International Physical Activity Questionnaire (IPAQ)
- Weight and Height Information sheet
- Chart audit information on diagnosis of diabetes & comorbidities
- Store card number given to the participant and date.
- Notes inside cover of folder include: dates when data entered into the computer program, date of letters sent to patient or issues noted with data.

2) Network drive of office computer houses:

- a) The deidentified PASW and Excel files of the Study Data.
- b) Participant Information - name, telephone number(s) (only address if I had to make a home visit or email if subject contacted me by this method of recruitment).
- c) Recruitment information – general information about number of business cards and Research Participation Information and Consent forms given to women, number of women recruited by site, number of women recruited by flyer versus direct phone call or email from participant as method of recruitment.
- d) Participant Checklist- checklist of visits, phone conversations, surveys, weight , height completed, materials given or sent.
 - a. Dates when women completed or returned the Survey, Daily Log and IPAQ and when data was, and entered into the computer program.
 - b. Date & time of clinic visit 1 and date of distribution to the women, date of return, where completed (clinic or home) and type of return (visit or mail) for each of the following:

- Research Subject Information & Consent form
 - Middle-aged Women & Physical Activity Survey
 - Accelerometer
 - Accelerometer Information Sheet
 - Daily Log
 - Weight measured – second person initials
 - Height measured – second person initials
 - Notes: any comments or problems with data collection
- Date & time of clinic visit # 2 and the date of distribution or downloading, where completed (clinic or home) and type of return (visit or mail) for the following:
 - IPAQ
 - Accelerometer data
 - Printed copy of the accelerometer data graph
 - Notes: any comments or problems with data collection
 - Store card
 - Record of telephone calls made to the woman by the investigators by date & time of call, what questions they had, whether they were given reminders about accelerometer wear and daily log.
- 3) Encrypted Flashdrive # 1 houses items as listed above in # 2) Study Data, Participant information, Recruitment Information, and Participant Checklist for transportation of data from the clinics to the Network drive and data backup to prevent loss.
- 4) MSU laptop computer houses the Accelerometer Data under my documents. The MSU

computer is utilized to initialize and download the data using ActiLife5 software and to analyze accelerometer data through a specialized program called MeterPlusTM. All data is deidentified by use of only subject ID numbers and is transferred to the N:drive for backup.

- 5) Encrypted Flashdrive # 2 houses the Study Roster Key: The study roster key is the direct link between the subject name and the subject ID number. The encrypted flashdrive # 2 is used at the clinic sites only by the investigator and only when necessary to connect the subject name to the study data file for the return visit, for potential follow-up phone calls, or for chart audits.
- 6) External hard-drive: The Study Roster key is backed up weekly to an external harddrive. Both the Encrypted Flashdrive # 2 and the External hard-drive are locked in a file cabinet in the investigator's home office file. The home is protected by a security system in use when no one is home and during the night.
- The recycle bins of all computers are emptied daily of any recycled study data.

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REFERENCES

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