

ASSESSING THE FEASIBILITY AND ACCEPTABILITY OF A
HEALTH ACTION PROCESS APPROACH PHYSICAL
ACTIVITY AND SEDENTARY BEHAVIOR SELF-GUIDED
WORKBOOK IN RURAL ADULTS WITH TYPE 2 DIABETES

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The undersigned, appointed by the dean of the Graduate School, have examined the dissertation entitled

ASSESSING THE FEASIBILITY AND ACCEPTABILITY OF A HEALTH ACTION
PROCESS APPROACH PHYSICAL ACTIVITY AND SEDENTARY BEHAVIOR
SELF-GUIDED WORKBOOK IN RURAL ADULTS WITH TYPE 2 DIABETES

Presented by Chelsea Howland, a candidate for the degree of doctor of philosophy, and hereby certify that, in their opinion, it is worthy of acceptance.

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DEDICATION

This dissertation is dedicated to my husband, Drew Howland, and parents Bob and Carol Acord. My husband, Drew, inspires me follow my passion and pursue a career that provides me with happiness and satisfaction. He has provided me with endless support as I pursued my doctoral degree and always manages to bring me back to centeredness. When met with challenges I felt I could not overcome, he helped me to self-reflect and develop solutions through seeing there are multiple paths to an end. My parents have instilled a passion to seek knowledge and continually work to achieve my goals. My fathers' lived experience with diabetes inspired me to pursue a line of research with rural individuals with type 2 diabetes. My mother inspired me to become a registered nurse and has provided years of invaluable insight that have helped me develop as a compassionate nursing professional. Her thoughtfulness and willingness to listen have helped me stay true to my path. My parents have tirelessly supported me in pursuing my dreams, laying a lifelong foundation for me to achieve my goals. I am grateful for the patience, kindness and support to pursue my dreams I have received.

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Assessing the Feasibility and Acceptability of a Health Action Process Approach
Physical Activity and Sedentary Behavior Self-Guided Workbook in Rural Adults with
Type 2 Diabetes

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Dr. Bonnie Wakefield, Dissertation Advisor

ABSTRACT

Physical inactivity and increased amounts of time spent sedentary pose a significant health risk for adults with Type 2 diabetes (T2DM); increasing physical activity (PA) and reducing sedentary behavior can improve diabetes outcomes. Rural adults are disproportionately affected by T2DM and experience barriers to diabetes self-management resources creating a disparate health situation. Mobile health technology interventions can improve health outcomes and are a resource which can bridge barriers in access to diabetes self-management resources in rural populations. However, little research has been conducted in rural populations delivering a PA and sedentary behavior change intervention using mobile health technology strategies. There is a dearth of rigorously developed and evaluated mobile health technology interventions for rural adults with T2DM, making it difficult to understand the appropriateness for rural adults, mechanisms of behavior change, and validity of outcomes derived. This dissertation study evaluated the feasibility and safety, acceptability, and preliminary effects of a novel Health Action Process Approach model guided PA and sedentary behavior intervention for rural adults with T2DM. This study found that the intervention was acceptable and appropriate for rural adults. Feasibility data collected provided evidence for intervention refinement. A moderate significant effect size was detected post-intervention for

increased leisure-time self-reported PA ($r = .48, p = .04$). Large non-significant effect sizes were observed post-intervention for reduction in sedentary time spent using a computer ($r = .51, p = .11$) and watching television ($r = .59, p = .06$). Detected effect sizes suggest the intervention impacted PA and sedentary behaviors as intended and warrant future evaluation as a fully powered study to evaluate intervention efficacy is larger, more diverse samples. With future research and the transition of evidence to a mobile health technology platform, health disparities in a vulnerable rural population with T2DM could be improved, resulting in positive health outcomes and reductions in chronic disease burden.

CHAPTER ONE

GENERAL INTRODUCTION

Diabetes is a chronic, progressive disease which affects glycemic control in 34.1 million United States adults, with 90 – 95% of individuals affected by Type 2 diabetes (T2DM; ADA, 2022a; CDC, 2020). Individuals with T2DM experience a relative insulin deficiency and peripheral insulin resistance, resulting in hyperglycemia (ADA, 2022a). A relative insulin deficiency occurs in the presence of normal or elevated pancreatic insulin secretion due to the inability of the pancreas to produce adequate insulin to compensate for cellular insulin resistance (ADA, 2022a). The exact underlying etiology of T2DM remains unknown; however, the risk of developing T2DM increases with age, obesity, and inadequate physical activity (PA; ADA, 2022a). Women with a history of gestational diabetes mellitus or polycystic ovarian syndrome, individuals with hypertension or dyslipidemia, individuals who are of African American, Native American, Hispanic/Latino, and Asian American races and ethnicities, and individuals with a strong familial genetic predisposition are at increased risk for developing T2DM (ADA, 2022a). In the United States diabetes affects men and women equally; individuals over the age of 45 and Black, Asian, and Hispanic individuals are more greatly affected (CDC, 2020).

Rural individuals demonstrate an increased prevalence for T2DM (Callaghan et al., 2020; Massey et al., 2010). Additionally, rural areas demonstrate higher overall and hospital mortality rates related to T2DM (Dugani et al., 2021). The underlying cause of increased prevalence is multifactorial, inclusive of individual, environmental, social, and infrastructural factors (Brown-Guion et al., 2013; Dugani et al., 2021; Ross et al., 2015). Rural populations have demonstrated lower rates of healthy lifestyle factors, including

adequate PA and sleep, a normal body weight, not smoking, and minimal alcohol intake in comparison to urban adults which may increase the risk of developing T2DM (Dugani et al., 2021; Whitfield et al., 2019).

Maintaining Glycemic Control through Diabetes Self-Management Activities

To maintain glycemic control and prevent and delay chronic complications of T2DM, individuals must participate in complex diabetes self-management activities. Facets of diabetes self-management activities include PA, nutrition, medication adherence, screening activities, smoking cessation, and the management of psychosocial issues (ADA, 2022b; ADA, 2022c). Inadequate diabetes self-management can result in the development of chronic macrovascular and microvascular complications, inclusive of coronary artery disease, stroke, peripheral vascular disease, retinopathy, nephropathy, and neuropathy (Cannon et al., 2018). Diabetes Self-Management Education and Support services provide foundational support for individuals to develop the knowledge and skills necessary to make complex health decisions within the context of day-to-day living (ADA, 2022b).

Physical Activity and Sedentary Behavior

Increasing PA and reducing sedentary behaviors are essential components of diabetes self-management (ADA, 2022b; Colberg et al., 2016). Physical activity includes all skeletal muscle movements which increase energy expenditure (ADA, 2022b; Bull et al., 2020). Individuals with T2DM are recommended to perform regular aerobic and resistance PAs, with older adult populations receiving additional recommendations to incorporate balance and flexibility training (ADA, 2022b). Current guidelines recommend participation in 150 minutes of moderate-to-vigorous intensity PA weekly,

occurring over three or more days of the week, with less than two consecutive days between bouts of PA (ADA, 2022b; Bull et al., 2020). Participation in regular PA leads to improvements in insulin resistance, glycemic control, blood pressure, and triglycerides (ADA, 2022b). For individuals who do not regularly participate in PA, the duration and intensity of activities should be gradually increased over time, taking into consideration safety and glucose management (ADA, 2022b).

Sedentary behavior is a separate concept, with shared importance for maintaining glycemic control (Colberg et al., 2016; ADA, 2022b). Sedentary behaviors are inclusive of any waking behavior with a low energy expenditure which occurs while sitting, reclining, or lying (Bull et al., 2020). Common examples of situations in which sedentary behaviors occur include while using a computer, watching television, performing desk-based work, and driving a vehicle (Bull et al., 2020). Reducing the amount of time spent sedentary by standing or walking every 30 minutes can aid in improving glycemic control (Colberg et al., 2016; ADA, 2022b). Despite robust evidence supporting the role of increasing PA and reducing sedentary behaviors, many adults with T2DM struggle to incorporate PA into their day-to-day lives.

Impact of Rurality on Diabetes Self-Management & Physical Activity

Rural adults are less likely to receive diabetes self-management education and face unique barriers impeding access to diabetes and health resources (Brown-Guion et al., 2013; Bolin et al., 2015b). Primary care provider and specialist (i.e., endocrinologist) shortages in rural areas, financial constraints, limited employment opportunities and lower socioeconomic status, lower levels of education and health literacy, and long travel distances and a lack of affordable transportation impact rural adults' ability to access and

use diabetes health resources (Bolin et al., 2015a; Bolin et al., 2015b; Ross et al., 2015). Unique barriers specific to PA and sedentary behavior change in rural populations include distrust in primary care provider recommendations to increase PA, concerns about their ability to increase PA, fear of reprisal and exclusion from peer networks, and competing life priorities (Bell et al., 2013; Bhattacharya, 2012; Miller et al., 2010). Limited access to facilities to perform PA and equipment further impact the potential variety of PA rural adults can incorporate into their lifestyle (Bell et al., 2007; Smalls et al., 2014).

Use of Telehealth to Overcome Access Barriers

Telehealth is an effective strategy to overcome barriers in access to diabetes and health resources in rural populations and has demonstrated the ability to improve diabetes outcomes (ADA, 2022c; Lepard et al., 2015). Through telehealth, health information is exchanged using electronic communication pathways, including through internet-based websites and mobile applications (Tuckson et al., 2017). A greater diversity in populations reached can be achieved through use of mobile applications to provide diabetes and health resources to rural individuals (Ryan, 2018; Massey et al., 2010).

Current State of Research

Interventions delivered using a website or mobile application platform demonstrate the ability to increase PA, decrease sedentary behaviors, and improve glycemic control in adults with T2DM (Connelly et al., 2013; Howland & Wakefield, 2021; Konerding & Szel, 2021; Kongstad et al., 2019). Sedentary behavior is seldom recognized as a unique component independent of PA in studies reviewed (Howland & Wakefield, 2021). Few studies utilize both objective and self-report PA and sedentary

behavior outcome measurement methods, which impacts the ability to obtain accurate results within the context of individual behavioral domains (Howland & Wakefield, 2021; Prince et al., 2008). Intervention design, including the direct integration of theoretical constructs is incompletely described in most articles, which limits the ability to understand the underlying mechanisms of behavior change (Connelly et al., 2013; Howland & Wakefield, 2021; Kongstad et al., 2019). Goal setting and participant feedback behavior change techniques resulted in improved outcomes (Konerding & Szel, 2021). Little research has been conducted in rural populations with T2DM to gain insights into the feasibility and acceptability of PA and sedentary behavior change interventions (Howland & Wakefield, 2021).

Conclusions

A critical gap exists in the development and rigorous evaluation of theory-driven mobile applications to increase PA and reduce sedentary behaviors in rural adults with T2DM (Howland & Wakefield, 2021). Prior to developing a mobile application, it is integral to evaluate the feasibility and acceptability, and eventual efficacy of intervention content and measurement methods in the intended for use population. The purpose of this dissertation project was to evaluate the feasibility and safety, and acceptability of a Health Action Process Approach model guided PA and sedentary behavior self-guided workbook, accelerometer, and study measures in rural adults with T2DM. The Health Action Process Approach model predicts behavior change by integrating cognitive and behavioral constructs along a continuum of self-efficacy-based stages (Schwarzer, 2008; Schwarzer et al., 2011). This research study addresses the evaluation of feasibility and acceptability of an educational and cognitive behavioral skill building 4-week self-guided

workbook and accelerometer intervention guided by the Health Action Process Approach model. Findings from this study will be used to refine the self-guided workbook, choice of accelerometer, and evaluation methods prior to evaluating intervention efficacy and the underlying mechanisms of behavior change in rural adults with T2DM in future studies.

The subsequent chapters in this dissertation (Chapters 2 – 5) are components of the dissertation project. Chapter two is an integrative review of telehealth interventions for PA and sedentary behavior self-management in adults with T2DM. The review identified a critical gap in knowledge surrounding the use of telehealth interventions intended to increase PA and reduce sedentary behaviors in rural populations with T2DM which informed this dissertation project by providing foundational knowledge for the self-guided workbook development, selection and inclusion of behavior change techniques, and choice of outcome measures. Chapter three, the research proposal supporting this dissertation project, was submitted for the National Institute for Nursing Research Ruth L. Kirschstein Predoctoral Individual National Research Service Award. Chapter four is the dissertation study procedures and findings. Chapter five provides a synthesis of the dissertation project in the context of relevant literature and describes the significance of this dissertation projects contributions to the nursing profession.

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CHAPTER TWO

ASSESSING TELEHEALTH INTERVENTIONS FOR PHYSICAL ACTIVITY AND SEDENTARY BEHAVIOR SELF-MANAGEMENT IN ADULTS WITH TYPE 2 DIABETES MELLITUS: AN INTEGRATIVE REVIEW

Howland, C. & Wakefield, B. (2021). Assessing telehealth interventions for physical activity and sedentary behavior self-management in adults with type 2 diabetes mellitus: an integrative review. *Research in Nursing & Health*, 44(1), 92 – 110.

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Abstract

Type 2 diabetes is a chronic disease, requiring lifestyle management to prevent chronic complications. Increasing physical activity and reducing sedentary behavior are integral to maintaining glycemic control. The purpose of this study was to (1) appraise and synthesize the literature about physical activity and sedentary behavior intervention delivery via telehealth strategies in adults with type 2 diabetes mellitus and (2) to evaluate what is known about the effectiveness of such interventions on physical activity, sedentary behavior, and glycemic control. An integrative literature review was carried out, including the electronic databases PubMed, CINAHL, and PsychInfo, searching for articles published within the past 10 years, meeting specified inclusion and exclusion criteria, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement guidelines. Seventeen studies were included. Significant improvements in physical activity and sedentary behavior were identified in web and mobile phone-based interventions. Modest improvements in glycemic control were

reported. Theoretical framework use and integration was limited, and intervention length and follow-up varied greatly in the studies reviewed. Outcomes were measured using both self-report and objective measures, but objective measures were used less frequently. Further, few studies have been conducted in the United States or in rural populations. Web and mobile phone-based telehealth interventions to increase physical activity, reduce sedentary behaviors, and improve glycemic control have been supported by the literature. A need exists for future studies that are theory-driven, include dose-specific measures, self-report and objective measures, and long-term follow-up. Examining intervention effects in rural populations is needed.

Type 2 diabetes mellitus (T2DM) is a chronic disease process requiring lifestyle management to maintain normal glycemic levels, and to prevent or delay the onset of chronic complications. In the United States, 34.1 million adults aged 18 or older are living with known T2DM, with an estimated 7.3 million adults remaining undiagnosed (Centers for Disease Control and Prevention, 2020). Despite continued efforts in prevention, the prevalence of T2DM in US adults is estimated to increase to 60.6 million by the year 2060 (Lin et al., 2018).

Physical activity (PA) is an integral lifestyle management component, which aids in maintaining glycemic control (GC; American Diabetes Association [ADA], 2019b). The ADA (2019b) recommends adults with T2DM participate in 150 minutes of moderate-to-vigorous PA weekly to reduce glycated hemoglobin (A1C) levels, triglycerides, blood pressure, and insulin resistance. Periods of PA, specifically aerobic PAs, should last a minimum of 10 minutes, with the goal of reaching 30 minutes per day, most days of the week, not allowing for more than 2 days between activity sessions (ADA, 2016, 2019c).

Sedentary behavior (SB) is a separate, but an equally important, component to maintain GC (ADA, 2016). SBs, which occur while lying or sitting, require low amounts of energy expenditure (ADA, 2016). Reducing prolonged periods of time spent sedentary every 20–30 minutes with light walking activity aids in improving GC (ADA, 2016). While there is strong evidence supporting the importance of increasing PA and decreasing SB, many adults with T2DM continue to struggle to meet recommended guidelines (ADA, 2016, 2019c).

Telehealth is defined as the exchange of information using electronic

communications to improve patient health and outcomes (Tuckson et al., 2017). The use of telehealth technology to improve monitoring, feedback, and high-quality healthcare access to patients is continuing to grow (Tuckson et al., 2017). Communication between patients and clinicians through video conferencing, telephone calls, e-mail, remote wireless monitoring, and the Internet can provide chronic disease management care (Tuckson et al., 2017). Wearable monitors, smartphones, mobile apps, video conferencing, e-mail, and games can provide valuable health education and PA monitoring (Tuckson et al., 2017). Incorporating both Internet and mobile technology-based interventions can reach a more diverse population than using Internet-based technology alone (ADA, 2019b).

Few systematic reviews have been conducted to explore the literature about PA and SB interventions delivered using a telehealth strategy to adults with T2DM. No identified reviews focused on SB interventions delivered using a telehealth strategy in this population. Two systematic reviews examined the use of telehealth strategies to promote PA in adults with T2DM, identifying the use of telehealth strategies to deliver PA interventions in adults with T2DM as effective (Connelly et al., 2013; Kongstad et al., 2019). Connelly et al. (2013) reviewed literature published between January 1991 and March 2013 and Kongstad et al. (2019) reviewed literature published before May 2017. Both systematic reviews provided evidence to support the need for tailored feedback delivered in a format the participant finds meaningful and the inclusion of self-monitoring features, such as a logbook (Connelly et al., 2013; Kongstad et al., 2019). While both systematic reviews identified a relationship between studies with a strong methodology (i.e., full theoretical integration, intervention descriptions, use of objective

and subjective outcome measures) and clinically important outcomes, there has been a little description of how interventions were developed, including the content included, full theoretical concept integration in the intervention or outcome measures, and the use of both objective and subjective outcome measures by the studies reviewed (Connelly et al., 2013; Kongstad et al., 2019). To provide additional insight into the current state of the literature, the purpose of this integrative review was to (1) appraise and synthesize the literature about PA and SB intervention delivery via telehealth strategies in adults with T2DM and (2) evaluate what is known about the effectiveness of such interventions on PA adherence, SB reduction, and GC.

Methods

Search Methods

To be included in this literature review, a health behavior intervention designed to increase PA, and/or reduce SB must have been delivered using a telehealth strategy to community-dwelling adults with T2DM with the aim of improving GC. “Telehealth” was defined as the use of technology to communicate an intervention using the Internet through websites and mobile device technologies. “Physical activity” was defined as activities produced through skeletal muscle contraction which result in energy expenditure above a basal level, measured as levels of PA, time spent physically active, or steps taken (US Department of Health and Human Services, 2018). “Sedentary behavior” was defined as activity that requires low amounts of energy expenditure, occurs while sitting, reclining or lying, measured as time spent sedentary, the number of sedentary periods, breaks in sedentary time, and as time spent in specific sedentary activities (US Department of Health and Human Services, 2018). “Glycemic control” was

defined as an A1C <7% and/or pre-prandial blood glucose levels of 80–130 mg/dl (ADA, 2019a).

The literature search of databases was conducted in October 2019. The following databases were included in the search: PubMed, CINAHL, and PsychInfo. Ancestry searches of eligible publication reference lists were performed to identify additional relevant publications not identified through the original database search. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines were followed (Moher et al., 2009). The search strategy was limited to include articles published within the past 10 years, English language only, and full text available. The key terms “diabetes,” “intervention,” and “internet or website or web-based or mobile or phone” were entered into the database search box with the term “physical activity or exercise.” Then the three key terms were re-entered with the following search term, “sedentary or sitting time.” Articles were initially screened by reading the title, then the abstracts of relevant publications were read to determine eligibility. If eligibility could not be determined by reading the abstract, the full text was reviewed.

To determine study eligibility, the following specific inclusion and exclusion criteria were applied to make final publication selections. Specific inclusion criteria included (a) community-dwelling adults (age \geq 18 years); (b) access to full report; (c) participants diagnosed with T2DM; (d) PA and/or SB intervention delivered via telehealth strategy; (e) outcome measures for PA (levels of PA, time spent active, and steps taken) and/or SB (time spent sedentary, the number of sedentary periods, breaks in sedentary time, and as time spent in specific sedentary activities); (f) available in the English language; (g) published after January 1, 2009. Study exclusion criteria include (a)

non-community-dwelling participants; (b) under the age of 18 (age \leq 17 years); (c) diabetes diagnosis other than T2DM; (d) interventions focused on diabetes self-management behaviors that did not include PA or SB.

Study Selection

Initial database searches yielded 946 articles, with an additional 7 articles identified through ancestry searches. After removing duplicate articles, several articles were excluded by reading the title. The abstracts of 94 articles were screened for potential inclusion based on eligibility criteria, with 45 full-text articles reviewed.

Primary study quality was assessed using the Physiotherapy Evidence Database (PEDro) scale, a scale commonly used in PA research (Maher et al., 2003; Morton, 2009; Verhagen et al., 1998). The PEDro Scale contains 11 criteria to appraise external validity (Criterion 1), internal validity (Criteria 2–9), and the presence of sufficient inferential statistical data (Criteria 10–11; Maher et al., 2003). External validity (Criterion 1) was evaluated based on the inclusion of specific eligibility criteria (Maher et al., 2003; Verhagen et al., 1998). Internal validity (Criteria 2–9) was evaluated by assessing subjects' random allocation to groups, group allocation concealment, group similarity at baseline, blinding of subjects, blinding of interventionist, blinding of assessors who measured at least one key outcome, obtaining at least one key outcome from 85% of subjects initially allocated to groups, and using an intention-to-treat analysis on at least one key outcome (Maher et al., 2003; Verhagen et al., 1998). Presence of sufficient inferential statistical data (Criteria 10–11) was evaluated based on the presence of between-group statistical comparisons reported on at least one key outcome and the presence of both point measures and measures of variability for at least one key outcome

(Maher et al., 2003; Verhagen et al., 1998). Seventeen articles met the inclusion criteria for the literature review; see Figure 1 for the PRISMA flow diagram.

Data Extraction

The primary author (C. H.) independently extracted all data from the articles included; the second author (B. J. W.) independently reviewed and confirmed the data extraction. Discrepancies between authors were resolved through discussion; the two authors discussed discrepancies and came to a consensus. The following data were extracted: theoretical framework, study design type, sampling method, sample size, attrition rates, study location(s), inclusion and exclusion criteria, participant characteristics, measurement duration and follow-up timeframes, intervention design and telehealth delivery format, outcome measures specific to PA, SB, and GC, other outcomes measures pertinent to the study, and study findings. Table 1 provides an overview of the articles included in the review.

Results

Study Characteristics

Characteristics of the 17 studies are summarized in Table 1. Sample sizes ranged from 20 to 1229. The mean age of participants ranged from 46 to 66.7 years. In seven studies, there were more females than males enrolled in the study (Akinci et al., 2018; Chang et al., 2018; Hansel et al., 2017; Lorig et al., 2010, 2016; Richardson et al., 2010; Van der Weegen et al., 2015). One study did not report the number of female or male participants enrolled (Liebreich et al., 2009). Race and/or ethnicity were not reported in most studies, but when reported, the majority of participants were Non-Hispanic, White (Glasgow et al., 2010, 2012; Lorig et al., 2016; Richardson et al., 2010).

Quality Assessment

Findings from the study quality assessment are presented in Table 2. The PEDro scale does not indicate specific cut-points to identify the level of quality; that said, the more criteria present, the greater the study quality (Maher et al., 2003; Verhagen et al., 1998). Twelve of the seventeen studies scored at least seven on the PEDro scale (Akinci et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010; Muller et al., 2017; Richardson et al., 2010; Yom-Tov et al., 2017). All studies included specific details about eligibility criteria and included point measurements. Fourteen studies included a between-groups statistical comparison on at least one outcome measure. Twelve studies clearly specified random group allocation and the inclusion of intention-to-treat analysis on at least one outcome measure. Ten studies had similar groups at baseline and blinded assessors. Seven studies concealed group allocation. Due to the nature of the studies included, participants and interventionists were not blinded to their group allocation. However, in four studies (Connelly et al., 2017; Hansel et al., 2017; Muller et al., 2017; Yom-Tov et al., 2017) the interventions were completely online without an interventionist.

Research Design

Thirteen articles were randomized controlled trials, randomizing participants to groups, using simple random assignment or block randomization (Akinci et al., 2018; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010; Muller et al., 2017; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015; Yom-Tov et al., 2017). Five

randomized controlled trials compared two levels of the intervention with a control group (Akinci et al., 2018; Glasgow et al., 2010, 2012; Lorig et al., 2010; Van der Weegen et al., 2015). Two studies used a quasi-experimental design (Chang et al., 2018; Lorig et al., 2016). Two studies used a mixed-methods design, with a qualitative component used for intervention development, with one including a randomized controlled trial and one a quasi-experimental design component as pilot studies (Connelly et al., 2017; Verwey et al., 2014).

Location of Studies

Only one study was conducted in an exclusively rural population (Connelly et al., 2017). Five studies were conducted in the United States, with one in Michigan, two in Colorado, and two with non-specified locations (Glasgow et al., 2010, 2012; Lorig et al., 2010, 2016; Richardson et al., 2010). Twelve studies included were conducted internationally (Akinci et al., 2018; Chang et al., 2018; Connelly et al., 2017; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Muller et al., 2017; Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017). Studies conducted internationally did not disclose if US populations had been included in their sample (Akinci et al., 2018; Chang et al., 2018; Connelly et al., 2017; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Muller et al., 2017; Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017).

Theoretical Frameworks

Eight studies did not include a theoretical framework to guide the intervention (Akinci et al., 2018; Hansel et al., 2017; Lorig et al., 2010, 2016; Muller et al., 2017; Van

der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017). Chang et al. (2018) developed an intervention driven by Minimal Psychological Intervention design features. Eight studies included theoretical frameworks to guide intervention development, including the Transtheoretical Model, Social-Ecology Theory, 5A's Self-Management Model, Theory of Planned Behavior, Social Cognitive Theory, Self-Regulation Framework, Health Action Process Approach Model, and Social Influence Theory (Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Poppe et al., 2019; Richardson et al., 2010). Social Cognitive Theory was included in three studies (Kooiman et al., 2018; Liebreich et al., 2009; Richardson et al., 2010). Commonalities in the theoretical frameworks used to guide intervention development included partial to full integration of the framework within the intervention design and addressing health behavior change constructs, such as social support, self-efficacy, perceived behavioral control, action planning, and self-monitoring (Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Poppe et al., 2019; Richardson et al., 2010). Through theoretical framework integration, four common intervention components were identified, education, planning, self-monitoring logbooks, and tailored feedback, in studies with improvement in outcome measures (Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Poppe et al., 2019; Richardson et al., 2010).

Intervention Design and Length

Types of Telehealth Interventions

Ten studies delivered the intervention in only a web-based format (Akinci et al.,

2018; Connelly et al., 2017; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010, 2016; Muller et al., 2017; Richardson et al., 2010). Two studies used a mobile app for intervention delivery (Chang et al., 2018; Yom-Tov et al., 2017). Three studies used a combined web and mobile device delivered intervention (Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014). Two studies supplemented a web-based intervention delivery format with telephone calls (Glasgow et al., 2010, 2012).

Intervention Components

Thirteen common components were identified in the 17 studies included, see Table 3. The most common intervention feature was education about diabetes self-management and/or PA (Chang et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010, 2016; Muller et al., 2017; Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014). A logbook for self-monitoring was included in 11 studies, planning or goal setting was addressed in 9 studies, and tailored feedback was included in 9 studies (Chang et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010, 2016; Muller et al., 2017; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017). Additional intervention components included videos, quizzes, barrier identification, local activities, peer support, reminder messages, professional facilitators, and peer facilitators.

Intervention Length and Contact Frequency

The duration of interventions ranged from 2 to 6 months. Availability and

delivery of intervention content varied between studies. One study provided daily feedback to participants (Yom-Tov et al., 2017). One study delivered intervention content three times per week (Akinici et al., 2018). Seven studies delivered intervention content or provided feedback weekly (Glasgow et al., 2010, 2012; Hansel et al., 2017; Liebreich et al., 2009; Lorig et al., 2010, 2016; Poppe et al., 2019). Eight studies provided open access to intervention content (Chang et al., 2018; Connelly et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Muller et al., 2017; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey et al., 2014).

Follow-up Periods

Most studies reported only post-intervention measurements, with no additional follow-up period. Two studies also conducted a 9-month follow-up (Jennings et al., 2014; Van der Weegen et al., 2015). A 12-month follow-up was conducted in three studies (Glasgow et al., 2012; Lorig et al., 2010, 2016).

Outcome Measurement

Physical Activity and Sedentary Behavior Measures

The primary method of PA outcome measurement was by self-report; which was used in 11 studies (Chang et al., 2018; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010, 2016; Muller et al., 2017; Poppe et al., 2019). PA self-report measures included the Diabetes Self-Care Behaviors Scale, the Community Health Activities Model Program for Seniors Questionnaire, the International Physical Activity Questionnaire, the Godin Leisure-Time Exercise Questionnaire, and a 1-item Physical Activity Questionnaire (Chang et al., 2018; Glasgow et al., 2010, 2012; Hansel et al., 2017; Jennings et al., 2014;

Kooiman et al., 2018; Liebreich et al., 2009; Muller et al., 2017; Poppe et al., 2019). Two studies did not disclose the PA tool used (Lorig et al., 2010, 2016). Objective measures of PA were used less frequently, in only eight studies. Pedometers, waist-worn accelerometers, and a cell phone accelerometer were used to collect objective PA measures (Akinci et al., 2018; Connelly et al., 2017; Hansel et al., 2017; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017). SB was reported in two studies using an accelerometer and three studies using the International Physical Activity Questionnaire and the Longitudinal Ageing Study Amsterdam–Sedentary Behavior Scale (Connelly et al., 2017; Jennings et al., 2014; Muller et al., 2017; Poppe et al., 2019).

Glycemic Control

GC was most frequently evaluated by the glycated hemoglobin level (Akinci et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Kooiman et al., 2018; Lorig et al., 2010, 2016; Yom-Tov et al., 2017). Glycated hemoglobin levels are the gold-standard measurement to evaluate average GC over approximately 3 months; using fasting glucose levels alone would be considered a limitation as they provide minimal information about overall GC (ADA, 2019a). Glycated hemoglobin lab specimens were primarily collected in clinic or laboratory settings (Akinci et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Kooiman et al., 2018; Yom-Tov et al., 2017). High-performance liquid chromatography methods were used to analyze blood specimens in three studies (Connelly et al., 2017; Glasgow et al., 2010, 2012). In two studies, specimen collection kits were mailed to participants who self-collected blood specimens, one using a BIOSAFE Kit (Lorig et al., 2010) and the

other not naming the specific kit (Lorig et al., 2016), before returning the kit to researchers. All studies measuring GC also measured PA. In addition to glycosylated hemoglobin levels, fasting glucose was included in three studies as a measure of GC (Akinci et al., 2018; Connelly et al., 2017; Hansel et al., 2017).

Other Outcome Measures

Multiple other outcome measures were included in the studies. Outcome measures related to website usage were included in six studies (Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Muller et al., 2017; Richardson et al., 2010). Additional biomarkers and anthropometric measures were included in six studies (Akinci et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Hansel et al., 2017; Kooiman et al., 2018). Several studies included additional outcome measures evaluating diabetes knowledge, quality of life, health literacy and resource utilization, behavioral self-management, and mental health (Akinci et al., 2018; Chang et al., 2018; Glasgow et al., 2010, 2012; Hansel et al., 2017; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2010, 2016; Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014; Yom-Tov et al., 2017).

Attrition From Telehealth Interventions

Three studies reported overall attrition rates ranging from 10.8% to 30.3% (Hansel et al., 2017; Lorig et al., 2010, 2016). Attrition rates for intervention groups ranged dramatically from 0.7% to 57.9%, with most studies falling between 20% and 40% (Akinci et al., 2018; Chang et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Muller et al., 2017; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey

et al., 2014). In two studies with attrition rates of 31.4% (Glasgow et al., 2012) and 52.3% (Akinci et al., 2018), a commonality identified was a lack of feedback or interventionist involvement. Longer study lengths were also identified as a commonality in studies with higher attrition rates; with attrition rates of 31.4% being reported at 12 months (Glasgow et al., 2012) and 57.9% at 9 months (Jennings et al., 2014). Control group attrition rates were overall lower, ranging from 1.5% to 39.6%, with most studies falling between 10% and 16% (Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Richardson et al., 2010; Van der Weegen et al., 2015). One study did not report attrition rates (Yom-Tov et al., 2017).

Intervention Impact

Physical Activity and Sedentary Behavior Impact

Significant improvements in PA were observed in 10 studies (Akinci et al., 2018; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Lorig et al., 2016; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey et al., 2014). Connelly et al. (2017) reported small effects on moderate to vigorous PA when using a Transtheoretical Model-driven web-based PA intervention. Using the Theory of Planned Behavior to drive the intervention, Jennings et al. (2014) found significant increases in self-reported total and moderate-intensity PA and decreases in weekday and weekend sitting. Significant long-term improvement in PA was identified at the 9- and 12-month follow-up points in two studies (Lorig et al., 2016; Van der Weegen et al., 2015). Improvement in sedentary time was reported as a small-to-moderate effect (Connelly et al., 2017). One study identified significant improvements in PA and SB,

using a Health Action Process Approach Model and Self- Regulation Theory-driven intervention (Poppe et al., 2019).

Impact on GC

Four studies reported significant improvements in GC, with one reporting moderate effects (Akinici et al., 2018; Connelly et al., 2017; Hansel et al., 2017; Lorig et al., 2016; Yom-Tov et al., 2017). Akinici et al. (2018) demonstrated significant improvements in both A1C and fasting glucose. Lorig et al. (2010) noted greater improvements in A1C in participants with a baseline A1C >7%. At a 12-month follow-up, Lorig et al. (2016) identified significant decreases in A1C. Clinically relevant, nonsignificant improvements in A1C were identified in two studies (Glasgow et al., 2010, 2012).

Discussion

This review supports the use of web and mobile phone-based strategies to deliver PA and SB interventions to adults with T2DM. However, many of the studies reviewed did not include a theoretical framework to drive intervention development, intervention components specific to SB, or use objective outcome measures. Additionally, few studies reviewed focused on rural populations in the United States.

Intervention Design

Web and mobile phone-based interventions have demonstrated the ability to improve outcome measures. Health behavior change interventions focused on PA and SB resulted in greater improvements than interventions targeted toward diabetes self-management overall (Akinici et al., 2018; Connelly et al., 2017; Glasgow et al., 2010, 2012; Jennings et al., 2014; Kooiman et al., 2018; Liebreich et al., 2009; Muller et al.,

2017; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015; Verwey et al., 2014). Additionally, only three studies used a combined web and mobile phone-based delivery system (Poppe et al., 2019; Van der Weegen et al., 2015; Verwey et al., 2014). While 81% of US households were reported to have a computer with an Internet subscription in 2016, it was identified that households that only had Internet access via a smartphone device were more likely to be low-income, Black, or Hispanic (Ryan, 2018). Using a combined web and mobile phone-based delivery system will increase intervention accessibility to diverse populations who do not own a computer. While several studies have been presented which include an intervention focused on improving PA and reducing SB, further research is needed to provide additional support for interventions that combine web and mobile-phone delivery system or compare the effects of combined interventions.

This review identified only one study that included an intervention specific to SB (Poppe et al., 2019). SB has been identified as a separate, while equally relevant, component to diabetes self-management (ADA, 2016). Therefore, interventions focused solely on improving PA are not adequate to produce improvements in SB (Martin et al., 2015; Prince et al., 2014). SB must be included in future research studies as a separate component, to better understand the ability of web and mobile phone-based health behavior change interventions to make changes in SB.

To further improve web and mobile phone-based interventions, additional studies, that are clearly driven by theoretical constructs must be conducted. Nearly half of the reviewed studies did not include any theoretical framework, making it difficult to fully understand the health behavior change mechanisms that resulted in study outcomes. Of

the studies that did include a theoretical framework, few made full framework integration clear. By developing interventions that are theory-driven, mechanisms of change and resultant outcomes can be better understood.

Outcome Timeframes and Measurement

Studies identified by this review included a broad range of intervention timeframes and measurement periods. No studies included elucidated a dose-specific intervention period, which would be beneficial to better understand the minimum required intervention and point where additional intervention delivery does not affect the outcome. Few studies reviewed included long-term follow-up measures after the post-intervention outcome measures. Including long-term follow-up measures would provide evidence of the study interventions' ability to produce long-term health behavior change. To further improve long-term outcome measurement, identifying methods to reduce attrition rates is necessary, to reduce internal validity threats.

Evaluating outcome measures of studies reviewed revealed that self-report measures are most commonly used to measure PA and SB. Differences between self-report measures of PA and objective measures have been identified (Arvidsson et al., 2019; Prince et al., 2008). Prince et al. (2008) found both under- and overreporting of self-reported PA compared with objective measures. While no clear trends in under- or overreporting have been identified, self-report measures that categorize PA by the level of intensity demonstrate a trend with larger differences in self-report and objective measures when higher intensity levels (i.e., vigorous activity) are reported (Prince et al., 2008). Additionally, PA self-report measures are not adequate to fully examine SB. It is necessary to include measurement tools specific to SB to understand its domains and

modes (Prince et al., 2017).

The inclusion of accelerometry to provide objectively measured PA and SB is the most used method in clinical and epidemiological research (Arvidsson et al., 2019). However, accelerometry has not been widely used to evaluate web and mobile phone-based interventions in adults with T2DM. This may be due to the high cost associated with accelerometers and complex data processing and analysis required (Arvidsson et al., 2019). Nevertheless, to most accurately evaluate PA and SB requires objective measures in future studies. Although objective measures provide important data, it is important to include self-report measures to better understand contextual factors related to PA and SB, such as domains and modes of activity. Using a combined measurement approach will provide a more comprehensive understanding of participant behaviors.

Technologies Used

The focus of this review of web and mobile phone-based interventions for PA and SB self-management in adults with T2DM identified four categories of technologies used: web only, mobile phone (application) only, web and mobile phone (application), and web and telephone. A common thread remained among studies was the incorporation of personalized feedback with education and self-monitoring activities, delivered as either an automated feature based on participant responses or through discussion with peers, professionals, and study facilitators. Hanlon et al. (2017) identified improvements in GC in people with T2DM with telehealth systems that incorporated feedback and some educational and lifestyle interventions. In another systematic review of reviews, the most effective interventions for diabetes self-management were identified as including tailored education, analyzing patient data, and providing individualized feedback (Greenwood et

al., 2017). Regardless of the type of technology used, providing individualized feedback and using a person-centered design is necessary to engage participants and create sustainable health behavior change.

Rural Populations

This review has demonstrated a lack of research performed in rural communities. Rural adults are disproportionately affected by T2DM, having a 17% higher prevalence rate than urban adults (Massey et al., 2010). Rural adults face unique barriers, including long travel distances, cultural barriers, a lack of healthcare providers, and reduced access to diabetes self-management education (Bolin et al., 2015). Telehealth technologies can be used to improve access to diabetes self-management education in rural adults (Bolin et al., 2015). Due to the increased need and feasibility of web and mobile phone-based interventions, it is necessary to conduct future studies in rural adults with T2DM to better understand their effectiveness in this population.

Limitations

Although a systematic approach was taken, it is possible that relevant studies were missed if they were not indexed in a computerized database. Further, there is a potential for missed studies, due to the 10-year limit, the use of articles only published in English, and the inclusion of articles available only in full-text format. Another limitation of this study was the inclusion of studies that did not have a primary focus on improving PA and/or reducing SB, with non-specific outcome measures, due to the limited amount of literature published on the topic.

Conclusions

This integrative literature review adds to the literature by identifying positive

outcomes for participants who receive PA and/or SB interventions using web and mobile phone-based technologies. This evidence provides support for diabetes education practices, elucidating necessary evidence to drive the use of web and mobile phone-based PA and SB strategies, which will improve access to invaluable diabetes self-management resources to diverse populations. It provides evidence of the need for additional studies that are theory-driven, targeted specifically toward PA and SB, studies with specified intervention doses, in time or number of telehealth visits, and includes long-term follow-up with both objective and self-report measures. Further, the need for interventions in rural populations has been revealed.

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Conflict of Interests

The authors declare that there are no conflict of interests.

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Table 1*Table of Studies*

Study	Theoretical Framework	Sample characteristics	Intervention description	Control description	PA, SB, and/or GC-related outcome measurement	Results	Conclusions
Akinci et al. (2018)	None reported	Adults with T2DM for at least 1 year, an A1C >6.5 – 11%, aged 40 – 65 years old, who had high-speed internet access in their homes, from an endocrinology clinical in Turkey <i>n</i> = 65 Mean Age (SD): 52.5 (6.4) years Female: 80% Race/ethnicity: not reported	An 8-week intervention comparing supervised aerobic and resistance exercise training, under physical therapist supervision, three times per week, in 50 – 60-minute bouts, with 4 – 6 other study subjects (<i>n</i> =22) with Internet-based aerobic and resistance exercise videos, three times per week, available through a study website (<i>n</i> =21). The internet-based exercise group submitted reports of exercise electronically and received a short telephone message on Mondays as a reminder to exercise	An educational brochure about the importance and benefits of PA and exercise in people with T2DM with practical lifestyle tips provided during a one-time counseling session (<i>n</i> =22)	Baseline and 8-week measurements Steps per day, 6-minute walking distance, A1C, and fasting glucose	Found a significant increase in steps per day (supervised: 1298.67 steps, <i>p</i> =.04; Internet: 1258.05 steps, <i>p</i> =.001), increase in 6-minute walking distance (supervised: 29.32 m, <i>p</i> <.001; Internet: 30.5 m, <i>p</i> <.05), decrease in A1C (supervised: 0.8%, <i>p</i> <.001; Internet: 0.91%, <i>p</i> <.05) and decrease in fasting glucose (supervised: 39.45 mg/dL, <i>p</i> =.001; Internet: 35.4 mg/dL, <i>p</i> <.001) in both intervention	Results support the use of a web-based exercise program

Chang et al. (2018)	Minimal Psychological Intervention	Adults with T2DM, with no serious complications, aged 20 years or older in China <i>n</i> = 30 Mean Age (SD): 46 (8.9) years Female: 80% Race/ethnicity: not reported	A 10-week intervention, using a mobile phone app (Facebook), within a closed community, including education and quizzes, and a forum to share experiences with other members, structured around cognitive, affective, psychological, and behavioral themes	One group pre-post design	Baseline and 10-week measurements 32-item Diabetes Self Care Behavior Scale, measuring foot care, diet control, exercise, medication compliance, and self-monitoring blood sugar	groups at 8 weeks Found an overall significant increase in Diabetes Self Care Behaviors (<i>p</i> =.01), with a significant increase in exercise self-care behavior (<i>p</i> =.017) and non-significant findings in self-monitoring blood sugar (<i>p</i> =.185)	Results support the use of a mobile phone app-based intervention to improve diabetes self-care behaviors, but were limited due to a small sample size, and need for a more robust methodology
Connelly et al. (2017)	Transtheoretical Model	Adults with T2DM, managed with oral medications, aged 18 years or older, who had computer and internet access, living in rural Scotland <i>n</i> = 31 Mean Age (SD): 66.7 years Female: 41.9% Race/ethnicity: not reported	A 6-month intervention comparing a website with PA education (<i>n</i> =10) and a website with PA education and interactive features, including a PA logbook, activity tracker, virtual coach, goal development, challenges, and local activities (<i>n</i> =11)	Written PA educational materials similar to website materials (<i>n</i> =10)	Baseline, 3- and 6-months measurements Minutes/week in levels of PA, step counts, time spent sedentary, sedentary bouts, A1C, and fasting glucose	Found an increase in MVPA in the website only group (20.3 min/week, <i>d</i> =0.15), decreases in total sedentary time in all groups (Website only: 147 min/week, <i>d</i> =0.18; Website with interactive features: 271 min/week, <i>d</i> =0.5; Control: 160 min/week, <i>d</i> =0.2),	Results support the use of a web-based PA intervention but demonstrated the addition of interactive features do not increase activity more than a web-based intervention alone

Glasgow et al. (2010, 2012)	Social-Ecological Theory, 5 A's Self-Management Model	<p>Adults with T2DM, with a BMI ≥ 25 kg/m², with at least 1 risk factor for heart disease, aged 25 – 75 years old, who had telephone and internet access, in Colorado, USA</p> <p><i>n</i> = 463</p> <p>Mean Age (SD): 58.4 (9.2) years</p> <p>Female: 49.8%</p> <p>Race/ethnicity: 6.7% American Indian/Alaskan Native, 1.6% Asian, 15.4%</p>	<p>A 12-month intervention comparing a website with PA education, action plans and goal setting for medication adherence, exercise, and food choices, a logbook for 3 daily goals and immediate feedback based on goal success in the past 7 days, graphic displays of physiologic measures, a moderated forum, quizzes, motivational tips, community</p>	<p>Enhanced usual care with computer-based health risk appraisal feedback and recommended preventative care behaviors (<i>n</i>=132)</p>	<p>Baseline, 4- and 6-months measurements</p> <p>Community Health Activities Model Program for Seniors Questionnaire (total weekly caloric expenditure in PA) and A1C</p>	<p>increases in light activity in the website with interactive feature group (23.6 min/week, <i>d</i>=0.1), and decreases in A1C in website with interactive features and control groups (0.4%, <i>d</i>=0.34; 0.4%, <i>d</i>=0.45) at 3 and 6 months</p> <p>Found a significant increase in weekly total weekly caloric expenditure in both intervention groups at 4 and 12 months (149±356 cal/week, <i>p</i>=.019; 677±46 cal/week, <i>p</i><.05). Modest, non-significant improvements in A1C at 4 and 12 months</p>	<p>Results support the use of a web-based PA intervention but demonstrate the need a more intensive we-based program to see long-term effects</p>
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Hansel et al. (2017)	None reported	<p>Black or African American, 72% White; 21.5% Latino</p> <p>Adults with T2DM, receiving stable medication therapy, with an A1C 5.6 – 8.5%, with an email address and internet access in France</p>	<p>resources, and periodic prompting providing motivational information ($n=169$) with a group receiving the website with the addition of follow-up calls from an interventionist and group attendance with other participants ($n=162$)</p> <p>A 4-month intervention using a web-based nutritional support tool to improve lifestyle habits for diet and PA using 4 modules which could be accessed simultaneously, including a diet and daily steps logbook, weekly menu and shopping list development, PA education, and brief PA videos ($n=60$)</p>	<p>Usual care described as continuing care with general practitioner ($n=60$)</p>	<p>Baseline and 4-months measurements</p> <p>IPAQ – S (self-reported duration and frequency of PA), aerobic fitness levels, A1C, and fasting glucose</p>	<p>Found a significant reduction in A1C in the intervention group (0.3%, $p<.001$). No significant differences in self-reported PA, aerobic fitness levels, or fasting glucose</p>	<p>Results support the use of a web-based nutritional support tool to improve glycemic control, but demonstrate the need for a more focused PA intervention to see improvements in PA</p>
Jennings et al. (2014)	Theory of Planned Behavior	<p>Adults with T2DM, who are not receiving diabetes</p>	<p>A 3-month intervention using a PA website, including</p>	<p>Usual care with limited access to PA website;</p>	<p>Baseline, 3- and 9-month measurements</p>	<p>Found a significant increase in self-reported total</p>	<p>Results support the use of a web-based PA and SB</p>

		education or meeting national PA guidelines, over 18 years old, with email and internet access in Australia <i>n</i> = 397 Mean Age: 58 years Female: 47.6% Race/ethnicity: not reported	educational modules, social support, positive reinforcement, personalized feedback, goal setting, and planning activities (<i>n</i> =195)	home page and contact information only (<i>n</i> =202)	IPAQ-L (self-reported duration and frequency of PA and SB in min/week)	PA (370.6 min/week, <i>p</i> <.01) at 3 months, increase in moderate-intensity PA at 3 months (189.5 min/week, <i>p</i> <.05), and decreases in weekday and weekend sitting (110.9 min/week, <i>p</i> <.001; 100.3 min/week, <i>p</i> <.001) at 3 months and (67.2 min/week, <i>p</i> <.05) at 9 months	intervention
Kooiman et al. (2018)	Social Cognitive Theory	Adults with T2DM, with an A1C $\geq 7.5\%$, who are 18 years or older, with computer and internet access in the Netherlands <i>n</i> = 72 Mean Age (SD): 56.3 (11.4) years old Female: 47.2%	A 3-month intervention using a Fitbit activity tracker and access to an online self-tracking program, aimed to optimize knowledge about living a healthy lifestyle, increase awareness of individual PA, and self-efficacy, through information about health consequences,	Usual care described as visits every 3 months with a nurse or primary care provider (<i>n</i> =32)	Baseline and 3-month measurements Steps per day, a 1-item PA questionnaire measuring engagement in 30 minutes of MVPA per day, A1C, and advanced glycation end products	Found a significant increase in self-reported MVPA (1.5 \pm 3 days/week, <i>p</i> =.047) and steps per day (1255 \pm 1500 steps, <i>p</i> =.01) in the intervention group. There were no significant changes in A1C or advanced glycation end	Results support the use of a pedometer and web-based PA intervention but would benefit from including additional long-term follow-up

		Race/ethnicity: not reported	setting behavioral and outcome goals, identifying barriers and problem solving, action planning, behavioral self- monitoring, receiving feedback, and habit formation (<i>n</i> =40)			products	
Liebreich et al. (2009)	Social Cognitive Theory	Adults with T2DM, with no contraindications to PA, who are 18 years or older, with email and internet access in Canada <i>n</i> = 49 Mean Age: 54.1 (10.3) years old Female: not reported Race/ethnicity: not reported	A 3-month intervention using a PA website based on SCT which provided education using five sections including a weekly topic, education, research, fitness tips, and PA myths, a PA logbook, community message forum, and e-mail counseling with a study coordinator (<i>n</i> =25)	Received access to control group website with static links to Canadian Diabetes Association Clinical Practice Guidelines; no specific direction on physical activity was given (<i>n</i> =24)	Baseline and 3- month measurements Godin Leisure Time Exercise Questionnaire (self-reported leisure time PA)	Found a significant increase in leisure time MVPA (35 min/week, <i>p</i> =.052) and MET-minutes PA adjusted for BMI (171 MET-minutes, <i>p</i> =.043)	Results support the use of a web-based PA intervention, driven by SCT but would benefit from including additional long-term follow-up
Lorig et al. (2010)	None reported	Adults with T2DM, who are 18 years or older, with internet access in the United States <i>n</i> = 761	A 6-month intervention compared an IBDSM Program, with six weekly sessions, including PA education, a	Usual care was not described (<i>n</i> =270)	Baseline, 6- and 18-month measurements Self-report PA scale measured total minutes per	Found no significant improvements in self-reported PA and significant improvement of A1C in the	Results support the use of an IBDSM to improve PA but demonstrated no improvement

Mean Age: 54.3
years old

Female: 76%

Race/ethnicity:
14.5%
American
Indian/Alaska
Natives; others
not reported

weekly
questionnaire,
action plan
development, a
discussion center
with interactive
threaded bulletin
boards,
interactive
measures,
including a
medication and
exercise log,
audio relaxation
exercises, meal
planning, glucose
monitoring tools,
and links to
diabetes related
websites, a
private messaging
center, and a copy
of a book to use
as a reference
(*n*=259) with an
IBDSM program
plus two peer
facilitators
reminded
participants to log
on, provided
modeling of
action planning
and problem
solving, offered
encouragement,
posted on bulletin
boards, and
monitored posts
for inappropriate
content (*n*=232)

week of
aerobic
exercise and
A1C

IBDSM only
group at 6
months
(0.034±0.844%,
p=.036).
Identified
stronger
improvements
in A1C in
participants
with a baseline
A1C >7%
(*p*<.01) during
subgroup
analysis.

when
reinforcement
features were
added.
Identified
participants
with elevated
A1C
demonstrated
greater
improvements
than others

Lorig et al. (2016)	None reported	Adults with T2DM, aged 18 years or older, who are affiliated with an Anthem Health Plan in the United States <i>n</i> = 1229 Mean Age: 57.7 years old Female: 66.5% Race/ethnicity: 74.4% Non-Hispanic White, 12.4% Black, Hispanic 7.4%	A 6-week intervention which made comparisons between a face to face (<i>n</i> =1000) and web-based diabetes self-management program (<i>n</i> =229), including education about enhancing self-efficacy, healthy eating, exercise, understanding glucose monitoring, communication with family, friends, and healthcare providers, hypoglycemia, depression, emotional difficulties, sick day, medication management, problem solving, decision making, and action planning, with two peer facilitators	No control group; two intervention groups were compared	Baseline and 12-month measurements Self-report PA scale measured total minutes per week of aerobic exercise and A1C	Found significant decrease in A1C (0.447%, <i>p</i> <.001) and increases in aerobic exercise (16.7 min/week, <i>p</i> <.001) in combined groups. No significant differences were found between face to face and web-based groups	Results support the use of a web-based diabetes self-management program, demonstrating similar efficacy to traditional face to face programs; however, self-enrollment and a lack of control group limit the generalizability of this study
Muller et al. (2017)	None reported	Adults with T2DM, aged 18 years or older, with access to the internet, who were able to read	An intervention (length not included in publication) comparing two web-based PA	No control group; two intervention groups were compared	Baseline and post-intervention measurements IPAQ – S (self-reported	Found significant increases in beliefs in benefits of PA (interactive: 0.22, <i>p</i> <.001;	Results support the use of web-based diabetes PA intervention and

		in English, German, or Mandarin, in the United Kingdom, Austria, Germany, Ireland, and Taiwan	interventions, using a static plain text version ($n=497$), and an interactive version with personalized audio-visual features ($n=548$), including sequences demonstrating lifestyle and PA activities, a PA planner, tailored feedback, and images based on responses to questions. Both versions included five sections about knowledge of PA benefits, advice on the selection of PA, advice of planning PA, success stories, and access to additional information about PA		duration and frequency of PA and SB) and self-reported beliefs, confidence, and intention related to PA	static: 0.10, $p=.01$), greater confidence in undertaking PA (interactive: 0.35, $p<.001$; static: 0.34, $p=.001$), and stronger intention to increase PA (interactive: 0.49, $p<.001$; static: 0.35 $p<.001$). No significant differences between the interactive and plain text versions	demonstrated the impact of using person-based approaches to design
		$n = 1045$					
		Mean Age: 62 years old					
		Female: 36.4%					
		Race/ethnicity: not reported					
Poppe et al. (2019)	Self-regulation framework, Health Action Process Approach Model	Adults with T2DM, who are literate in Dutch, able to use a computer with internet access, and having not participating in the MyPlan 2.0	A 5-week web and mobile-phone based intervention using five weekly sessions about PA or SB and the creation and evaluation of	Usual care, but not described ($n=18$)	Baseline and 5-week measurements IPAQ – L (self-reported duration and frequency of PA and SB),	Found significant increases in objectively measured moderate PA (8.48 min/day, $p=.05$) and MVPA (8.43 min/day,	Results support the use of self-regulated choice of a PA or SB web-based intervention on improving PA and SBs

			<p>qualitative study in Belgium</p> <p>$n = 54$</p> <p>Mean Age: 62.7 years old</p> <p>Female: 37%</p> <p>Race/ethnicity: not reported</p>	<p>personal goals with an optional mobile app including five modules for daily support, with a gamification element. During the first week, participants selected either a PA ($n=24$) or SB ($n=12$) intervention group</p>		<p>LASA-SB (self-reported total sedentary time on weekdays), and objectively measured number of breaks from sedentary time, sedentary bouts, total sedentary time, number of steps, levels of PA, and total PA</p>	<p>$p=.049$) in the PA intervention group and increases in breaks in sedentary time in the SB group (0.62 breaks/day, $p=.005$)</p>	
Richardson et al. (2010)	Social Cognitive Theory, Social Influence Theory	<p>Adults with T2DM or coronary artery disease, with a BMI ≥ 25 kg/m², with a valid email address, email access weekly, an internet connected computer using Windows XP or Vista, who lead a sedentary lifestyle in Michigan, USA</p> <p>$n = 324$</p> <p>Mean Age (SD): 52 (11.4) years old</p>	<p>A 4-month web-based intervention, including components to upload pedometer data, receive step-count feedback, individually assigned and gradually increasing step-counts, and individually tailored motivational messages ($n=70$) compared to a group which received the web-based intervention with</p>	<p>No control group; two intervention groups were compared</p>	<p>Baseline and 4-month measurements</p> <p>Daily step counts</p>	<p>Found a significant increase in daily step counts in both groups (No online community: 1579 steps, $p<.001$; With online community: 1974 steps, $p<.001$). No differences between groups on daily step counts</p>	<p>Results support the use of a web-based intervention to increase daily steps but demonstrated that online community features did not have an influence</p>	

		Female: 66%	access to an online community ($n=254$)				
		Race/ethnicity: 1% American Indian, 3% Asian, 6% Black, 86% 2% Other, 86% White; 2% Hispanic					
Van der Weegen et al. (2015)	Not reported	Adults with T2DM or COPD, aged 40 – 70 years old, who participate in less than 30 minutes per day MVPA on 5 or more days of the week, with a BMI ≥ 26 kg/m ² for T2DM or stable respiratory functioning for COPD in the Netherlands $n = 199$ Mean Age: 57.9 (7.6) years old Female: 51.3% Race/ethnicity: 6% Non-Dutch	A 3-month web and mobile phone-based intervention comparing a group receiving a nurse delivered Self-Support Program, which includes four nurse consultations, education, and local activities, an activity monitor tool that included a mobile and web-app, and monitored feedback ($n=65$) with a group receiving only the Self-Support Program ($n=66$)	Usual Care but not described ($n=68$)	Baseline, 4 – 6 and 9-months measurements Minutes per day MVPA	Found a significant increase in MVPA in the web and mobile-phone added group compared to the control group (11.73 min/day, $p<.001$) and self-support program only group (7.86 min/day, $p<.003$) at the 4-month and 9-month points (10.59 min/day, $p<.001$; 9.41 min/day, $p<.001$ respectively)	Results support the use of an interactive web and mobile phone-based intervention to increase PA in addition to a traditional self-support program
Verwey et al. (2014)	Not reported	Adults with T2DM or COPD, over age 40, with a BMI ≥ 25 kg/m ² for T2DM and	A 3-month mixed-methods pilot study of a web and mobile phone-based	One group pre-post design	Baseline, 2- and 3-months measurements Minutes per day	Found a significant increase in mean activity levels (10.6	Results support the use of an interactive web and mobile phone-based

			Gold Criteria 2 or 3 for COPD in the Netherlands	intervention with a nurse delivered Self-Support Program, which includes four nurse consultations, education, and local activities, with a monitoring and web and mobile-phone based feedback tool, with qualitative interviews after each nurse consultation		MVPA	min/day, $p=.02$)	intervention to increase PA in additional to a traditional Self-Support Program
			$n = 20$					
			Mean Age: 60 years old					
			Female: 45%					
			Race/ethnicity: not reported					
Yom-Tov et al. (2017)	Not reported	Adults with T2DM, with an A1C over 6.5%, leading a sedentary lifestyle with no dedicated PA program, with an Android based smartphone and data connection plan from an endocrinology and diabetes outpatient clinic in Israel	A 26-week intervention of a mobile phone app that collects data about PA performed and uses a reinforcement learning algorithm to provide personalized text messages that would most likely increase PA the next day ($n=20$)	Once weekly unchanging reminder to exercise ($n=7$)	Baseline and 6-month measurements Amount and rate of walking, and A1C	Found significant A1C reductions in participants allocated to the personalized text message group, those with a higher baseline A1C, and lower baseline activity levels ($R^2=.405$, $p<.01$). The personalized text message group had a non-significant increase in walking rates compared to the control group	Results support the use of a personalized text message, based on activity performance, to increase PA	
			$n = 27$					
			Mean Age: 56.9 years old					
			Female: 33.3%					

Race ethnicity: not
reported

Note. Abbreviations: A1C, glycated hemoglobin; BMI, body mass index; cal/week, calories per week; COPD, chronic obstructive pulmonary disorder; GC, glycemic control; IBDSM, Internet Based Diabetes Self- Management; IPAQ-L, International Physical Activity Scale–Long Version; IPAQ-S, International Physical Activity Scale–Short Version; LASA-SB, Longitudinal Ageing Study Amsterdam–Sedentary Behavior; MET, metabolic equivalent; MVPA, moderate-to-vigorous physical activity; PA, physical activity; SB, sedentary behavior; SCT, Social Cognitive Theory; T2DM: Type 2 diabetes mellitus

Table 2*Study Quality Assessment*

PEDro Criteria	Eligibility specified	Randomisation	Allocation concealed	Groups similar at baseline	Subjects blinded	Interventionist blinded ^a	Assessors blinded ^b	Key outcome obtained from 85%	Intention to treat analysis	Between group statistical outcome	Point measure	Total Score
Akinci et al. (2018)	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	8
Chang et al. (2018)	Y	N	N	N	N	N	N	N	N	N	Y	2
Connelly et al. (2017)	Y	Y	Y	Y	N	Y	N	N	N	Y	Y	7
Glasgow et al. (2010, 2012)	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	8
Hansel et al. (2017)	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	10
Jennings et al. (2014)	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	8
Kooiman et al. (2018)	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	7
Liebreich et al. (2009)	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	8
Lorig et al. (2010)	Y	Y	N	Y	N	N	Y	N	Y	Y	Y	7
Lorig et al. (2016)	Y	N	N	N	N	N	N	N	Y	Y	Y	4
Muller et al. (2017)	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	9
Poppe et al. (2019)	Y	Y	Y	N	N	N	N	N	N	Y	Y	5
Richardson et al. (2010)	Y	Y	N	Y	N	N	Y	N	Y	Y	Y	7

Van der Weegen et al. (2015)	Y	N	N	N	N	N	Y	N	Y	Y	Y	5
Verwey et al. (2014)	Y	N	N	N	N	N	N	N	N	N	Y	2
Yom-Tov et al. (2017)	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y	8

Note: The Physiotherapy Evidence Database (PEDro) scale was used to rate the quality of studies included in this review (Maher et al., 2003; Verhagen et al., 1998). Abbreviations: N, no; Y, yes.

^aFour studies were completed online without the involvement of an interventionist (Connelly et al., 2017; Hansel et al., 2017; Muller et al., 2017; Yom-Tov et al., 2017).

^bFive study outcome assessments were completed online without the involvement of an assessor (Glasgow et al., 2010, 2012; Jennings et al., 2014; Liebreich et al., 2009; Lorig et al., 2010).

Table 3*Intervention Components*

Study	Intervention components											
	Education	Videos	Quizzes	Planning (Goal Setting)	Barrier identification	Self- monitoring logbook	Tailored Feedback	Local activities	Peer support	Reminder message	Professional facilitator	Peer facilitator
Akinci et al. (2018)		X								X		
Chang et al. (2018)	X		X			X		X	X		X	
Connelly et al. (2017)	X			X		X	X	X			X	
Glasgow et al. (2010, 2012)	X		X	X		X	X	X	X			
Hansel et al. (2017)	X	X				X						
Jennings et al. (2014)	X			X			X		X			
Kooiman et al. (2018)	X			X	X	X	X					
Liebreich et al. (2009)	X					X			X		X	
Lorig et al. (2010)	X		X	X		X	X		X			X
Lorig et al. (2016)	X			X								X
Muller et al. (2017)	X			X			X					
Poppe et al. (2019)	X		X	X	X	X	X			X		
Richardson et al. (2010)				X		X	X		X			
Van der Weegen et al. (2015)	X					X		X				

Verwey et
al. (2014)

X

X

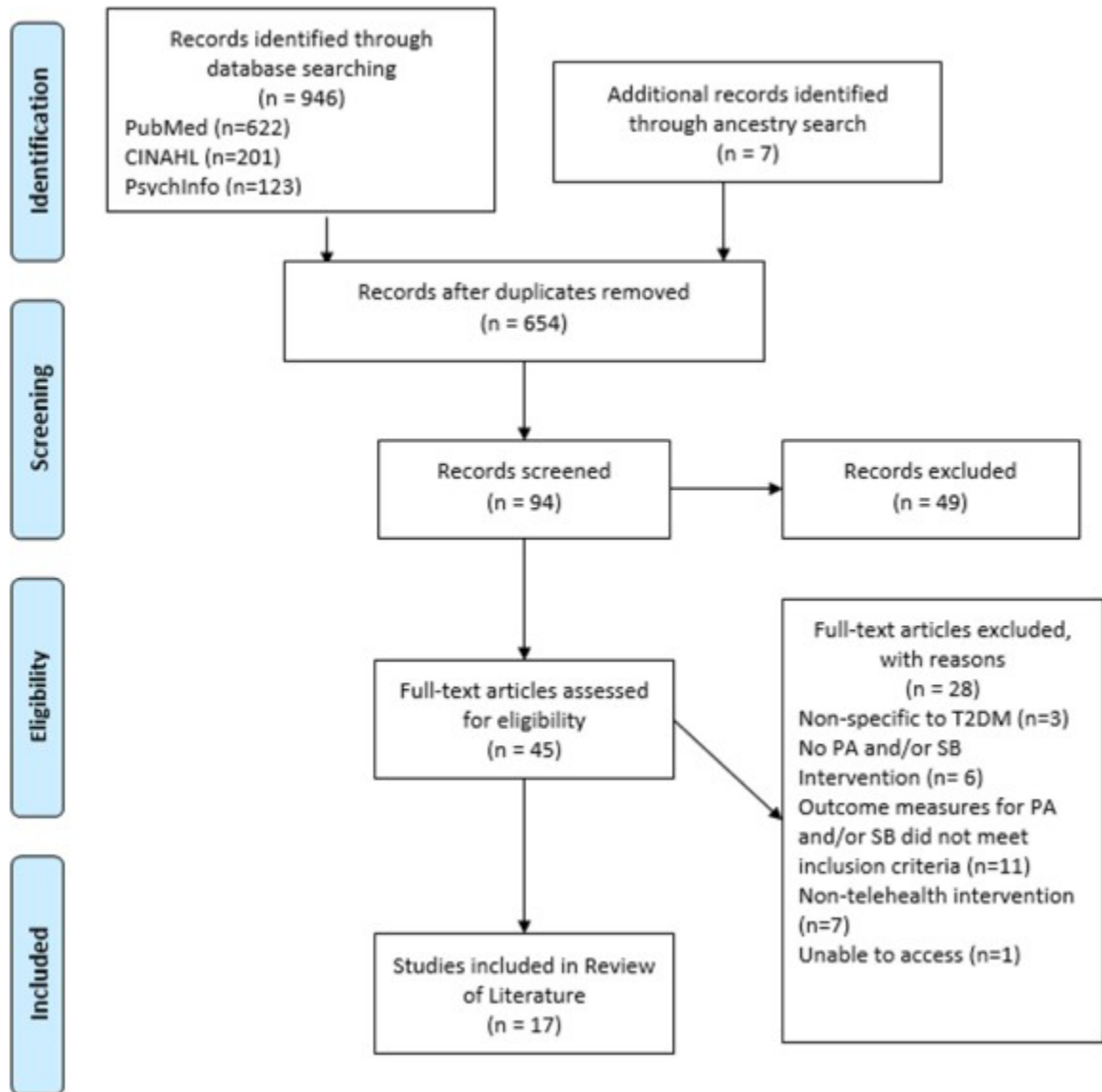
X

Yom-Tov et
al. (2017)

X

Figure 1

PRISMA Flow Diagram



Note. Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA)

diagram detailing the process of study selection (Moher et al., 2009). PA, physical

activity; SB, sedentary behavior; T2DM, type 2 diabetes

CHAPTER THREE

METHODS

The following research proposal is a modified version of the proposal which was submitted to the National Institute of Nursing Research Ruth L. Kirschstein Predoctoral Individual National Research Service Award.

Specific Aims

Type 2 diabetes (T2DM) is a chronic disease process which impacts 34.1 million United States (US) adults and is the 7th leading cause of death (Centers for Disease Control and Prevention [CDC], 2020). Despite continued efforts in diabetes prevention and management the incidence of diabetes continues to increase, with 1.5 million new cases diagnosed in 2018 (CDC, 2020). The estimated cost of diagnosed diabetes is \$327 billion annually in the US (American Diabetes Association [ADA], 2018). Physical activity (PA) is an integral diabetes self-management component to maintain glycemic control which many adults with T2DM struggle to incorporate into their lifestyle (ADA, 2019; ADA, 2021b; ADA, 2021c; Colberg et al., 2016). While strong evidence exists to support increasing PA in adults with T2DM, only 44.2 – 65.1% meet recommended guidelines (ADA, 2021b).

Rural adults are disproportionately affected by T2DM with a 17% higher prevalence rate than urban adults and consistently higher mortality rates (Callaghan et al., 2020; Massey et al., 2010). Unique barriers encountered by rural adults establish a disparate health situation in relation to the availability of diabetes self-management education and health resources compared to urban adults (Bolin et al., 2015a; Bolin et al., 2015b). Telehealth technologies using internet websites and mobile phone applications can be

used to improve access to diabetes self-management education and resources (Bolin et al., 2015a). Web and mobile phone-based PA and sedentary behavior interventions have demonstrated the ability to increase PA and reduce sedentary behaviors in adults with T2DM (Connelly et al., 2013; Connelly et al., 2017; Glasgow et al., 2010; Glasgow et al., 2012; Howland & Wakefield, 2021; Jennings et al., 2014; Kongstad et al., 2019; Kooiman et al., 2018; Liebreich et al., 2009; Mitchell et al., 2019; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015). However, few studies using a web and mobile phone application strategy to deliver a PA and sedentary behavior intervention have been conducted with a clearly integrated theoretical framework making it difficult to identify the mechanisms of behavior change and interpret the resultant outcomes (Howland & Wakefield, 2021). Further, little research has been conducted in rural populations to address the unique barriers experienced and the growing need for rigorous, theory driven interventions in this population (Connelly et al., 2017; Howland & Wakefield, 2021).

Increasing PA and decreasing sedentary behaviors requires a health behavior change for many rural adults with T2DM (ADA, 2019; ADA, 2021b; ADA, 2021c; Colberg et al., 2016). The Health Action Process Approach (HAPA) model integrates cognitive and behavioral constructs along a continuum to predict behavior change and within self-efficacy-based stages, which can be used to guide intervention development (Schwarzer, 2008; Schwarzer et al., 2011). This study evaluated the feasibility and acceptability of a HAPA model structured PA and sedentary behavior self-guided workbook, accelerometer use, and study measures. Four, weekly self-guided workbook modules incorporated the HAPA model as an underlying framework. Study participants

wore a wrist-worn accelerometer to self-monitor PA (steps per day). This study used a descriptive design, collecting data before and after study workbook completion using self-report and objective measures, and open-ended interview questions to evaluate the feasibility and acceptability of recruitment, eligibility criteria, the workbook and accelerometer, attrition, and proposed study measures. Due to the lack of research in this vulnerable and underserved population it is necessary to establish knowledge of feasibility and acceptability to provide evidence for further refinement for the rural adult prior to conducting future studies evaluating study components as an intervention. The purpose of this feasibility and acceptability study was to identify findings to inform future refinement of the self-guided workbook and measures for the intended population prior to testing the efficacy of the refined study components as an intervention and transitioning to a web and mobile phone-based platform.

Aim 1

To evaluate the **feasibility and safety** of a HAPA model guided PA and sedentary behavior self-guided workbook, accelerometer, and study measures in rural adults with T2DM.

Research Questions:

1a. What are the recruitment rates of the study? How long did it take to recruit the targeted number of participants? What challenges were encountered related to recruitment and retention of rural adults with T2DM from primary care clinics? Are eligibility criteria inclusive enough to obtain an adequate sample? What are the attrition rates in the study? Why did participants drop out of the study?

1b. To what extent do the participants adhere to the workbook and accelerometer use? To what extent are study measures completed?

1c. Were there any adverse events or safety problems?

1d. What are the preliminary effects of the workbook and accelerometer on PA, sedentary behavior, and diabetes knowledge?

Aim 2

To evaluate the **acceptability** of a HAPA model guided PA and sedentary behavior self-guided workbook, accelerometer, and study measures in rural adults with T2DM.

Research Questions:

2a. How satisfied were participants with the workbook, accelerometer, and study measures? Would participants continue to use the workbook or accelerometer? Are the workbook, accelerometer, and measures appropriate for rural adults with T2DM?

2b. What challenges did participants have with the workbook, accelerometer, and study measures?

2c. What is the participant time burden to complete the workbook and study measures?

This research study is consistent with the National Institute of Nursing Research's mission to increase knowledge of chronic disease self-management and aligns with the Healthy People 2030 goal to reduce the burden of disease and improve quality of life in people with T2DM. The findings of this study fill a gap in the literature surrounding rural adults with T2DM which is imperative to address as the use of technology to reach rural populations continues to rapidly expand.

Research Strategy

Significance

Impact of Type 2 Diabetes

T2DM is an increasingly common chronic disease process caused by a progressive loss of β -cell insulin secretion combined with cellular insulin resistance that results in abnormal blood glucose levels (ADA, 2021a). Diabetes self-management education, medical nutrition therapy, routine PA, smoking cessation counseling, and psychosocial care are the cornerstone of diabetes self-management, providing the foundational tools necessary to maintain glycemic control (ADA, 2021b). Inadequate self-management of lifestyle factors increases the risk for developing complications of T2DM, such as coronary artery disease, stroke, peripheral vascular disease, retinopathy, nephropathy, and neuropathy (Cannon et al., 2018). In the US, 34.1 million adults are impacted by T2DM (CDC, 2020). In the next 10 years, the number of people diagnosed with T2DM is projected to increase to 55 million (Cannon et al., 2018). The estimated cost of diabetes in the US is \$327 billion annually through direct medical costs and losses in productivity (ADA, 2018).

Diabetes in Rural Populations

Rural adults are disproportionately impacted by T2DM with a 17% higher prevalence rate than urban adults and consistently higher mortality rates (Callaghan et al., 2020; Massey et al., 2010). In addition to being disproportionately impacted by T2DM, rural adults are less likely than urban adults to receive diabetes self-management education (Brown-Guion et al., 2013). Rural adults with T2DM face unique barriers that establish a disparate health situation in relation to availability of diabetes resources

compared to urban adults (Bolin et al., 2015a; Bolin et al., 2015b). Barriers faced by rural adults include health care provider shortages, financial constraints, long travel distances, and lower levels of education and health literacy (Bolin et al., 2015a; Bolin et al., 2015b; Ross et al., 2015).

Physical Activity and Sedentary Behavior in Relation to Type 2 Diabetes

PA is an integral component of the diabetes self-management plan and essential to maintaining glycemic control (ADA, 2019; ADA, 2021b; ADA, 2021c; Colberg et al., 2016). PA is defined as movement produced by skeletal muscles that increases energy expenditure (Bull et al., 2020; ADA, 2021b). Adults with T2DM are recommended to participate in 150 minutes or more of moderate-to-vigorous PA (MVPA) weekly to reduce glycated hemoglobin levels, triglycerides, blood pressure, and insulin resistance (ADA, 2019; ADA, 2021b). PA should be spread over at least 3 days per week, with no more than 2 consecutive days without activity occurring (ADA, 2021b; Bull et al., 2020). Objective measures of PA in adults with T2DM have demonstrated that only 44.2 – 65.1% meet the American Diabetes Association (ADA) recommended guidelines (ADA, 2021b).

Reducing sedentary behavior is a separate, but equally important strategy for maintaining glycemic control (Colberg et al., 2016). Sedentary behaviors require low levels of energy expenditure and occur while lying, reclining, or sitting (Bull et al., 2020; Colberg et al., 2016). Extended bouts of sedentary time are associated with poor glycemic control (Colberg et al., 2016). Additionally, higher amounts of time spent sedentary are associated with increased morbidity and mortality, independent of MVPA participation (Colberg et al., 2016). To improve glycemic control, the ADA recommends reducing

prolonged sedentary bouts with briefs periods of standing or low-intensity walking every 20 – 30 minutes (Colberg et al., 2016). While there is strong evidence to support the roles of increasing PA and reducing sedentary behaviors on glycemic control, many adults with T2DM continue to struggle to meet ADA recommended guidelines (ADA, 2021b).

Use of Telehealth to Improve Access to Resources

To overcome barriers faced by rural adults, telehealth can be used to improve access to diabetes health resources (ADA, 2021c; Bolin et al., 2015a). Telehealth involves the exchange of health information using electronic communication, including the use of internet-based websites and mobile phone applications (Tuckson et al., 2017). While a gap in internet access exists in rural populations, the gap continues to close with 65 - 67% of rural adults having internet access (Martin, 2018). Additionally, households which only had internet access via a mobile phone were more likely to be low-income, Black, and Hispanic (Ryan, 2018). Thus, incorporating a mobile phone-based telehealth platform may help to reach more rural adults, as 71% of rural adults own a smartphone with an internet connection (ADA, 2021b; Massey et al., 2010; Pew Research Center, 2019).

Current State of Research

Web and mobile phone-based interventions have demonstrated the ability to increase PA, decrease sedentary behaviors, and improve glycemic control in adults with T2DM (Connelly et al., 2013; Connelly et al., 2017; Glasgow et al., 2010; Glasgow et al., 2012; Howland & Wakefield, 2021; Jennings et al., 2014; Kongstad et al., 2019; Kooiman et al., 2018; Liebreich et al., 2009; Mitchell et al., 2019; Poppe et al., 2019; Richardson et al., 2010; Van der Weegen et al., 2015). When included, sedentary

behavior is rarely addressed independent of PA (Howland & Wakefield, 2021; Poppe et al., 2019). Self-report is the most common outcome measurement method for PA and sedentary behavior, with few studies using both self-report and objective measures for PA and sedentary behavior (Jennings et al., 2014; Poppe et al., 2019). It is integral to use a combined outcome measurement approach with both self-report and objective measures for PA and sedentary behavior to obtain accurate activity information and contextual information about the modes and domains in which activities occur. A relationship between studies with strong methodology and significant outcomes has been identified, but there has been little exploration into intervention design or outcome measures, including the role of theory in intervention development or the quality of outcome measures used (Connelly et al., 2013; Howland & Wakefield, 2021; Kongstad et al., 2019). Little research has been conducted in rural populations to gain insight into the feasibility or acceptability of such interventions (Connelly et al., 2017; Howland & Wakefield, 2021).

While a plethora of T2DM and PA mobile phone applications exist on the consumer market, few are based in health behavior change theory, tailored to adults with T2DM, or subjected to rigorous testing prior to release. In a review of diabetes related digital health tools, 4 out of 35 mobile phone applications included a PA or exercise component (Doyle-Delgado & Chamberlain, 2020). Only 1 mobile phone application, *MyFitnessPal*, utilized custom goal setting for PA and community support features (Doyle-Delgado & Chamberlain, 2020). The European Association for the Study of Diabetes and the ADA Diabetes Technology Group have issued a call for researchers to

develop, validate, and openly share evidence based mobile phone applications and patient outcomes data (Fleming et al., 2020).

Theoretical Framework

The HAPA model integrates cognitive and behavioral constructs along a continuum to predict health behavior change and within self-efficacy-based stages to guide targeted health behavior change (Schwarzer, 2008; Schwarzer et al., 2011). Viewing the HAPA model constructs along a continuum provides a framework for how behavioral intention is developed, behaviors are planned, and actions are carried out and maintained (Schwarzer, 2008; Schwarzer et al., 2011). Grouped within self-efficacy-based stages, the HAPA model constructs provide insights into the distinct mindsets experienced when implementing a health behavior change (Schwarzer, 2008; Schwarzer et al., 2011). By operationalizing constructs of the HAPA model, a comprehensive health behavior change intervention can be developed which bridges the intention-behavior gap and provides a framework for sustained health behavior change in adults with T2DM (see Table 4 and Figure 2; Rohani et al., 2018; Schwarzer, 2008; Schwarzer et al., 2011).

Table 4

Key Constructs and Definitions of HAPA Model

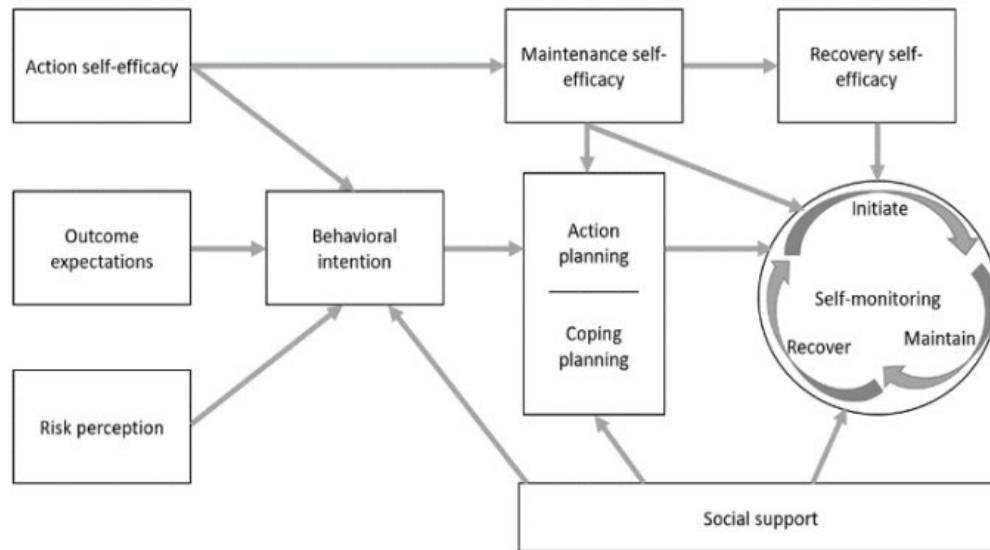
HAPA Model Construct	Definition
Action Self-Efficacy	The belief necessary skills are possessed to increase PA and decrease sedentary behavior.
Outcome Expectancy	Expectations about health outcomes if PA increased and sedentary behavior decreased.
Risk Perception	Perceived health outcome risk if PA and sedentary behaviors are not changed.
Behavioral Intention	Commitment to increase PA and decrease sedentary behaviors.
Maintenance Self-Efficacy	The belief that barriers to making PA and sedentary behavior changes can be overcome.
Action Planning	Logistic planning to make change.
Coping Planning	Planning for anticipated barriers.
Recovery Self-Efficacy	The belief in the ability to overcome failures and recover from setback.

Social Support A resource which enables adoption of health behavior change.

Note. (Schwarzer, 2008; Schwarzer et al., 2011)

Figure 2

Model of Physical Activity Behavior Change in Rural Adults with Diabetes



Note. (Schwarzer, 2008; Schwarzer et al., 2011)

Innovation

This feasibility and acceptability study represents an innovative design, including a self-guided workbook with full theoretical construct incorporation from the HAPA model, which will provide a rich understanding of the mechanisms of health behavior change and framework for interpreting the resultant outcomes in future studies. Focusing on an underserved population of rural adults and using a combined outcome measurement approach (i.e., both PA and sedentary behavior) provided invaluable evidence to the existing body of literature. This study provided support for the potential to reach a diverse population of patients, which can improve health behaviors by increasing PA and reducing sedentary behaviors, improve glycemic control, and reduce the burden of T2DM improving patient outcomes. The significant number of adults not meeting PA guidelines

requires the development of interventions specific to PA health behavior change in T2DM. Due to the lack of theory driven health behavior change PA and sedentary behavior interventions in this population and increasing demand for web and mobile phone-based interventions, the need for rigorous development and evaluations of proposed study components is imperative prior to testing the efficacy of the study components as an intervention.

Approach

Study Design

The proposed study used a descriptive design evaluating the feasibility and acceptability of a self-guided workbook which integrated concepts of the HAPA model to increase PA and decrease sedentary behaviors (developed by the primary investigator [PI]), accelerometer use, and proposed measures in rural adults with T2DM. Assessing feasibility is indicated when there is uncertainty about whether study components can be used in a future intervention study (Eldridge et al., 2016). The Conceptual Framework of Feasibility Studies was used to guide the methodological design of this proposed study (Eldridge et al., 2016). Research questions were developed based on broad feasibility study classification categories of process, resource, and scientific outcomes (Thabane et al., 2010). The purpose of this study was to provide evidence to further refine the study components for rural adults prior to conducting a future study to evaluate the proposed study components as an intervention. Due to the dearth of research using web and mobile phone-based platforms to deliver theory-based PA interventions in rural adults with T2DM, it is essential to conduct preliminary research prior to transitioning to a web and

mobile phone-based delivery platform. Feasibility and acceptability were measured using self-report and objective measures, and open-ended interviews with participants.

Setting and Sample

Rural residence in Illinois was determined by participants residential address within a community defined as rural in the Jersey Community Hospital (JCH) Community Needs Assessment Report (Jersey Community Hospital Community Health Needs Assessment Working Group, 2019). Participants were recruited from a Jersey Community Hospital Medical Group (JCHMG) primary care clinic associated with JCH, a rural critical access hospital in Southwest Illinois. The JCH service area is comprised of approximately 1,008 square miles with a population of approximately 91,183 (90 people per square mile; Jersey Community Hospital Community Health Needs Assessment Working Group, 2019). Residents in the catchment area of JCH report 26.8% participate in no PA (Illinois average is 22%) and 11.5% of residents have diabetes (Illinois average is 10.2%; Jersey Community Hospital Community Health Needs Assessment Working Group, 2019). The Illini clinic is the largest primary care clinic in the region with 10 primary care providers (PCP) (7 physicians, 1 physicians' assistant, and 2 nurse practitioners) and was the primary recruitment site. For this study, a convenience sample of rural community dwelling adults was obtained. The planned study sample size was 15 participants to allow for adequate safety and adverse event identification and provide preliminary recruitment evidence (Polit & Beck, 2017). Due to a consent rate of 60 – 75% in similar studies, a minimum of 25 participants were planned to be approached for study enrollment (Connelly et al., 2017; MacPhail et al., 2014).

Inclusion/Exclusion Criteria

Prior to study inclusion, participants were screened via self-report using an eligibility inclusion checklist with inclusion and exclusion criteria. For this sample, inclusion criteria included (1) diagnosed with T2DM, (2) rural community dwelling residence within a rural community defined by the JCH Community Needs Assessment, (3) aged 18 – 75 years old, (4) able to speak, read, and write in English, (5) not meeting ADA guidelines of 150 minutes per week of MVPA, (6) able to increase PA without restrictions per their PCP risk assessment screening, and (7) having a PCP associated with JCHMG. Exclusion criteria included (1) being diagnosed with type 1 or gestational diabetes mellitus and (2) cognitive impairment.

Subject Recruitment and Retention

For the study duration, the PI met with PCPs and staff at JCHMG to identify potential participants scheduled for routine clinic visits during the following four weeks using basic inclusion criteria (aged 18 – 75 years old, T2DM, no PA restrictions, rural residence). The PI mailed a letter signed by the PCP and PI describing the study and inviting participation of potential participants. The letter included a copy of the consent form and a stamped postcard for the patient to return indicating they were not willing to participate in the study (opt-out approach). Study flyers were placed in the primary care clinic waiting area and patient care rooms. Additional participants not identified prior to the visit, but who met basic inclusion criteria had contact information provided by the PCP to the PI. Social media platforms (i.e., Facebook) were used to recruit potential participants by placing an add targeted towards rural adults with T2DM who had a PCP

at JCHMG, with a phone number and email address to contact the PI for study recruitment (Herbell & Zauszniewski, 2018).

After the participants scheduled routine clinic visit, the PI contacted participants who have not declined, described the study in more detail, obtained verbal consent for participation, completed an eligibility screening checklist, and scheduled an initial meeting. Participants had the option to meet with the PI after their routine clinic visit at the JCHMG clinic. The Six-item Screen to Identify Cognitive Impairment among Potential Subjects for Clinical Research was used to screen for cognitive impairment (Callahan et al., 2002). The instrument has high sensitivity (88.7%) and specificity (88%) to identify cognitive impairment in adults (Callahan et al., 2002). A cut-point of 3 missed answers was applied to determine study eligibility (Callahan et al., 2002). Potential participants screened who did not meet inclusion criteria were thanked and their contact information was destroyed. The PCP notified the PI if a potential participant was no longer eligible to participate due to PA restrictions.

A mutually agreeable time and space for an initial visit was identified between the participant and PI. Social distancing precautions were maintained, and personal protective equipment was provided to the participant by the PI. Participants who were not comfortable meeting in-person had the option to meet virtually using Zoom videoconferencing technology. Participants received compensation, a Visa gift card, by mail at the end of the study or upon withdrawal from the study after returning the self-guided workbook, accelerometer, and charging devices by mail with a pre-paid envelope. To encourage participant retention, compensation was based on the following guidelines: \$5 for completing baseline questionnaires and workbook module 1, \$10 for workbook

module 2, \$10 for workbook module 3, and \$15 for workbook module 4, completing post-study questionnaires, and returning the self-guided workbook, accelerometer, and charging devices.

Self-Guided Workbook

The study evaluated a self-guided workbook which integrated the HAPA model to provide a framework for behavior change. The workbook was developed by the PI prior to participant recruitment using Community Based Participatory Research (CBPR) methods. Workbook content was consistent with the Association of Diabetes Care and Education Specialists Diabetes Care and Education Curriculum (3rd edition) and ADA Exercise and Diabetes Clinician's Guide (Association of Diabetes Care and Education Specialists [ADCES], 2021; Colberg et al., 2013). Results of this study will lead to future revisions and reassessments of feasibility. The HAPA model framework was used to structure the workbook, with participants progressing through the three HAPA model self-efficacy-based stages in four weekly modules.

Workbook Development. A CBPR approach was used to develop the self-guided workbook. The PI collaboratively developed the self-guided workbook with a Community Advisory Board (CAB) consisting of two rural community members, two rural community health workers, and a rural primary care physician. The PIs PhD committee members, who have CBPR, diabetes, patient education, and rural health expertise provided oversight and input into the workbook development. The broad learning goals of the workbook were to (1) develop and reinforce general T2DM self-management knowledge, (2) understand the relationship between PA, sedentary behavior, and T2DM, (3) evaluate personal facilitators and barriers to making a lifestyle change,

(4) identify how to safely increase PA, (5) develop a plan for behavior change, (6) evaluate progress towards goals, and (7) identify social support resources. See table 5 for workbook goals and objectives.

Table 5

Workbook Broad Goals and Learning Objectives

Broad Goals	Learning Objectives
Developing and reinforcing general T2DM self-management knowledge.	Demonstrate general knowledge of T2DM Define diabetes self-management activities Explain the role of self-monitoring in diabetes
Understanding the relationship between physical activity, sedentary behavior, and T2DM.	Describe the benefits of physical activity on diabetes Describe the effects of sedentary behaviors on diabetes
Evaluate personal facilitators and barriers to making a lifestyle change.	Identify personal benefits and drawbacks of engaging in more PA Describe personal skills and resources to support engaging in more PA Identify personal benefits and drawbacks of reducing time spent sedentary Describe personal skills and resources to support reducing time spent sedentary Identify things you need before being active.
Identify how to safely increase physical activity	Describe PA safety and symptoms to report to your healthcare provider Describe the importance of self-monitoring blood sugar before and after being physically active and what to do if it is too high or too low Identify strategies to prevent low blood sugar when physically active Review precautions to take if taking insulin when increasing activity Compare current behaviors with healthier behaviors Identify physical activities that fit your lifestyle
Develop a plan for behavior change	Choose one physical activity to do Identify strategies to reduce time spent sedentary Choose one strategy to reduce time spent sedentary Develop an action plan for behavior change Identify barriers for behavior change Create a list of solutions for identified barriers
Evaluate progress towards goals.	Make use of the logbook to self-monitor behavior changes Evaluate progress towards goals Identify needed changes to action plan for behavior change
Identify social support resources.	Describe the role of social support on diabetes self-management performance Identify one source of social support that is a friend or family member <u>Identify one source of social support in your community</u>

Two rural community needs assessment reports which serve overlapping rural communities located in Southwestern Illinois were evaluated to identify priority community needs. Identified priority community needs included a need for improved

access to endocrinology specialists services and a need for education addressing diabetes, specifically the need for exercise at all ages (Carlinville Area Hospital, 2019; Jersey Community Hospital Community Health Needs Assessment Working Group, 2019). The CAB provided additional insights into the unique needs of rural adults with T2DM and provided feedback about the appropriateness of the workbook. Existing community strengths and resources, such as community recreational areas, fitness centers, and health department programs were built upon with the study workbook. Feedback from the CAB was sought and integrated during all points of the research study, to establish and facilitate a collaborative, equitable partnership, empowering rural community members. Study findings will be disseminated to members of the CAB and rural community members through local newsletters and at community meetings in the future.

With input from CAB members integrated, the workbook was reviewed for clarity, readability, validation of concepts, and appropriateness for rural adults with T2DM. Content experts, including a certified diabetes educator (CDE), a primary care provider, and the PIs PhD committee members, as well as, two lay persons, rural adults, validated concepts, clarity, readability, and appropriateness for rural adults. The content experts and lay persons provided comments and suggestions for the workbook.

In addition, readability was evaluated using the Flesch Kincaid Reading Ease Score and Flesch Kincaid Grade Level. The workbook was written for low-literacy level adults, to accommodate the diverse needs of rural adults with T2DM. Workbook content was written using clear and simple, plain language at a 4th to 6th grade reading level (National Institute of Health, 2018). The Flesch Kincaid Reading Ease Score measures readability on a scale of 1 to 100, with higher values indicating easier readability (Jindal

et al., 2017). A value of 80 – 100 indicates a readability level equivalent to a 4th to 6th grade reading level (Jindal et al., 2017). The Flesch Kincaide Grade Level measures readability based on United States grade level (Jindal et al., 2017). Both the Flesch Kincaid Reading Ease Score and Flesch Kincaide Grade Level demonstrate convergent validity and high reliability ($\alpha=.95 - .96$; Jindal et al., 2017).

After an iterative review and development process involving the CAB and PhD committee members, the workbook and accelerometer was pilot tested with a rural adult with T2DM. Pilot testing involved completing the 4 weekly workbook modules and using an accelerometer for self-monitoring. At the end of the pilot testing period, the participant provided comments and suggestions to improve the workbook. The PI presented pilot information to the CAB and PhD committee to refine the workbook, prior to feasibility and acceptability testing.

Workbook Content. Each weekly module included three stages, “Think”, “Plan”, and “Do” to address the three HAPA model self-efficacy-based stages. Stage 1 “Think” began with participants taking a personal risk assessment quiz about PA and sedentary behavior, followed by education materials, and ending with a self-reflection. Activities performed in Stage 1 “Think” were enhanced by action self-efficacy, leading to the development of behavioral intention. Stage 2 “Plan” provided activities to identify effective behavior change techniques, develop personalized goals using a S.M.A.R.T. (specific, measurable, achievable, relevant, and time-bound) framework, and activities to identify barriers and solutions. Stage 2 “Plan” activities were enhanced by maintenance self-efficacy. Stage 3 “Do” focused on performance of new behaviors, self-monitoring, self-reflection of progress, and identification of social support resources. Recovery self-

efficacy enhanced performance of Stage 3 “Do” activities. See Table 6 for HAPA model construct operationalization within the self-guided workbook.

Table 6

Health Action Process Approach (HAPA) Model Construct Operationalization

Construct	Health Action Process Approach Model Based Stages		
	Think	Plan	Do
Risk Perception	Risk assessment quiz, education, and self-reassessment.	---	---
Outcome Expectancies	Education focused on benefits of making health behavior changes. Pros/cons activity. Personal skills assessment.	---	---
Action Self-Efficacy	Education about how to incorporate PA and SB changes into lifestyle.	---	---
Behavioral Intention	---	Health behavior change education.	---
Action Planning	---	Development of action plan using S.M.A.R.T. format.	---
Coping Planning	---	Barrier and solution identification activity.	---
Maintenance Self-Efficacy	---	Health behavior change education. Development of action and coping plans.	---
Recovery Self-Efficacy	---	---	Logbook for self-monitoring. Self-reflection activity.
Social Support	---	---	Education about identifying social support resources

Note. Physical activity (PA); Sedentary Behavior (SB); Specific, measurable, achievable, relevant, and time-bound (S.M.A.R.T; Schwarzer, 2008; Schwarzer et al., 2011)

Instructions about how to safely increase PA in adults with T2DM included education about the benefits of being active on glycemic control, cardiovascular disease risk, blood pressure, weight loss, and emotional state and mood (ADCES, 2021). The workbook used a lifestyle approach focus to increase PA, with education and examples of PA (ADCES, 2021; Colberg et al., 2013). Education about safety precautions included

seeking medical clearance when increasing PA to levels greater than brisk walking, foot screening and safety, checking blood glucose levels before and after PA, prevention of hypo- and hyperglycemia related to diabetes medications, and the treatment of hypoglycemia (ADCES, 2021; Colberg et al., 2013). The PI consulted the CDE if issues arose or there were concerns about participants safety during PA.

As a reminder to complete the weekly workbook module, participants received a weekly telephone call or text message on the day of their choice. During the initial visit, participants were provided with the workbook and an accelerometer and trained in their use. Participants who chose to meet virtually would have the workbook and accelerometer mailed to them prior to the initial visit. After one week, the PI called the participant to answer any questions related to completing the workbook and use of the accelerometer device.

Timing of Measures

Table 7 provides a for timeline of measure completion.

Table 7

Timeline for Measure Completion

	Week 0 (Baseline)	Weeks 1 – 4 (Self-Guided Workbook)	Week 5 (Post-Study)	Week 9 (Follow-up)
Measures	Demographic, HBPAI, S4- MAD, DKT2 IPAQ-L, MSQ	Accelerometer (Actigraph GT9X Link)	HBPAI, S4- MAD, DKT2 IPAQ-L, MSQ, Feasibility, Acceptability, Telephone Interview	HBPAI, S4- MAD, DKT2 IPAQ-L, MSQ

Note. DKT2: Revised Diabetes Knowledge Test; HBPAI: Health Action Process

Approach Based Physical Activity Inventory; IPAQ-L: International Physical Activity

Questionnaire-Long Version; MSQ: Marshall Sitting Questionnaire; S4-MAD: Social Support Scale for Self-care in Middle Aged Patients with Type 2 Diabetes (Craig et al., 2003; Fitzgerald et al., 2016; Marshall et al., 2010; Michigan Diabetes Research Center, 2015; Naderimagham et al., 2012; Rohani et al., 2016)

During the initial visit, the PI demonstrated how to access the baseline questionnaires using the Qualtrics system used at the University of Missouri (MU) and provided the participant with a hard copy of instructions. Participants completed the Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF) with the PI during the initial meeting. After completion of the 4-week self-guided workbook (Week 5), the participant received instructions via email, text, or telephone call and mail to complete the post-study questionnaires using Qualtrics. The participant received a pre-paid envelope to return the self-guided workbook, Actigraph GT9X Link, and charging devices week 5. One-month post-study (Week 9), participants received instructions via email, text, or telephone call and mail to complete follow-up questionnaires using Qualtrics. Participants who did not feel comfortable completing an electronic survey were provided with a hard copy of the study questionnaires (in-person or via mail) and an envelope with pre-paid postage to return them after completion.

Demographic Variables

Demographic variables (age, gender, race, ethnicity, number of years living with T2DM, diabetes medications, co-existing diseases, height, weight, body mass index, education, working status, and exposure to others with diabetes) were measured using an investigator developed questionnaire (see Appendix; U.S. Census Bureau, 2016; U.S. Census Bureau, 2017a; U.S. Census Bureau, 2017b). The REALM-SF is a 7- item

questionnaire measuring health literacy in adults (Table 8; Arozullah et al., 2007). The Environmental Supports for Physical Activity questionnaire is a 11-item tool measuring social and physical environmental factors that influence PA (Ainsworth et al., 2002). Including the identified demographic variables was necessary to acknowledge the complexity of PA and sedentary behavior change in rural adults with T2DM (MacKinnon, 2011).

Table 8

Study Constructs, Variable Operationalization and Instrument Validity and Reliability

Construct	Source/Instrument	Variable Operationalization
<i>Demographic Variables & Measures</i>		
Health Literacy Level	Self-report, REALM-SF	Concurrent validity, criterion validity Reliability ($\rho = 0.94$)
Environmental Supports for Physical Activity	Self-report, Social and Physical Environment Survey	Content validity Reliability ($\rho = 0.36 - 0.74$)
<i>Study Variables & Measures</i>		
Risk perception	Self-report, HBPAI	Content validity, face validity, construct validity ($\chi^2 = 3.21, df = 3, p = .38$) Reliability ($\alpha = 0.91$)
Outcome expectancies	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.93$)
Action self-efficacy	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.92$)
Behavioral intention	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.63$)
Action and Coping planning	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.97$)
Maintenance self-efficacy	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.90$)
Recovery self-efficacy	Self-report, HBPAI	Content validity, face validity, construct validity Reliability ($\alpha = 0.65$)
Social Support	Self-report, S4-MAD	Construct validity (relative $\chi^2 = 2.03, p < .001$) Reliability ($\alpha = 0.94$)

Diabetes Knowledge	Self-report, DKT2	Content validity Reliability ($\alpha = .77$)
Total time and domain specific physical activity	Self-report, IPAQ-L	Criterion validity ($\rho = 0.55 - 0.71$) Reliability ($\rho = 0.81$)
Total time and domain specific time spent sedentary	Self-report, MSQ	Criterion validity ($\rho = 0.15 - 0.74$) Reliability ($\rho = 0.23 - 0.84$)
Feasibility & Acceptability		
Feasibility	Self-report, various; Objective, wrist worn <i>accelerometer</i>	<i>Process</i> : recruitment, eligibility criteria, attrition rates, workbook, accelerometer, and study measures adherence; <i>Resource</i> : process time; <i>Scientific</i> : adverse events or safety problems and preliminary effects
Acceptability	Self-report, questionnaire; Telephone interview, Open-ended questions	Satisfaction, intent to continue to use, and perceived appropriateness, challenges, time burden

Note. (Ainsworth et al., 2002; Arozullah et al., 2007; Craig et al., 2003; Hagströmer et al., 2006; Fitzgerald et al., 2016; Marshall et al., 2010; Michigan Diabetes Research Center, 2015; Naderimagham et al., 2012; Polit & Beck, 2017; Rohani et al., 2016; Rosenburg et al., 2008; Thabene et al., 2010)

Study Variables and Measures

The HAPA model variables include risk perception, outcome expectancies, action self-efficacy, behavioral intention, action planning, coping planning, maintenance self-efficacy, recovery self-efficacy, and social support (Schwarzer, 2008; Schwarzer et al., 2011). The **HBP**AI was used to measure all model variables, except social support (Rohani et al., 2016). The HBPAI is a 34-item questionnaire measuring model constructs with a seven-point Likert scale (Rohani et al., 2016). Social support was measured using 5 items about PA from the **S4-MAD**, on a five-point Likert scale (Naderimagham et al., 2012).

Diabetes knowledge was measured using the **DKT2** (Fitzgerald et al., 2016; Michigan Diabetes Research Center, 2015). The **DKT2** is a 23-item multiple choice questionnaire measuring general diabetes knowledge in adults with T2DM (Fitzgerald et al., 2016; Michigan Diabetes Research Center, 2015). Diabetes knowledge domains measured included diet, exercise, glucose monitoring, causes and management of hypo- and hyperglycemia, insulin, foot care, acute and chronic complications of diabetes, and sick day management (Michigan Diabetes Research Center, 2015). Fourteen items from the **DKT2** were measured, as they are appropriate for all adults with T2DM (Michigan Diabetes Research Center, 2015).

The **Actigraph GT9X Link** (Actigraph, LLC) was worn by participants on their non-dominant wrist for the study duration, removing only for bathing or swimming. The device was activated by the PI during the initial visit or prior to being mailed to participants who chose to meet virtually. Using the Actigraph GT9X Link participants accessed their steps per day for self-monitoring activities while completing the self-guided workbook by viewing the watch face. Wear-time compliance was measured for the duration of the study using the devices wear-time sensor. Data were reported for steps taken, levels of PA, bouts of PA, total PA, bouts of sedentary time, and total time spent sedentary. Participant data which met the minimum wear time of 10 hours per day on 4 days of the week, including 1 weekend day, were reported (Miguelles et al., 2017). Participants received training and written step-by-step instructions to charge the accelerometer weekly for 3 hours using the charging devices provided. Participants received a weekly text message or email reminder to charge and wear the accelerometer. The PI downloaded data to a secured server accessible through the ActiLife analysis

software (ActiGraph, LLC) after receiving returned devices from study participants. While the Actigraph GT9X Link has a feature for participants to transmit data via Bluetooth, it requires additional devices and software, downloading data directly from the devices is more feasible and realistic given the scope of this study. In future studies, the Actigraph GT9X Link will be used to objectively measure PA and sedentary behavior.

The **IPAQ-L** assessed self-reported habitual PA in the past 7 days, within four domains (transportation, work-related, household, and leisure time) using a 25-item questionnaire, as duration in minutes and frequency in days for moderate-intensity and vigorous-intensity activity levels (Craig et al., 2003). Domain and activity level specific sub-scores were calculated (IPAQ, 2005). The **MSQ** assessed self-reported sedentary behaviors in five domains: travel, work, watching television, using a computer at home, and leisure-time other than watching television (Marshall et al., 2010). Participants reported sedentary behaviors as minutes per day on weekdays and weekend days for the five domains (Marshall et al., 2010). In this study, the IPAQ-L and MSQ provided context for interpretation of other data and allowed the PI to gain experience with the measures for use in subsequent studies.

Feasibility and Acceptability

Feasibility was assessed by evaluating *Process* (recruitment rates, length of time and challenges encountered during recruitment, eligibility criteria, self-guided workbook and accelerometer adherence, completion of study measures and rates of missing data, attrition rates, reasons for attrition and characteristics of those who leave the study), *Resource* (process time), and *Scientific* (adverse events or safety problems and preliminary effects) outcomes (Polit & Beck, 2017; Thabene et al., 2010). Workbook

adherence was measured by the PI by calculating the percentage of the workbook completed. Participants who dropped out of the study were contacted via telephone to identify the reason for dropping out.

Acceptability was assessed using an investigator developed questionnaire to evaluate satisfaction, intent to continue to use, and perceived appropriateness of the self-guided workbook and accelerometer; satisfaction and perceived appropriateness of study measures was obtained. A post-study telephone interview about satisfaction, intent to continue to use, perceived appropriateness, and challenges faced using the self-guided workbook, accelerometer, and study measures provided additional qualitative data to provide context to the acceptability self-report questionnaire. Participant contact field notes collected by the PI provided additional context to challenges encountered during the study. Time burden to complete the self-guided workbook and study measures was collected via self-report (Polit & Beck, 2017).

Data Management Plan

All data collected during the study were stored in OneDrive, a cloud based, secure data storage platform supported by MU. Data obtained from questionnaires were de-identified using participant identification (ID) codes and exported to an Excel spreadsheet. Participants were contacted via telephone to clarify missing or unclear data. Telephone interviews were audio recorded and transcribed verbatim (Polit & Beck, 2017). All study data were de-identified using participant ID codes to ensure privacy and confidentiality. All document hard copies and written notes were stored in a secure, locked file cabinet which only the PI has access to. All study files were kept according to MU policies and publication of manuscripts.

Data Analysis Plan

All quantitative data were analyzed using the SPSS Version 27 (IBM, Corp) by the PI under the guidance of University of Missouri statisticians. During the pre-analysis phase, missing data were coded (Polit & Beck, 2017). Patterns of missing data were analyzed to determine risk of bias (Polit & Beck, 2017). Descriptive statistics were generated and used to analyze participant characteristics, feasibility, and acceptability. See table 9 for planned data analysis. Qualitative descriptive thematic analysis methods were used to identify themes and patterns specific to acceptability from participant interviews and PI field notes (Polit & Beck, 2017). During analysis, qualitative data were integrated with quantitative data to provide additional context, depth, and breadth to result interpretation.

Table 9

Data Analysis Plan by Research Question

Research Question	Analysis Plan
Aim 1: Feasibility and Safety	
1a. What are the recruitment rates of the study?	Number of participants enrolled divided by the number approached
1a. How long did it take to recruit the targeted number of participants?	Time in days to reach targeted enrollment number of 15 participants
1a. What challenges were encountered related to recruitment?	Qualitative descriptive analysis of PI field notes
1a. Are eligibility criteria inclusive enough to obtain an adequate sample?	Number of participants eligible divided by the number of patients at clinic
1a. What are the attrition rates in the study?	Number of participants enrolled who complete baseline and post-study measures divided by the number enrolled
1a. Why did participants drop out of the study?	Qualitative descriptive analysis from follow-up interview
1b. To what extent do the participants adhere to the workbook and accelerometer use?	Percent of workbook completed; Wear-time compliance of accelerometer
1b. To what extent are study measures completed?	Percent of measures completed; Rates of missing data
1c. Were there any adverse events or safety problems?	Total reported; Number of participants who reported an adverse event or safety problem divided by the number of participants enrolled
1d. What are the preliminary effects of the workbook and accelerometer on PA, sedentary behavior, and T2DM knowledge?	Evaluate measures of central tendency (mean, median, standard deviation), compare means (Friedman's Test),

calculate approximate effect sizes (Wilcoxon Signed Rank Test, r), and 95% confidence intervals

Aim 2: Acceptability	
2a. How satisfied were participants with the workbook, accelerometer, and study measures?	Number of participants indicating high satisfaction divided by total number of participants; qualitative descriptive analysis of interview
2a. Would participants continue to use the workbook or accelerometer?	Number of participants rating high continue to use divided by the total number of participants; qualitative descriptive analysis of interview
2a. Are the workbook, accelerometer, and measures appropriate for rural adults with T2DM?	Number rating high for appropriateness divided by total number of participants; qualitative descriptive analysis of interview
2b. What challenges did participants have with the workbook, accelerometer, and study measures?	Qualitative descriptive analysis of interview and PI field notes
2c. What is the participant time burden to complete the workbook and study measures?	Report participant time spent completing the workbook, questionnaires, and post-study telephone interview

Limitations

The small sample size and use of convenience sampling for this preliminary feasibility and acceptability study limited generalizability of the findings. Using Zoom videoconferencing technology as an alternative communication method may have influenced participants willingness to enroll in the study. There was a potential that seasonal changes in weather influenced participants to a greater extent than the self-guided workbook. Repeated testing with self-report measures may have had a carryover effect and could have influenced the participants' responses on the post-study questionnaires. Participants may have under or over-report PA and time spent sedentary on self-report measures. Alternative approaches including a qualitative study with focus groups to develop workbook content was considered. However, due to the availability of established diabetes self-management and PA clinical guidelines qualitative focus groups solely to develop workbook content was excluded.

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Appendix

Study Measures

Six-Item Screen to Identify Cognitive Impairment among Potential Subjects for Clinical Research

Instructions: I would like to ask you some questions that ask you to use your memory. I am going to name three objects. Please wait until I say all three words, then repeat them.

Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat these words for me: APPLE-TABLE-PENNY. (Interviewer may repeat names 3 times if necessary but repetition not scored.)

Did patient correctly repeat all three words?

Yes

No

Question	Incorrect (0)	Correct (1)
What year is this?		
What month is this?		
What is the day of the week?		
What were the three objects I asked you to remember?		
Apple		
Table		
Penny		

Evaluation of Screening:

Time taken to complete questionnaire: _____ minutes

Did you have any difficulty understanding any of the questions you were asked: Yes

No

If yes, which questions were difficult to understand: _____

How could these questions have been asked so they were clearer to you?

Demographic Questionnaire

1. What is your age in years? _____ years

2. What is your sex?
 - Female
 - Male
 - I prefer not to respond

3. What is your race? Do you consider yourself... (You can select more than one option)
 - American Indian or Alaska Native
 - Asian
 - Black or African American
 - Native Hawaiian or Other Pacific Islander
 - White

4. Are you of Hispanic or Latino origin?
 - Hispanic or Latino
 - Not Hispanic or Latino
 - Don't know/not sure

5. How many years have you lived with type 2 diabetes? _____ years

6. Do you take any of the following diabetes medications? (You can select more than one option)
 - Injectable Insulin
 - Other Injectable Blood Sugar Lowering Medication
 - Oral Blood Sugar Lowering Medication
 - Other: _____

7. Other than type 2 diabetes, do you have any other health problems? Please list other health problems that you live with.

8. What is your weight in pounds? _____ lbs

What is your height in feet and inches?

9. Which one of the statements below best describes your highest level of education obtained?

No schooling completed

Nursey School

Grades 1 through 11

12th grade – no diploma

Regular high school diploma

GED or alternative credential

Some college credit, no degree

Associate's degree

Bachelor's degree

Master's degree

Professional degree beyond bachelor's degree

Doctorate degree

10. Which one of the statements below best describes your working status?

Employed

Unemployed

Retired

Other: _____

11. Do you have family or friends living with type 2 diabetes?

Evaluation of Form:

How long did it take you to complete the questionnaire? _____ minutes

Did you have any difficulty understanding any of the questions you were asked: Yes

No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Environmental Supports for Physical Activity Questionnaire

I will be asking you some questions about the neighborhood in which you live, followed by some questions about the community in which you live. For the purposes of this interview, neighborhood is defined as the area within one-half mile or a ten-minute walk from your house and community is defined as a 5-mile or 10-minute drive from your house.

1. In general, would you say that people in your neighborhood are...

- Very physical active
- Somewhat physically active
- Not very physically active
- Not at all physically active
- Don't Know/Not Sure
- Refused

2. Overall, how would you rate your neighborhood as a place to walk? Would you say...

- Very pleasant
- Somewhat pleasant
- Not very pleasant
- Not at all pleasant
- Don't Know/Not Sure
- Refused

3. For walking at night, would you describe the street lighting in your neighborhood as...

- Very good
- Good
- Fair
- Poor

Very poor

Don't Know/Not Sure

Refused

4. How safe from crime do you consider your neighborhood to be? Would you say...

Extremely safe

Quite safe

Slightly safe

Not at all safe

Don't Know/Not Sure

Refused

5. Generally speaking, would you say most people in your neighborhood can be trusted?

Yes

No

Don't Know/Not Sure

Refused

6. Does your neighborhood have any sidewalks?

Yes

No

Don't Know/Not Sure

Refused

7. Do you use any private or membership only recreation facilities in your community for physical activity?

Yes

No

My community does not have these facilities

Don't Know/Not Sure

Refused

8. Do you use walking trails, parks, playgrounds, sports fields in your community for physical activity?

Yes

No

My community does not have these facilities

Don't Know/Not Sure

Refused

9. Do you use shopping malls in your community for physical activity and/or walking program?

Yes

No

My community does not have shopping malls

Don't Know/Not Sure

Refused

10. Do you use any public recreation centers in your community for physical activity?

Yes

No

My community does not have public recreation facilities

Don't Know/Not Sure

Refused

11. Do you use schools that are open in your community for public recreation activities?

Yes

No

Schools in my community are not open for the public to use

Don't Know/Not Sure

Refused

Evaluation of Form:

How long did it take you to complete the questionnaire? _____ minutes

Did you have any difficulty understanding any of the questions you were asked: Yes

No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Rapid Estimate of Adult Literacy in Medicine – Short Form

Starting at the top of the list, please read each word aloud to me. If you don't recognize a word, you can say "pass" and move on to the next word. Your results will be kept strictly confidential.

	Correct	Mispronounced	No attempted
Word			
Fat			
Flu			
Behavior			
Exercise			
Menopause			
Rectal			
Antibiotics			
Anemia			
Jaundice			

Evaluation of Form:

How long did it take you to complete the questionnaire? _____ minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Health Action Process Approach Based Physical Activity Inventory

The following questions are about your physical activities. By physical activity, here, we mean 3 times a week activity, at least 30 minutes each, in which you can talk but cannot sing. Including brisk walking, running, biking, gardening and etc. Notice that routine walks as for doing daily tasks are not considered.

For each question, please put crosshairs in each square that best describes your beliefs or feelings about being physically active. Please answer all of the questions.

Risk Perception									
How high do you think your risk of the following items during your lifetime?									
Response Rating:	Very Unlikely	1	2	3	4	5	6	7	Very Likely
High cholesterol levels									
Heart attack									
Hypertension									
Osteoporosis									
Cardiovascular disease									

Action Self-Efficacy									
Imagine you're highly motivated to do physical activities. How long are you sure you can do it within the next week?									
Response Rating:	Not confident at all	1	2	3	4	5	6	7	Completely confident
10 minutes									
20 minutes									
30 minutes									

Outcome Expectancies									
What do you think will be the consequences for yourself if you engage in physical activity over the next two months?									
Response Rating:	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
Improving weight									
Improving blood sugar									
Improving blood cholesterol									

I will be physically healthier									
I will be happier									

Behavioral Intention									
..... to do at least 90 minutes per week moderate-intensity physical activity in the next 2 months									
Response Rating:	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
I intend...									
I will...									
I plan...									

Planning									
How much do you agree/disagree with the following items? I have planned:									
Response Rating:	Strong disagree	1	2	3	4	5	6	7	Strongly agree
when to do physical activity within the next week									
where to do physical activity within the next week									
how to do physical activity within the next week									
with whom to do physical activity within the next week									
what to do if something intervenes within the next week									

Maintenance Self-Efficacy
Imagine you have started to exercise regularly. Considering the following obstacles, how sure are you to continue?

I am sure I can continue my physical activity 3 times a week regularly, at least 30 minutes each, even if...									
Response Rating:	Not confident at all	1	2	3	4	5	6	7	Completely confident
It takes me long to make it a habit									
There is lack of facilities									
There is time limitation									
There are daily chores									
There is lack of patience									
I am overweight									
I am tired									
I am not accompanied by family									
There are bad weather conditions									

Recovery Self-Efficacy									
Imagine you have quit exercise. How sure are you to start it over again? I can start doing exercises regularly even if...									
Response Rating:	Not sure at all	1	2	3	4	5	6	7	Completely sure
I postpone my plans several time									
I did not follow physical activity for a week									
I did not follow physical activity for a month									
I am not able to pull myself together sometimes									

Evaluation of Form:

How long did it take you to complete the questionnaire? _____minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Social Support Scale for Self-care in Middle-Aged Patients with Type 2 Diabetes

This questionnaire deals with perceptions that you have about receiving social support from your family, friends and important others (such as physician) for physical activity. For each question, put a check mark or cross in the box for the answer that best describes your beliefs or feelings. Please answer all questions.

I have...	Never	Rarely	Sometimes	Often	Always
Somebody who encourages me to have physical activity regularly.					
Somebody who reminds me about various methods of physical activity (exercise, job or household activities).					
Somebody who pays the cost of registering in a gym or buying equipment for physical activity.					
Somebody who reminds me that I must have more physical activity when I am lazy.					
Somebody who asks me to join him/her for exercise.					

Evaluation of Form:

How long did it take you to complete the questionnaire? _____minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Diabetes Knowledge Test

We are interested in finding out more about your general knowledge of type 2 diabetes. For each question, select one answer.

1. The diabetes diet is:
 - a. the way most American people eat
 - b. a healthy diet for most people**
 - c. too high in carbohydrate for most people
 - d. too high in protein for most people

2. Which of the following is highest in carbohydrate?
 - a. Baked chicken
 - b. Swiss cheese
 - c. Baked potato**
 - d. Peanut butter

3. Which of the following is highest in fat?
 - a. Low fat milk**
 - b. Orange juice
 - c. Corn
 - d. Honey

4. Which of the following is a “free food”?
 - a. Any unsweetened food
 - b. Any dietetic food
 - c. Any food that says “sugar free” on the label
 - d. Any food that has less than 20 calories per serving**

5. Glycosylated hemoglobin (hemoglobin A1) is a test that is a measure of your average blood glucose level for the past:
- day
 - week
 - 6-10 weeks**
 - 6 months
6. Which is the best method for testing blood sugar?
- Urine testing
 - Blood testing**
 - Both are equally good
7. What effect does unsweetened fruit juice have on blood glucose?
- Lowers it
 - Raises it**
 - Has no effect
8. Which should not be used to treat low blood glucose?
- 3 hard candies
 - 1/2 cup orange juice
 - 1 cup diet soft drink**
 - 1 cup skim milk
9. For a person in good control, what effect does exercise have on blood glucose?
- Lowers it**
 - Raises it
 - Has no effect

10. Infection is likely to cause:
- a. **an increase in blood glucose**
 - b. a decrease in blood glucose
 - c. no change in blood glucose
11. The best way to take care of your feet is to:
- a. **look at and wash them each day**
 - b. massage them with alcohol each day
 - c. soak them for one hour each day
 - d. buy shoes a size larger than usual
12. Eating foods lower in fat decreases your risk for:
- a. nerve disease
 - b. kidney disease
 - c. **heart disease**
 - d. eye disease
13. Numbness and tingling may be symptoms of:
- a. kidney disease
 - b. **nerve disease**
 - c. eye disease
 - d. liver disease
14. Which of the following is usually not associated with diabetes:
- a. vision problems
 - b. kidney problems
 - c. nerve problems
 - d. **lung problems**

Evaluation of Form:

How long did it take you to complete the questionnaire? _____minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

International Physical Activity Questionnaire

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

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: Job-Related Physical Activity

This section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

D Yes

D No → **Skip to PART 2: Transportation**

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ **days per week**

D No vigorous job-related physical activity → **Skip to question 4**

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ **hours per day** _____ **minutes per day**

4. Again, think about only 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 **as part of your work**? Please do not include walking.

_____ **days per week**

- No moderate job-related physical activity → **Skip to question 6**

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day** _____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

- No job-related walking → **Skip to PART 2: Transportation**

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day** _____ **minutes per day**

PART 2: Transportation

These questions are about how you traveled from place to place, including places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

- No traveling in a motor vehicle → **Skip to question 10**

9. How much time did you usually spend on one of those day **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day** _____ **minutes per day**

Now think only about **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

- No bicycling from place to place → **Skip to question 12**

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day** _____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

- No walking from place to place → **Skip to PART 3: Housework, House Maintenance, and Caring for Family**

13. How much time did you usually spend on one of those days to **walk** from place to place?

_____ **hours per day** _____ **minutes per day**

PART 3: Housework, House Maintenance, and Caring for Family

This section is about some of the physical activity you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

- No vigorous activity in garden or yard → **Skip to question 16**

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day** _____ **minutes per day**

16. Again, think about only 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** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

- No moderate activity in garden or yard → **Skip to question 18**

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day** _____ **minutes per day**

18. Once again, think about only 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** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

- No moderate activity inside home → **Skip to PART 4: Recreation, Sport leisure-time physical activity**

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day** _____ **minutes per day**

PART 4: Recreation, Sport leisure-time physical activity

This section is about all the physical activities you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioning, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

- No walking in leisure time → **Skip to question 22**

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day** _____ **minutes per day**

22. Think about only 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 **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

- No vigorous physical activity in leisure time → **Skip to question 24**

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day** _____ **minutes per day**

24. Think about only 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 bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

No moderate physical activity in leisure time → **You are finished.**

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

_____ **hours per day** _____ **minutes per day**

Evaluation of Form:

How long did it take you to complete the questionnaire? _____ minutes

Did you have any difficulty understanding any of the questions you were asked: Yes

No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Marshall Sitting Questionnaire

Please estimate how many hours you spend SITTING EACH DAY in the following situations: *(please write your answer)*

	On a WEEKDay		On a WEEKEND Day	
	Hours	Minutes	Hours	Minutes
While traveling to and from places				
While at work				
While watching television				
While using a computer at home				
In your leisure time, NOT including television (e.g., visiting friends, movies, dining out, etc.)				

Evaluation of Form:

How long did it take you to complete the questionnaire? _____minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Satisfaction Questionnaire

Please indicate how satisfied you were with the following items. For each question, please put crosshairs in each square that best describes your beliefs or feelings. Please answer all of the questions.

	Not satisfied at all	1	2	3	4	5	6	7	Very satisfied
How satisfied were you with module 1 of the workbook?									
How satisfied were you with module 2 of the workbook?									
How satisfied were you with module 3 of the workbook?									
How satisfied were you with module 4 of the workbook?									
How satisfied were you with the section to log progress in the workbook?									
How satisfied were you with the step count watch?									
	Not at all	1	2	3	4	5	6	7	Very much so
Would you like to continue using the workbook?									
Did you feel the workbook was appropriate for an adult with T2DM living in									

a rural community?									
Would you like to continue using a step count watch?									

Evaluation of Form:

How long did it take you to complete the questionnaire? _____minutes

Did you have any difficulty understanding any of the questions you were asked: Yes
No

If yes, can you describe which questions were difficult to understand?

How could these questions have been asked so they were clearer to you or easier to understand?

Acceptability Telephone Interview Questions

1. Tell me what you think about the workbook?
2. Do you think completing the workbook had a negative, neutral, or positive effect on your physical activity levels? Describe the effect to me.
3. Do you think wearing the study watch had a negative, neutral, or positive effect on your physical activity levels? Describe the effect to me.
4. Do you think completing the workbook had a negative, neutral, or positive effect on your time spent sedentary? Describe the effect to me.
5. Do you think wearing the study watch had a negative, neutral, or positive effect on your time spent sedentary? Describe the effect to me.
6. How practical was completing the workbook once a week for you?
7. How practical was wearing the study watch for you?
8. Would you continue using the workbook if you could?
9. Were there any instances that completing the workbook was challenging for you? Describe any challenges you experienced.
10. Were there any instances when using the study watch was challenging for you? Describe the challenges you experienced.
11. Do you feel the time spent in the study was too long, too short, or just right?
12. Describe any challenges or inconveniences you faced completing the questionnaires.
13. Do you have any suggestions for how this study could be improved in the future?

Evaluation of Interview:

Time taken to administer: _____ minutes

CHAPTER FOUR: PART 1

PHYSICAL ACTIVITY INTERVENTION FOR RURAL ADULTS WITH TYPE 2 DIABETES: PILOT STUDY

*As the primary author, my colleagues and I plan to submit for publication to
the Western Journal of Nursing Research*

Abstract

Physical activity and sedentary behavior change can improve diabetes outcomes; however, rural adults struggle to make lifestyle changes. This quasi-experimental, repeated measures study evaluated the feasibility, acceptability, and preliminary effects of a Health Action Process Approach model guided physical activity and sedentary behavior change intervention. Sixteen rural community dwelling adults with T2DM (M age 61.5±9.2 years) were enrolled from a rural primary care clinic. Participants completed one workbook module weekly and wore a wrist-worn accelerometer to self-monitor steps for four weeks. Participants found the intervention acceptable and appropriate for rural adults. Recruitment strategies were feasible. Post-intervention leisure-time physical activity increased, with a moderate significant effect size detected ($r=.48$, 95% CI [0, 1732.50], $p=.04$). Large non-significant effect sizes were observed post intervention for reduced computer use and television watching sedentary behaviors. Detected effect sizes suggest the intervention impacted physical activity and sedentary behaviors warranting fully powered studies to test the intervention in larger, more diverse samples.

In 2018, 34.1 million United States adults were affected by diabetes, with 90 – 95% of diabetes diagnosis attributed to Type 2 diabetes (T2DM; American Diabetes Association [ADA], 2022a; Centers for Disease Control and Prevention [CDC], 2020). Rural populations demonstrate an increased prevalence (17%) for T2DM compared to urban populations (Callaghan et al., 2020) and are challenged with unique barriers impeding access to diabetes self-management education and diabetes health resources (Brown-Guion et al., 2013; Bolin et al., 2015). Diabetes self-management education is foundational for the development of knowledge and skills needed to perform complex diabetes self-management activities, essential to maintain glycemic control (ADA, 2022b). Diabetes self-management activities include participating in regular physical activity (PA), following medical nutrition guidelines, adhering to prescribed medications, participating in daily self-screening and annual health screening activities, smoking cessation, and engaging in activities to promote psychosocial health (ADA, 2022b). Inadequate diabetes self-management increases the risk for developing complications of diabetes, such as coronary artery disease, stroke, peripheral vascular disease, retinopathy, neuropathy, and nephropathy (Cannon et al., 2018). The management of T2DM is costly; individuals with diagnosed diabetes incur medical expenditures of \$9,601 annually, which are 2.3 times higher than costs incurred by individuals without T2DM, with additional costs acquired as disease burden and multimorbid conditions intersect (ADA, 2018).

Physical Activity & Sedentary Behavior in Rural Populations with T2DM

Incorporating lifestyle changes to increase PA and reduce sedentary behaviors are an essential component of the diabetes self-management plan (ADA, 2022b). PA is described as any activity that engages skeletal muscle movement, resulting in increased energy expenditure (Bull et al., 2020). Adults with T2DM are recommended to participate in 150 minutes of moderate-to-vigorous PA weekly, consisting of 30 daily minutes of aerobic activity and resistance training two to three times weekly to decrease blood sugar levels, insulin resistance, triglycerides, and blood pressure (ADA, 2022b). Objective measures have demonstrated that 44 – 65% of adults with T2DM reach the recommended 150 minutes of moderate-to-vigorous PA weekly, with rural older adults reaching recommended weekly guidelines as little as 23% of the time (ADA, 2022b; Kirk et al., 2015). Sedentary behaviors are a concept independent of PA, defined as activities that require low levels of energy expenditure and occur while sitting, reclining, or lying (Bull et al., 2020). Extended bouts of time spent sedentary are associated with poor glycemic control, and higher incidences of morbidity and mortality independent of moderate-to-vigorous PA performance (Colberg et al., 2016). To improve glycemic control and reduce health risks, adults with T2DM are recommended to reduce the amount of time spent sedentary and break up prolonged sedentary bouts with brief periods of standing or light-intensity walking every 20 – 30 minutes (Colberg et al., 2016).

Despite the known disproportionate impact of T2DM in rural communities, health disparities continue to exist in relation to the availability and accessibility of diabetes self-management education and health resources (Brown-Guion et al., 2013). Rural

adults' readiness for PA and sedentary behavior change are influenced by inadequate knowledge about T2DM, causes of T2DM, treatment plans, and complications of T2DM (Arcury et al., 2005). Further compounding barriers are limited access to facilities and equipment for PA and safety concerns surrounding poorly maintained roads and few sidewalks, narrowing the variety of PAs rural adults can incorporate into their lifestyle (Chrisman et al., 2015). Telehealth, defined as the exchange of medical information through electronic communication to improve patient health, is an effective strategy to overcome barriers to diabetes and health resource access and has demonstrated the ability to improve diabetes health outcomes (Tuckson et al., 2017). Tools specific to mobile health technology represent a facet of telehealth, which include wearable devices, smart phones and mobile applications, and websites (Tuckson et al., 2017). While known limitations exist in rural populations, incorporating wearable devices and mobile applications supported by a smart phone increases the ability to reach a diverse population of rural individuals. Developing PA and sedentary behavior interventions specific to rural populations are necessary to overcome barriers described.

In studies reviewed, interventions delivered via mobile applications and websites have demonstrated the ability to increase PA, decrease sedentary behaviors, and improve glycemic control in adults with T2DM (Connelly et al., 2013; Howland & Wakefield, 2021). However, despite promising patient outcomes, intervention development and methodological concerns exist. Few studies address sedentary behavior as a concept independent of PA (Poppe et al., 2019), making sedentary behavior change mechanisms difficult to identify. Greater improvements in PA and sedentary behavior are observed in targeted interventions than in general diabetes self-management interventions (Kooiman

et al., 2018; Poppe et al., 2019). Clear integration of a theoretical framework to support intervention development and delivery is often absent, making it difficult to ascribe active aspects of the intervention to theoretical constructs (Howland & Wakefield, 2021). Few studies measure PA and sedentary behavior using objective methods (Jennings et al., 2014; Poppe et al., 2019); most include self-report measures alone. Thus the accuracy of study outcomes using self-reported outcome measures may be biased by under-or-over reporting of PA (Howland & Wakefield, 2021; Prince et al., 2008). Further, little research has been conducted in rural populations to understand the feasibility or acceptability of PA and sedentary behavior interventions integrating mobile health technology in rural populations with T2DM (Connelly et al., 2017; Howland & Wakefield, 2021). Within the consumer marketplace, a plethora of T2DM and PA mobile applications and wearable devices exist; however, few are based on health behavior change theory, tailored to rural adults with T2DM, or rigorously evaluated prior to release. It is necessary to systematically develop and evaluate novel PA interventions in rural adults with T2DM, prior to transitioning to a mobile application delivery platform to understand the mechanisms of behavior change in the intended population.

This study operationalizes the constructs of the Health Action Process Approach (HAPA) model to develop a comprehensive health behavior change intervention focused on PA and sedentary behavior in rural adults with T2DM (Schwarzer et al., 2011). The HAPA model predicts behavior change by integrating cognitive and behavior constructs along a continuum, providing a framework for the development of behavioral intention, planning, enactment, and maintenance (Schwarzer et al., 2011). The HAPA model has been used previously in populations with T2DM and in studies involving PA and

sedentary behavior interventions to predict and guide behavior change (MacPhail et al., 2014; Poppe et al., 2019). When used to guide a PA and sedentary behavior telehealth intervention significant reductions in self-reported and objectively measured sedentary behaviors and increases in moderate and moderate-to-vigorous PA were observed (Poppe et al., 2019). The HAPA model includes nine major constructs grouped within three self-efficacy-based stages 1) risk perception, outcome expectancies, action self-efficacy and behavioral intention, 2) action planning, coping planning and maintenance self-efficacy, and 3) recovery self-efficacy, which are enhanced by social support (Schwarzer et al., 2011). Figure 3 includes construct definitions and depicts application of the HAPA model to increase PA and decrease sedentary behaviors.

Purpose

The purpose of this pilot study was to (a) determine feasibility and acceptability of a 4-week educational and cognitive skill building PA and sedentary behavior change intervention guided by the HAPA model in rural adults with T2DM; and (b) to explore preliminary effects of the intervention on diabetes knowledge, PA and sedentary behavior. This preliminary study represents the initial step in evaluating a PA and sedentary behavior change intervention prior to transitioning content to a mobile health technology platform. Study findings will inform development of a fully powered study aimed to increase PA and decrease sedentary behaviors in rural adults with T2DM.

Methods

Study Design, Setting, and Sample

This study used a quasi-experimental, one-group repeated measures design with semi-structured telephone interviews. This study was approved by the Institutional Review Board at the University of Missouri (IRB approval number 2063062).

Rural community dwelling adults were recruited from a Midwestern rural critical access 43-bed hospital primary care clinic from November 2021 through February 2022 using convenience sampling. Due to the preliminary nature of this study no power analysis was conducted to determine a needed sample size; this study aimed to recruit 15 participants. Participants were screened for eligibility and deemed eligible for participation if they were (1) diagnosed with T2DM, (2) rural community dwelling residents, (3) aged 18 – 75 years old, (4) able to speak, read, and write in English, (5) not exceeding 150 minutes of weekly moderate-to-vigorous PA at time of screening, (6) able to increase PA without restrictions per their primary care provider risk assessment screening, and (7) had a primary care provider associated with the recruitment clinic. Exclusion criteria included (1) being diagnosed with type 1 or gestational diabetes mellitus and (2) cognitive impairment. Cognitive impairment was evaluated using the Six-item Screen to Identify Cognitive Impairment Among Potential Subjects for Clinical Research, which demonstrates high sensitivity (88.7%) and specificity (88%) to identify cognitive impairment in adults; a cut-point of three missed answers was used to identify study eligibility (Callahan et al., 2002).

Intervention and Study Procedures

The intervention consisted of a researcher developed *Active for Life* workbook and a wrist-worn tri-axial accelerometer (Actigraph GT9X-Link, Actigraph, LLC) aimed to increase PA, decrease sedentary behavior, and improve diabetes knowledge in rural adults with T2DM. The self-guided *Active for Life* workbook was developed with input from rural community stakeholders including a primary care physician, certified diabetes educator, two community health workers, and two community members with T2DM experiences. A lifestyle approach and evidence-based behavior change techniques were incorporated to operationalize constructs of the HAPA model within the context of PA and sedentary behavior change in rural adults with T2DM. Workbook content is consistent with the Association for Diabetes Care and Education Specialists Diabetes Care and Education Curriculum (3rd edition) and American Diabetes Association Exercise and Diabetes Clinician's Guide (Association of Diabetes Care and Education Specialists [ADCES], 2021; Colberg et al., 2013). The workbook was written for low-literacy level adults, to accommodate the health literacy needs of a diverse population of rural adults, using clear and simple, plain language at a 5th grade readability level (Flesch Kincaid Grade Level; Jindal et al., 2017). Figure 4 describes the relationship between workbook broad learning goals, module specific learning objectives, and operationalization of HAPA model constructs within each weekly module.

Upon study enrollment, participants received the self-guided workbook and wrist-worn accelerometer and were trained in their use. Participants were instructed to complete one workbook module per week on any day of their choosing and use the logbook section daily. The logbook included activities to self-monitor blood glucose,

daily steps, PAs performed, and time spent sedentary. Use of the workbook was anticipated to take one hour each week. Participants were instructed to follow their primary care provider recommendations for monitoring blood glucose. Participants were instructed to wear the wrist-worn accelerometer on their non-dominant wrist for the 4-week intervention timeframe to self-monitor steps per day. Participants received daily step count feedback from the wrist-worn accelerometer and were instructed that the step count would reset to zero daily at midnight. Instructions were provided to remove the wrist-worn accelerometer during swimming, showering, bathing, and charging. Participants received a charging station and were trained in the procedure to charge and calibrate the device. Symbols on the wrist-worn accelerometer were explained to participants. Written instructions were provided for reference after the initial training session. Participants received a weekly text or telephone check-in message with reminders to complete the weekly *Active for Life* workbook module and charge the wrist-worn accelerometer; participants identified their preference for either text or telephone message upon enrollment.

The study duration was nine weeks. Participants were assessed at baseline, after completion of the *Active for Life* workbook (post-intervention at week 5), and four weeks later (follow-up at week 9). Feasibility was evaluated using recruitment, retention and safety data collected and from returned participant workbooks, accelerometers, and study measures. Acceptability was evaluated using post-intervention measures (described in the next section) and telephone interviews. Participants received monetary compensation for their time in the study up to a maximum of \$40 for those who completed the study.

Figure 5 provides an overview of the study procedures.

Measures

Participant Characteristics

Participant characteristics were collected via self-report. Age, gender, race, ethnicity, number of years living with T2DM, diabetes medications, co-existing conditions, height, weight, level of education, working status, and exposure to others with diabetes were collected using an investigator developed questionnaire. Body mass index was calculated using reported height and weight data. The Environmental Supports for PA 11-item questionnaire was used to measure social and physical environmental influences of PA ($\rho=.36-.74$; Ainsworth et al., 2002). Health literacy was assessed using the 7-item Rapid Estimate of Adults Literacy in Medicine-Short Form ($\rho=.94$; Arozullah et al., 2007).

Health Action Process Approach Model Constructs

The HAPA model constructs were measured using the HAPA Based PA Inventory and the Social Support Scale for Self-Care in Middle Aged Patients with T2DM. The 34-item HAPA Based PA Inventory is a valid and reliable ($\chi^2_3=3.21, p=.38$) seven-point Likert scale style questionnaire (Rohani et al., 2016). Inventory total and subscale scores are reported; with higher scores indicating stronger perceptions about factors which facilitate or inhibit PA (Total: 34 – 238; Risk perception: 5 – 35; Action self-efficacy: 3 – 21; Outcome expectancies: 5 – 35; Behavioral intention: 3 – 21; Planning: 5 – 35; Maintenance self-efficacy: 9 – 63; Recovery self-efficacy: 4 – 28; Rohani et al., 2016). Cronbach's α ranging from .54 - .99 were calculated in this study; estimates from prior work have ranged from .63 - .97 (Rohani et al., 2016). Five Likert scale items about PA from the Social Support Scale for Self-Care in Middle Aged

Patients with T2DM were used to measure social support ($\chi^2=2.03$, $p<.01$; Naderimaghani et al., 2012). The items were answered on a scale of zero (never) to four (always), where higher scores indicated greater perceptions of social support. The composite score is reported as the indicator of social support. Cronbach's α for the Social Support Scale for Self-Care in Middle Aged Patients with T2DM ranging from .78 - .81 were calculated in this study; previous studies have estimated Cronbach's α .94 (Naderimaghani et al., 2012).

Diabetes Knowledge

Diabetes knowledge was evaluated using 14 items appropriate to the study population from the Revised Diabetes Knowledge Test; the 9-items excluded were specific to insulin therapy which participants were not required to use to participate in this study (Michigan Diabetes Research Center, 2015). The Revised Diabetes Knowledge Test is a 23-item multiple choice questionnaire measuring general diabetes knowledge (i.e., diet, exercise, glucose monitoring, causes and management of hypoglycemia and hyperglycemia, insulin, foot care, acute and chronic complication, and sick day management) in adults with T2DM ($\alpha=.77$; Fitzgerald et al., 2016; Michigan Diabetes Research Center, 2015). The composite score (0 – 14), with a higher score indicating greater diabetes knowledge, was reported. Cronbach's α ranging from .09 - .38 were calculated in this study population.

Physical Activity and Sedentary Behavior

The International PA Questionnaire – Long version is a 25-item self-report questionnaire evaluating habitual PA over the past seven days within four domains (transportation, work-related, household, and leisure-time; Craig et al., 2003). Criterion

validity ($\rho=.55 - .71$) and reliability ($\rho=.81$) are established in similar populations (Hagströmer et al., 2006; Rosenberg et al., 2008). Participant self-reported PA are used to calculate a score in metabolic equivalent-minutes (MET-minutes; IPAQ, 2005). Each questionnaire item correlates with a MET value (i.e., walking = 3.3 MET, moderate = 4.0 MET, vigorous = 8.0 MET); the equation to calculate MET-minutes used in this study is *MET x activity minutes x activity days* (IPAQ, 2005). Domain specific (i.e., transportation, work-related, household, and leisure-time) and activity specific (i.e., walking, moderate, vigorous) are reported in this study (IPAQ, 2005).

The Marshall Sitting Questionnaire is a valid ($\rho=.15-.74$) and reliable ($\rho=.23-.84$) measure which assesses participants self-reported sedentary time in five domains (work, travel, watching television, using a computer at home, and leisure-time other than watching television) on weekdays and weekend days (Marshall et al., 2010). Participants report sedentary behaviors as minutes per day; total, domain specific, and weekday versus weekend day sedentary time are reported in this study (Marshall et al., 2010).

The Actigraph GT9X-Link (Actigraph, LLC), worn by participants on their non-dominant wrist for the study duration, is a research-grade tri-axial accelerometer which objectively measures PA and sedentary behavior. Accelerometer data were downloaded and analyzed using the ActiLife analysis software, version 6.13.4 (Actigraph, LLC). Data were included if a minimum wear time of 10 hours per day on 4 days of the week, including one weekend day, were met (Migueles et al., 2017). A 60-second epoch was applied to data; non-wear time was classified using Troiano (2007) cut-points (60-minutes or longer of zero consecutive counts per minute [cpm]). Freedson adult cut-points were applied to classify levels of PA (0-99 cpm: sedentary; 100 – 1951 cpm: light;

1952 – 5724: moderate; 5725 – 9498: vigorous; ≥ 9499 : very vigorous (Freedson et al., 1998). Objective measures of PA level (light, moderate, and vigorous), steps per day, sedentary time, and bouts of sedentary time are reported. Wear-time compliance was measured using the devices wear-time sensor.

Feasibility and Acceptability

Feasibility was assessed by evaluating recruitment and attrition, completion of the intervention and study measures, and intervention safety. Acceptability was assessed using an investigator developed 9-item Likert style satisfaction questionnaire, which evaluated satisfaction, intent to continue to use, and perceived appropriateness for rural adults of the self-guided workbook and accelerometer. Satisfaction with the workbook and accelerometer were scored from one (not satisfied at all) to seven (very satisfied), with higher scores indicating greater satisfaction (6 – 42). Intent to continue to use and perceived appropriateness of the workbook and accelerometer were scored from one (not at all) to seven (very much so), with each question scored independently. A post-study semi-structured telephone interview, lasting 10 minutes on average, about satisfaction, intent to continue to use, perceived appropriateness, and challenges faced using the *Active for Life* workbook, accelerometer, and study measures was conducted.

Data Analysis

Descriptive statistics were used to summarize participant characteristics. Quantitative data were analyzed using SPSS version 27 (IBMP Corp) using a .05 predetermined alpha level. Data were evaluated for missing values, extreme outliers, normality and homogeneity of variances. Outliers more than three standard deviations from the mean were removed per variable. Due to observed non-normal distributions and

the small sample size, non-parametric tests were performed. Freidman's tests were conducted to explore mean differences between baseline, post-intervention, and follow-up measures for self-reported HAPA model constructs, diabetes knowledge, PA, and sedentary behavior; Wilcoxon Signed Rank tests were conducted to calculate estimated effect sizes. Mean differences in baseline and post-intervention objective PA and sedentary behavior data were evaluated using Wilcoxon Signed Rank tests; estimated effect sizes were calculated. Approximate effect sizes were calculated using the test statistic z -score, with N representing the total number of observations, using the following equation $r = z/\sqrt{N}$ (Rosenthal, 1991). Using the calculated r value, .1 indicates a small effect, .3 indicates a moderate effect, and .5 indicates a large effect (Cohen, 1992); p -values and 95% Confidence Intervals are reported with effect sizes.

Collected qualitative data were analyzed using descriptive thematic analysis methods (Braun & Clarke, 2006). Telephone interviews were recorded and transcribed verbatim. Data familiarization occurred through transcription, reading and re-reading the data, and annotating initial ideas. Initial line-by-line coding involved systematically identifying features across the dataset. Next, meaningful categories were identified by analyzing and grouping codes, based on similarities in context, across all interviews coded. Identification of meaningful categories allowed for identification of emerging subthemes and themes describing participants perceptions of acceptability of the *Active for Life* workbook, wrist-worn accelerometer, and measures used. Emerging themes were reviewed by creating a thematic map of coded excerpts within categories and themes. Reviewed categories, subthemes, and themes were named and defined. Two researchers

participated in the coding and analysis (CRH, BJW). No qualitative data analysis software were used.

Results

A total of 33 patients were screened for eligibility; six potential participants screened did not meet inclusion criteria (one did not have a PCP at the recruitment clinic, two participated in more than 150 minutes of PA weekly, and three due to PA restrictions). Twenty-seven met eligibility criteria (82%) and 16 (59%) agreed to participate. The ten participants who completed baseline, post-intervention, and follow-up measures were included in the preliminary effects analysis. Intervention acceptability telephone interviews were conducted with 13 participants who completed the intervention. Of the 13 participants included in telephone interviews, one did not complete post-intervention or follow-up measures and two did not complete baseline, post-intervention, or follow-up measures, thus they were excluded from the preliminary effects analysis, but were included in the feasibility and acceptability analysis. Figure 6 depicts the flow of participants through the study.

Characteristics of Participants

Participants (N=13) were primarily obese (BMI 38.4 ± 10.5), non-Hispanic, Caucasian females, with an average age of 61.5 ± 9.2 years (Table 10). On average, participants had been living with T2DM for 10.7 ± 9.3 years and were taking diabetes medications. The majority of participants had 2 or more co-existing health problems and knew a friend or family member who also had T2DM. All participants had at least a high school or equivalent education and were at a 7th grade or higher health literacy level. The majority of participants were not employed. Participants identified their neighborhood as

a pleasant walking environment (76.9%) that is safe from crime (100%) with trustworthy neighbors (84.6%). Most participants identified their neighbors as being somewhat physically active (76.9%). Only 54% of participants identified having access to a sidewalk with the majority of participants identifying inadequate lighting (61.6%) in their neighborhood. The majority of participants included did not use private (84.6%), public (84.6%), or school (92.3%) recreational facilities in the community for PA. Most participants also did not utilize a mall environment for walking (76.9%) or community walking trails, parks, playgrounds or sports fields (92.3%) for PA.

Preliminary Effects

The detailed self-reported intervention outcomes over time are reported in Table 11 and summarized briefly. There were no significant changes in any of the nine measured HAPA model constructs across three measurement points. Planning (i.e., action and coping) increased across measurement points ($\chi^2_2 = .21, p = .90$). Participant perceived maintenance self-efficacy ($\chi^2_2 = 1.08, p = .58$) and social support ($\chi^2_2 = .84, p = .67$) increased from baseline to post-intervention, then maintained a level higher than baseline at the follow-up measurement point. Behavioral intention ($\chi^2_2 = 1.18, p = .55$) to perform PA and recovery self-efficacy ($\chi^2_2 = 2.00, p = .37$) modestly increased from baseline to post-intervention, but were not maintained at the follow-up point. Measures of action self-efficacy ($\chi^2_2 = .06, p = .97$) and outcome expectations ($\chi^2_2 = 1.36, p = .51$) decreased post-intervention, then saw increases at the follow-up measurement point. Participants perceived risk for developing health problems decreased across measurement points ($\chi^2_2 = .42, p = .81$). Total perceptions of HAPA model constructs decreased from baseline to follow-up measurement points ($\chi^2_2 = 1.40, p = .50$).

Participants' diabetes knowledge modestly improved after the intervention; however, the scores were not significantly different from baseline ($\chi^2_2 = 1.93, p = .38$). Furthermore, follow-up measures of diabetes knowledge continued to demonstrate modest non-significant increases in diabetes knowledge compared to baseline measurements.

No significant changes in self-reported PA and sedentary behavior changes were identified across measurement points. Self-reported total PA increased post-intervention from baseline, then decreased to a level above baseline at the follow-up measurement point ($\chi^2_2 = 1.56, p = .46$). Self-reported baseline walking ($\chi^2_2 = 1.92, p = .38$), moderate ($\chi^2_2 = .33, p = .85$), and vigorous ($\chi^2_2 = 4.00, p = .14$) intensity PA saw large increases at the post-intervention measurement point, with moderate intensity PA remaining higher than baseline at the follow-up point. Within the work-related domain PA increased across measurement points ($\chi^2_2 = 3.00, p = .22$). Domain specific baseline PA for leisure-time ($\chi^2_2 = 5.06, p = .08$) and household ($\chi^2_2 = .29, p = .87$) PA increased post-intervention then decreased to levels greater than baseline at the follow-up measurement point. Within the travel domain PA increased post-intervention then decreased below baseline at the follow-up point ($\chi^2_2 = .08, p = .96$).

There were no significant changes in self-reported sedentary behavior across measurement points. Participants saw decreases in time spent sedentary within the total ($\chi^2_2 = 2.30, p = .32$), weekday ($\chi^2_2 = 2.77, p = .25$), weekend day ($\chi^2_2 = 1.24, p = .54$), home computer use ($\chi^2_2 = 3.71, p = .16$), television watching ($\chi^2_2 = 5.73, p = .06$), and leisure-time ($\chi^2_2 = 2.53, p = .28$) sedentary behavior domains post-intervention. Increases in time spent sedentary were observed across all domains at the follow-up measurement

point. While increases in time spent sedentary were observed during the post-intervention to follow-up measurement points within the weekday, home computer use, and leisure-time domains participants' maintained sedentary levels lower than baseline. Time spent sedentary increased in the travel related domain ($\chi^2_2 = 1.29, p = .53$).

Objective measures of PA were collected before and after the intervention via accelerometer (Actigraph GT9X-Link, Actigraph, LLC) and are described in detail in Table 12. Participants increased their weekly steps post-intervention ($z = -.53, 95\% \text{ CI } [-9347.50, 13397.50], p = .59$), but maintained a similar level of energy expenditure ($z = -.84, 95\% \text{ CI } [-.04, .07], p = .40$). Time spent sedentary increased from baseline to post-intervention ($z = -.42, 95\% \text{ CI } [-571, 333], p = .68$). Both light intensity ($z = -.18, 95\% \text{ CI } [-391, 433], p = .86$) and moderate intensity ($z = -.06, 95\% \text{ CI } [-122, 152], p = .95$) activity increased from baseline to post-intervention. While sedentary time increased, the modest increases in light and moderate intensity activity levels displaced the percentage of time spent sedentary. The percentage of time spent sedentary decreased from baseline to post-intervention ($z = -.18, 95\% \text{ CI } [-3.58, 3.58], p = .86$). Additionally, decreases in the percentage of time spent performing light intensity activity were observed from baseline to post-intervention ($z = -.42, 95\% \text{ CI } [-3.07, 3.22], p = .68$). The percentage of time spent performing moderate intensity activity increased modestly from baseline to post-intervention ($z = -.77, 95\% \text{ CI } [-.94, 1.40], p = .44$). No participants reached vigorous activity per objective measurements. Participants experienced a greater number of sedentary bouts ($z = -.53, 95\% \text{ CI } [-22, 10.50], p = .59$), with breaks post-intervention ($z = -.53, 95\% \text{ CI } [-24, 10.50], p = .59$).

Estimates of Intervention Effect Size

Due to the preliminary nature of data reported, estimated effect sizes were calculated and are reported in Tables 12 and 13. A moderate significant effect size was detected between baseline and post-intervention measurement points for self-reported increases in leisure-time PA ($r = .48$, 95% CI [0, 1732.50], $p = .04$). A large effect size was detected between baseline and post-intervention related to decreases in the self-reported home computer use sedentary behavior domain ($r = .51$, 95% CI [-480, 0], $p = .11$); however, between post-intervention and follow-up measurement points a large effect size was detected due to increased sedentary behavior ($r = .50$, 95% CI [0, 60], $p = .08$). Additionally, a large effect size was detected between baseline and post-intervention related to decreases in self-reported television watching sedentary behavior ($r = .59$, 95% CI [-120, 0], $p = .06$); a moderate effect size was detected due to increased time spent watching television between the post-intervention and follow-up measurement points ($r = .39$, 95% CI [-180, 360], $p = .23$). Additional moderate non-significant effect sizes were detected relative to increases in self-reported total PA between the baseline-post-intervention ($r = .41$, 95% CI [-309, 5019], $p = .09$) and baseline-follow-up ($r = .38$, 95% CI [-514, 2742], $p = .11$) points, and in the vigorous intensity activity baseline-post-intervention ($r = .32$, 95% CI [0, 660], $p = .18$) and post-intervention-follow-up points ($r = .32$, 95% CI [-660, 0], $p = .18$). Moderate non-significant effect sizes were detected in work-related domain specific PA between baseline-post-intervention ($r = .32$, 95% CI [0, 254.5], $p = .18$) and baseline-follow-up ($r = .32$, 95% CI [0, 504], $p = .18$), and baseline-follow-up household domain PA measurement points ($r = .32$, 95% CI [-450, 2040], $p = .18$). Within the sedentary travel domain, moderate effect sizes were observed relative

to increases in time spent sedentary between the baseline-post-intervention ($r = .44$, 95% CI [0, 115], $p = .08$) and baseline-follow-up ($r = .42$, 95% CI [-5, 147.50], $p = .14$) measurement points. Small effect sizes were observed between measurement points across constructs of the HAPA model, social support, diabetes knowledge, and within objective measures of PA.

Feasibility and Acceptability

Participants were recruited over a three-month period, resulting in a 48.5% recruitment rate. Thirteen of 16 participants completed baseline measures, the intervention, and participated in a post-study telephone interview, resulting in an 81.3% intervention completion rate. Ten of 16 participants enrolled completed all study measures. Attrition rates were 37.5%, with two participants dropping out (12.5%), one withdrawn due to safety concerns (6.3%), and three lost to follow-up (18.8%).

Participants who dropped out reported inadequate time to participate in the study due to work and family commitments. The median completion of the *Active for Life* workbook was $82.6\% \pm 39.1\%$; on average participants wore the wrist-worn accelerometer $82.2\% \pm 10.3\%$ of the 4-week wear-time duration. One participant experienced a localized skin irritation at the wear-location of the wrist-worn accelerometer during the study.

Acceptability

Participants reported high levels of satisfaction with the *Active for Life* workbook and wrist-worn accelerometer; 90% reported satisfaction with workbook modules one, two and the wrist-worn accelerometer, and 80% reported satisfaction with workbook modules three, four, and the logbook. Half of participants indicated they would like to continue to use the workbook after completing the intervention; 80% of participants

indicated interest in continuing to use the wrist-worn accelerometer. The majority of participants (70%) identified the intervention as appropriate for rural community dwelling adults with T2DM. Telephone interviews resulted in the identification of four themes; Table 14 provides an overview of identified themes, subthemes, and narrative exemplars.

Theme 1: Intervention Features

Participants interviewed described *Active for Life* workbook, wrist-worn accelerometer, and survey (measure) features and behaviors related to interacting with those features that both facilitated and inhibited use. Two identified subthemes included facilitators and barriers. Aspects related to usability and functionality facilitated engagement with and completion of study materials. Participants identified the *Active for Life* workbook as interesting, easy to use, self-explanatory, and well organized. Others' found the weekly content practical to apply to their lives. Flexibility in use patterns allowed participants to complete the workbook within the context of their preferred lifestyle. Participants identified the wrist-worn accelerometer as easy to use and charge, describing high levels of satisfaction and interest in continued use. Participants described the 4-week study length as "just right". While participants described many features and behaviors facilitating engagement with study materials, barriers existed. Some participants described the activities within the workbook as repetitive and sought increased variety in weekly content. Challenges with the wrist-worn accelerometer included sudden loss of battery power, difficulty seeing the watch face, forgetting to review step counts at the end of the day, the watch not tracking all PA, and skin irritation from the watchband. Other participants described interest in a different intervention

length; with some identifying a brief intervention with less activity content as preferable and others requesting additional time to complete the intervention.

Theme 2: Short-and-Long Term Behavior Change Outcomes

A second theme emerged related to participants planning and enactment of PA, sedentary behavior, and health outcome changes. Short-term and long-term behavior health outcomes were identified as subthemes. Short-term behavior outcomes are described as the positive effect on PA, sedentary behavior, and health related to use of the *Active for Life* workbook and wrist-worn accelerometer. Participants described increasing their PA, and sitting less and breaking up sedentary bouts more frequently. Secondary to increasing PA and decreasing sedentary behaviors participants described improvements in feelings of wellness, increased energy, improved sleep, and weight loss. Others' described motivation to engage with other behaviors to manage co-existing chronic conditions. Long-term behavioral outcomes were related to participants description of interest in or planning for long-term behavior change. Participants indicated interest in continuing to use the *Active for Life* workbook or self-monitoring blood glucose and PA. Several participants identified owning an activity tracking watch and others inquired about how to obtain a consumer grade wearable device.

Theme 3: Facilitators and Barriers of Behavior Change

A third theme related to the personal, intrapersonal, and environmental factors influencing behavior change emerged with two subthemes identified (facilitators and barriers). Participants described increased perceptions and awareness of activity levels through PA and sedentary behavior self-monitoring and self-reflection. Other participants described attaining motivation from participation in the intervention. Increased

motivation resulted in PA and sedentary behavior change, as well as behavior changes within other domains of health. Participants described interest in smoking cessation, increased compliance with prescribed obstructive sleep apnea treatments, and making dietary changes. Use of *Active for Life* workbook led to the development of cognitive-behavior skills to set goals, plan actions, create alternative plans, and self-monitor outcomes, which participants identified as beneficial repeatedly during interviews. External support sources, including friends and spouses, impacted behavior change by holding participants accountable to planned goals. Participants described enhancement of diabetes knowledge to support behavior change, by increasing knowledge of health problems associated with diabetes. Barriers to behavior change included living a sedentary lifestyle and longstanding habits, in which participants reported spending many waking hours watching television. Participants identified the holiday season, travel, weather, and COVID-19 as barriers to behavior change. Other participants expressed a fear of change, describing fears of failure or feeling stressed to achieve planned goals. The burden of multimorbid chronic disease was described as a barrier to increasing activity levels, with several participants describing difficulties balancing symptom management and PA.

Theme 4: Rural Influence

The final theme which emerged describes the influence of the rural environment on PA preferences. Participants described limited opportunities for outdoor activity due to uneven walking surfaces, unmarked and maintained country roads, and a lack of sidewalks. Participants primarily described participating in PA within their homes, inclusive of increasing the amount of household activity completed, indoor walking, use

of an exercise bike, and lifting personal weights. Some participants described participating in activities outside of the home, including water aerobics and walking the grocery store aisles, but described preferences not to enroll in a gym. Many participants described using television commercials as a cue to break up sedentary time with walking.

Discussion

This preliminary pilot study revealed several useful findings. First, collaborating with rural community stakeholders and primary care providers at a rural critical access hospital clinic is a viable strategy to engage with rural community members with T2DM. Second, integrating constructs of the HAPA model into a PA and sedentary behavior change intervention for rural adults with T2DM was associated with increased diabetes knowledge and PA, and reduced sedentary time. Third, the intensity level, domains, and types of PA which changed in relation to the intervention were identified, with a moderate significant effect size identified related to increases in the leisure-time PA domain. Fourth, the intervention demonstrated large, estimated effects on domain specific sedentary behaviors. Fifth, while the workbook and wrist-worn accelerometer were deemed appropriate and acceptable by rural adults with T2DM, evidence was obtained to support intervention refinement. Finally, feasibility data demonstrated areas for improvement related to participant retention.

Engaging with community stakeholders to develop the self-guided *Active for Life* workbook resulted in the development of an intervention which was appropriate and acceptable for rural adults with T2DM. Additionally, community stakeholder engagement aided in the development of community relationships which established recruitment site buy-in and facilitated participant recruitment. Rural primary care providers served as

gatekeepers to the target population, providing access and facilitating development of a trusting relationship with potential participants (Thurman & Harrison, 2020). Participant recruitment was further facilitated by establishing a flexible recruitment plan, which was convenient to participants and reduced travel related burden.

Rohani et al. (2018) demonstrated strong significant relationships between action self-efficacy, behavioral intention, action/coping planning, and behavior enactment. The present study findings of HAPA model construct outcomes indicated that the intervention resulted in modest improvements in behavioral intention, action/coping planning, and social support. Action self-efficacy remained unchanged after receipt of the intervention. Measures of behavior enactment (self-reported and objectively measured PA and sedentary behavior) demonstrated modest, non-significant changes in PA and sedentary behavior. Risk perception has a weak, non-significant relationship with behavioral intention (Rohani et al., 2018). In this study, participants' perceived risk perception decreased post-intervention, which may indicate that participants perceived their risk of health problems decreased after completing the intervention and increasing their PA. Rohani et al. (2018) identified weak-moderate associations between outcome expectations and behavioral intention. Outcome expectations decreased post-intervention, which may have been influenced by participants perceptions of goal enactment. Maintenance self-efficacy has demonstrated a weak-moderate significant association with action/coping planning and a strong, non-significant association with behavioral enactment (Rohani et al., 2018). Increases in maintenance self-efficacy across measurement points were observed in this study. Recovery self-efficacy has demonstrated a moderate non-significant relationship with behavioral enactment (Rohani

et al., 2018). An increase in recovery self-efficacy was detected from baseline to post-intervention points, which decreased below baseline at the follow-up point. The relationships of social support on constructs of the HAPA model have yet to be explored.

Improvements in diabetes knowledge were observed both post-intervention and at the follow-up measurement point; however, small effect sizes were detected. As participants of this study had on average lived with T2DM for 10 years or longer, a high baseline level of diabetes knowledge was present likely causing a ceiling effect. Based on anecdotal written comments on measures returned by participants, participants may have struggled with wording on some questions of the Revised Diabetes Knowledge Test. For example, “any dietetic food” and describing measurements of glycosylated hemoglobin in days, weeks, or months. These terms could be clarified on future iterations of the measure to improve clarity for participants.

The inclusion of self-reported and objective measures of PA and sedentary behavior allowed for identification of change in activity domain and intensity. Data obtained from interviews provided further evidence of the specific types of PA and cues for breaks in sedentary behavior. The moderate significant effect size detected in the leisure-time PA domain, moderate effect sizes in household and work-related PA domains, and large effect sizes in home computer use and television watching sedentary behavior domains provide evidence of PA and sedentary behavior domains most effected by the intervention. Through interviews participants described increasing activities performed within the home. The targeted increase of indoor activities may have been impacted by poor weather conditions, as this study was conducted during the winter months, and COVID-19, which limited feelings of safety the availability of public or

group PA options. These findings are congruent with seasonal barriers to PA identified in rural populations (Gien et al., 2017; Jones et al., 2021). Additional research is needed to understand the impact of COVID-19 on PA choices and domains in rural adults with T2DM. Further, participants description of using television commercials as a cue to break bouts of time spent sedentary correlates with the self-reported changes in sedentary and PA.

Participant number of steps per day increased, which is consistent with self-reported perceived increases in walking PA. However, objective PA measures indicate that participants spent a greater percentage of their day sedentary, than in light or moderate intensity activity levels post-intervention. The differences in self-reported and objective measures of PA and sedentary behavior observed are consistent with descriptions of both under-and-over reporting of PA and sedentary behavior when using self-report measures (Prince et al., 2008). While no single trend has been identified relative to under-or-over reporting, it is known that self-report measures of PA often do not result in accurate descriptions of PA, but do provide insights into modes and domains of activities performed (Prince et al., 2008). Additionally, the modest changes in objectively measured PA and sedentary behavior may have been influenced by differences in participants wear-time of the wrist-worn accelerometer, leading to missed capturing of time spent sedentary or active.

Our retention rate was lower than an intervention which utilized a consumer grade wearable device to self-monitor PA (62.5%, 91.7%, respectively; Kooiman et al., 2018). However, retention rates were higher than another community-based intervention targeted towards rural older adults (41.1%; Nichols et al., 2021). Several factors may

have contributed to retention rates. Participants who indicated interest in and enrolled in the intervention were likely motivated to engage in behavior change, based on their interest in enrolling in the study. While participants identified the intervention as acceptable, the level of participant burden may have impacted study participation and feedback were received on areas for improvement which could reduce burden and improve retention. Retention was a high priority, with strategies including weekly check-in messages and incrementally increasing financial compensation for the study duration. Lastly, a greater number of participants completed the intervention and telephone interview (n=13), but were lost-to-follow due to incomplete measures indicating that completion and return of study measures may have been too burdensome for the population.

While the intervention was identified as acceptable and appropriate for rural adults intervention modifications may be needed; this study provides evidence to improve acceptability and safety, and reduce participant burden. Modifications to the *Active for Life* workbook include revising activities to reduce repetition and improving continuity between the logbook and action planning activities. Additional activities related to overcoming barriers will be explored. To reduce participant burden, individual activities within the workbook will be evaluated for future inclusion and the process for completing study measures will be re-evaluated. While the HAPA model constructs are operationalized throughout the workbook, additional emphasis may be needed on activities related to action self-efficacy and risk perceptions. Replacement of the research-grade wrist-worn accelerometer with a consumer-grade wearable device (i.e., activity tracking watch) could reduce the risk of localized skin irritation from the device

band, improve participant feedback from the device, and potentially improve wear-time compliance.

Due to the preliminary nature of this pilot study, a small sample size was obtained, and no power analysis was conducted. The enrolled sample is homogenous; future studies may require the inclusion of multiple recruitment settings to obtain a diverse sample of participants. The small, homogenous sample limits generalizability of the study findings to larger populations. The primary investigator was a member of the recruitment community and had pre-existing established relationships with providers, which may have influenced the ability to develop relationships with community stakeholders and impacted recruitment rates. The use of telephone interviews may have impacted the ability to interpret participants non-verbal cues, limiting understanding of acceptability. Additionally, the small effects observed in diabetes knowledge could have been the result of high levels of baseline diabetes knowledge or recall bias, as participants completed the Revised Diabetes Knowledge Test three times within nine weeks and could have increased their diabetes knowledge from completing the measure. It is difficult to identify if recall bias is present in this study, but should be evaluated in future studies.

This study adds to the body of literature by providing evidence of the feasibility, acceptability, and preliminary effects of a HAPA model guided PA and sedentary behavior intervention in a population of rural adults with T2DM. The development and successful implementation of appropriate, accessible interventions within clinical settings is integral to the growing needs of a vulnerable rural population, facing a high burden of chronic disease. Additionally, this study supports the preliminary evaluation of a PA and

sedentary behavior change intervention in a real-world setting, which will be transitioned to a mobile health technology platform in the future. The moderate to large estimates of intervention effect size warrant further investigation with fully powered research studies in the future.

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Table 10*Participant Characteristics*

Baseline characteristic	No. (Percentage)
Gender (n=13)	
Female	8 (61.5)
Male	5 (38.5)
Race (n=13)	
White	13 (100)
Ethnicity (n=13)	
Not Hispanic/Latino	12 (92.3)
Don't know/not sure	1 (7.7)
Education (n=12)	
High School Diploma or GED	10 (76.9)
Some college credit, no degree	1 (7.7)
Associate degree	1 (7.7)
Employment (n=12)	
Employed	2 (15.4)
Unemployed	1 (7.7)
Retired	6 (46.2)
Disability	3 (23.1)
Health Literacy Level (n=16)	
7 th to 8 th grade	1 (6.2)
High School	15 (93.8)
DM Medications (n=12)	
No Medications	3 (23.1)
Injectable Insulin + Oral Blood Sugar Lowering Medication	4 (30.8)
Oral Blood Sugar Lowering Medication	5 (38.5)
Other Health Problems (n=12)	
None Reported	3 (23.1)
1	2 (15.4)
2 – 3	4 (30.8)
4 or more	4 (30.8)
Family or Friend with T2DM (n=13)	
Yes	12 (92.3)
No	1 (7.7)

Table 11*Comparison of Active for Life Intervention Self-Reported Outcome Results by Time*

	Baseline		Post-Intervention		Follow-up		χ^2	<i>df</i>	<i>p</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
HBPAI									
HBPAI Total (n=10)	140.6	28.7	140.3	56.4	132.6	45.3	1.40	2	.50
Risk perception (n=9)	21.1	9.6	20.1	7.8	18.8	9.8	.42	2	.81
Action self-efficacy (n=9)	12.2	4.7	12	5.8	12.2	6.6	.06	2	.97
Outcome expectancies (n=9)	32.8	11.1	27.0	7.5	28.7	4.5	1.36	2	.51
Behavioral Intention (n=9)	10.7	6.1	11.8	7.3	10.1	6	1.18	2	.55
Planning (n=9)	21.9	9.3	22.4	11.5	23.6	10	.21	2	.90
Maintenance Self-efficacy (n=10)	30.9	14.1	37.1	19.1	35	16.8	1.08	2	.58
Recovery Self-efficacy (n=9)	14.8	6	15	9.9	13.1	7.7	2.00	2	.37
S4-MAD (n=10)									
Social Support	8.6	5.2	10.3	4.7	9.6	5.1	.84	2	.67
DKT2 (n=10)									
Diabetes Knowledge	9.5	2	9.9	2	10	1.4	1.93	2	.38
IPAQ-L (n=9)									
Total PA (MET-min/wk)	1236	1065	3431	3207	2383	2203	1.56	2	.46
Walking PA (MET-min/wk)	216	383	926	1365	556	792	1.92	2	.38
Moderate PA (MET-min/wk)	207	302	1282	2322	931	1303	.33	2	.85
Vigorous PA (MET-min/wk)	107	320	327	764	107	320	4.00	2	.14
Work domain (MET-min/wk)	4	11	102	206	158	347	3.00	2	.22
Travel domain (MET-min/wk)	209	385	315	683	202	254	.08	2	.96
Household domain (MET-min/wk)	880	828	2310	2310	1659	2014	.29	2	.87
Leisure domain (MET-min/wk)	143	316	705	705	365	686	5.06	2	.08
MSQ (min/wk)									
Total sitting time (n=7)	886	499	807	378	909	391	2.30	2	.32
Weekday sitting time (n=7)	461	201	427	185	451	179	2.77	2	.25
Weekend day sitting time (n=6)	496	262	443	120	533	149	1.24	2	.54
Work domain (n=1)	840	--	720	--	780	--	--	--	--
Travel domain (n=6)	84	46	112	73	137	79	1.29	2	.53
Computer domain (n=4)	135	158	60	69	90	77	3.71	2	.16
TV domain (n=4)	360	170	285	133	465	247	5.73	2	.06
Leisure domain (n=5)	138	66	102	111	136	101	2.53	2	.28

Note. HBPAI: Health Action Process Approach Model Based Physical Activity

Inventory; S4-MAD: Social Support Scale for Self-care in Middle Aged Adults with

T2DM; DKT2: Revised Diabetes Knowledge Test; IPAQ: International Physical Activity

Questionnaire; MSQ: Marshall Sitting Questionnaire; MET: metabolic equivalents;

min/wk: minutes per week

Table 12*Effect Sizes of Accelerometer-Obtained Physical Activity and Sedentary Behaviors (n=9)*

	<u>Baseline</u>		<u>Post-Intervention</u>		<i>z</i>	<i>p</i>	<i>r</i>	95% CI [#]	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				Lower	Upper
METS (n=8)	1.4	.2	1.4	.3	-.84	.40	.21	-.04	.07
Steps per week	57,619	15,784	59,222	22,097	-.53	.59	.13	-9347.50	13397.50
Sedentary bouts	92.8	51.7	96.7	48.9	-.53	.59	.13	-22.00	10.50
Sedentary breaks	92.3	51.7	95.7	48.9	-.53	.59	.13	-24.00	10.50
Sedentary time (min/wk)	3955	1684	4147	1533	-.42	.68	.10	-571.00	333.00
Light time (min/wk)	3535	674	3616	928	-.18	.86	.04	-391.00	433.00
Moderate time (min/wk)	610	255	614	344	-.06	.95	.01	-122.00	152.00
Sedentary %	48.9	14.1	48.8	14.2	-.18	.86	.04	-3.58	3.58
Light %	43.6	10.6	43.5	10.0	-.42	.68	.10	-3.07	3.22
Moderate %	7.5	4.2	7.7	5.1	-.77	.44	.18	-.94	1.40

Note. [#]: Related-Samples Hodges Lehman Median Difference 95% Confidence Interval

Table 13

Effect Sizes of Intervention on Self-Reported Outcome Results by Time

	Baseline – Post-Intervention					Post-Intervention – Follow-up					Baseline – Follow-up				
	z	p	95% CI [#]		r	z	p	95% CI [#]		r	z	p	95% CI [#]		r
			Lower	Upper				Lower	Upper				Lower	Upper	
HBPAI (n=10)															
HBPAI Total	-.05	.96	-35.00	35.00	.01	-.66	.51	-38.50	21.50	.15	-.66	.51	-37.00	-25.00	.19
Risk perception	-.42	.68	-9.00	7.00	.10	-.28	.78	-7.00	5.50	.06	-.99	.32	-7.50	1.50	.23
Action self-efficacy	-.24	.81	-5.00	6.00	.06	-.11	.92	-3.00	5.00	.02	0	1	-9.00	8.50	0
Outcome expectancies	-1.13	.26	-20.50	2.00	.25	-.34	.74	-4.50	9.00	.08	-.98	.33	-14.00	3.00	.23
Behavioral Intention Planning	.00	1.00	-3.50	4.50	0	-.73	.47	-7.00	1.00	.17	-.32	.75	-3.50	1.50	.07
Maintenance Self-efficacy	-.06	.95	-6.50	7.50	.01	-.68	.50	-2.00	4.00	.16	-.59	.55	-5.50	9.50	.14
Recovery self-efficacy	-.05	.96	-14.00	26.00	.01	-.06	.95	-19.50	13.00	.01	-.31	.76	-10.50	18.50	.07
	-.65	.52	-7.50	6.50	.15	-.51	.61	-11.00	6.00	.12	-.42	.67	-8.00	5.00	.10
S4-MAD (n=10)															
Social Support	-1.07	.28	-2.00	5.50	.24	-1.00	.32	-2.00	.500	.22	-.61	.54	-2.50	4.50	.14
DKT2 (n=10)															
Diabetes Knowledge	-.70	.48	-1.00	-1.50	.16	-.11	.92	-1.00	1.50	.02	-.85	.39	-1.00	2.00	.19
IPAQ-L (n=9)															
Total PA	-1.72	.09	-309.00	5019.00	.41	-.53	.59	-3915.00	1887.00	.13	-1.60	.11	-514.00	2742.00	.38
Walking PA	-1.27	.20	-198.00	2046.00	.30	-.73	.46	-1782.00	759.00	.17	-.94	.35	-198.00	1188.00	.22
Moderate PA	-.94	.35	-270.00	3120.00	.22	-.11	.92	-2780.00	1440.00	.03	-1.36	.17	-160.00	1680.00	.32
Vigorous PA	-1.34	.18	0	660.00	.32	-1.34	.18	-660.00	0	.32	0	1	0	0	0
Work domain	-1.34	.18	0	254.50	.32	-.45	.65	-66.00	318.00	.11	-1.34	.18	0	504.00	.32
Travel domain	-.14	.89	-445.50	940.50	.03	-.11	.92	-676.50	198.00	.03	-.34	.74	-544.50	396.00	.08
Household domain	-.68	.50	-435.00	4890.00	.16	-.17	.87	-4040.00	1800.00	.04	-1.35	.18	-450.00	2040.00	.32
Leisure domain	-2.02	.04*	0	1732.50	.48	-.73	.47	-1732.50	643.50	.17	-1.07	.29	-49.50	990.00	.25
MSQ (n=9)															
Total sitting time	-.84	.40	-357.50	162.50	.21	-.56	.57	-135.00	180.00	.13	-.25	.80	-165.00	240.00	.10
Weekday sitting time	-.63	.53	-157.50	82.50	.16	-.34	.73	-210.00	60.00	.08	-.42	.67	-150.00	180.00	.11
Weekend day sitting time	-.93	.35	-270.00	120.00	.21	-.82	.41	-120.00	270.00	.22	-.14	.89	-80.00	207.50	.04
Work domain	-.45	.66	-120.00	1140.00	.22	-1.07	.29	-720.00	60.00	.38	--	--	--	--	--
Travel domain	-1.75	.08	0	115.00	.44	0	1	-135.00	60.00	0	-1.46	.14	-5.00	147.50	.42

Computer domain	-1.60	.11	-480.00	0	.51	-1.73	.08	0	60.00	.50	-1.00	.32	-180.00	0	.35
TV domain	-1.86	.06	-120.00	0	.59	-1.22	.23	-180.00	360.00	.39	-.84	.40	-150.00	210.00	.24
Leisure domain	-1.24	.22	-210.00	60.00	.33	-.73	.47	-30.00	70.00	.20	0	1	-120.00	150.00	0

Note. HBPAI: Health Action Process Approach Model Based Physical Activity Inventory; S4-MAD: Social Support Scale for Self-care in Middle Aged Adults with T2DM; DKT2: Revised Diabetes Knowledge Test; IPAQ: International Physical Activity Questionnaire; MSQ: Marshall Sitting Questionnaire; *: statistically significant at .05 alpha level; #: Related-Samples Hodges Lehman Median Difference 95% Confidence Interval

Table 14

Telephone Interview Themes, Subthemes, and Narrative Excerpts

Theme	Subtheme	Exemplar Statements
Workbook, Watch, and Survey Features	Facilitating Features	<p><i>"I do like the organization of it [workbook]...it was pretty straight forward...everything was clear and ya know detailed"</i></p> <p><i>"like I said, I love that little watch"</i></p> <p><i>"...the first week you are trying to get adjusted to doing something different, and so the second week you are more on track and making your goals and the third week you are still at it...so by four weeks I think is a good time frame"</i></p>
	Barrier Features	<p><i>"well whenever I did stuff around the house upstairs....like if I would go from the living room to the kitchen...or the kitchen to the ya know without steadily walking...it didn't count, I don't think it was counting my steps..."</i></p> <p><i>"I guess there were two days I didn't get the steps recorded. And one I feel asleep on the couch and woke up after midnight and then it was like it started over a new day and I didn't know how many steps I had gotten that day because I feel asleep on the couch"</i></p> <p><i>"well it seems like it was hard to come up with different answers. You know it may ask some of the same questions because you've already answered a certain way...I'm like do I just repeat what I've already answered or try to think up something different"</i></p>
Short-and-Long Term Behavior Change Outcomes	Short-term behavior and health outcomes	<p><i>"I believe it had a positive effect on my PA levels. I have been doing more and trying to do more"</i></p> <p><i>"...positive effect because some of things in the workbook gave you suggestions like getting up during commercials watching TV and walking a little bit and getting up more often and actually moving a little more..."</i></p> <p><i>"...I've felt better, I'm losing weight again"</i></p> <p><i>"The workbook made me realize, that over a year ago I stopped using my CPAP that I'd used for 5 or 6 years...this reminded me to use it again...it clear my brain up again...I'm sleeping better at night, stay in bed, and taking less naps..."</i></p>
	Long-Term behavior change	<p><i>"I've got my other uh tracking spreadsheet that I had from before in front of me now...right here beside me...so every time I'm checking my blood sugar I'm writing it down and keeping track of it...and I still have my other Fitbit thing, so I'm still keeping some track of my steps per day and all that kind of stuff"</i></p>
Facilitators and Barriers of Behavior Change	Physical activity and sedentary behavior change facilitators	<p><i>"It's kind of eye opening, because I didn't realize just how much I was sitting"</i></p> <p><i>"I would keep the book by my side, and I'd look at it...and it was like okay I have to get up and walk"</i></p> <p><i>"And I'm gonna start going down like the other end of my floor level, go upstairs, walk the 8th floor, then come back down and go do the 7th. Every time I get stronger and stronger I'm going to do more levels of doing down more flights of steps and more up steps because it seems like it really work"</i></p> <p><i>"...and even when the weather was bad outside, we have an extremely long porch on the back side of the house and I would just walk up and down, ya know, across, ya know, for ya know...5 minutes or so"</i></p> <p><i>"...every week writing out my goals and what not, and ya know keeping those goals in track I think was a huge benefit to me..."</i></p>

Physical activity
and sedentary
behavior change
barriers

“well my husband helps a lot...because he will go downstairs and he will be working on stuff. So then I’m like well I better go down there and walk ya know”

“...ever since I’ve been diagnosed with diabetes, I probably learned more though your workbook than I knew before”

“I’m set in my ways and I’m not going to go out and walk so many miles or anything and that’s just me personally”

“And I know right now things are difficult with the omicron and stuff ya know...and that that has really ummm, put a limit on things too. I never though in my whole lifetime that we would ever be in this type of situation. I am...with my health issues, I try not go places and do things...so I’m ya know, everything I do has to be done right here in the house”

“...I was afraid if I set goals that were out there and if I didn’t complete them I would feel, ya know, like a failure”

“Because most of this stuff doesn’t happen short term at all...it happens over a very long period of time. It’s kind of one of those diseases that you really don’t feel it until it’s already got ahold of you pretty good”

“...like if I when I would go downstairs or go outside, which I haven’t done much because of the cold weather”

Rural Influence

“I have the TV on for noise ya know more than anything. And when the commercial come I thought okay well you need to get up and get moving”

“I never would have thought about walking during commercials and stuff like that...that was a good tip...”

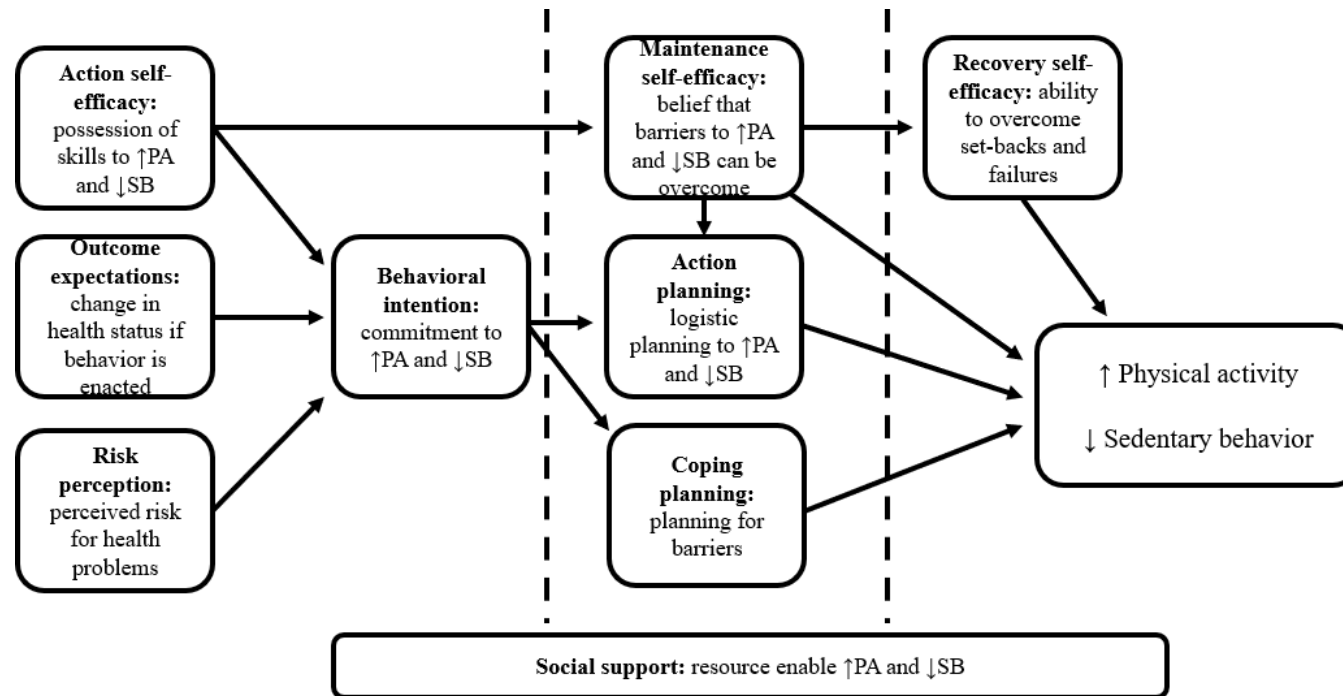
“...there’s no place to walk out here unless I drive somewhere to walk.ya know...there I live on a country road and there’s only four houses on that road, but you go down the hill they don’t take care of the road anymore and it’s eroded down there and if a car comes there’s no place to go”

“my daughter belongs to a gym but that isn’t anything that we would ever do”

“walking laps in the house and doing exercises at the counter in the kitchen and lifting weight in the house...and sometimes going out in the garage or going and doing things for farming activities”

Figure 3

Application of the HAPA Model to Physical Activity and Sedentary Behavior Change



Note. Dashed lines delineate self-efficacy-based stages.

Figure 4

Active for Life Workbook Broad Goals, Learning Objectives, and Construct Operationalization

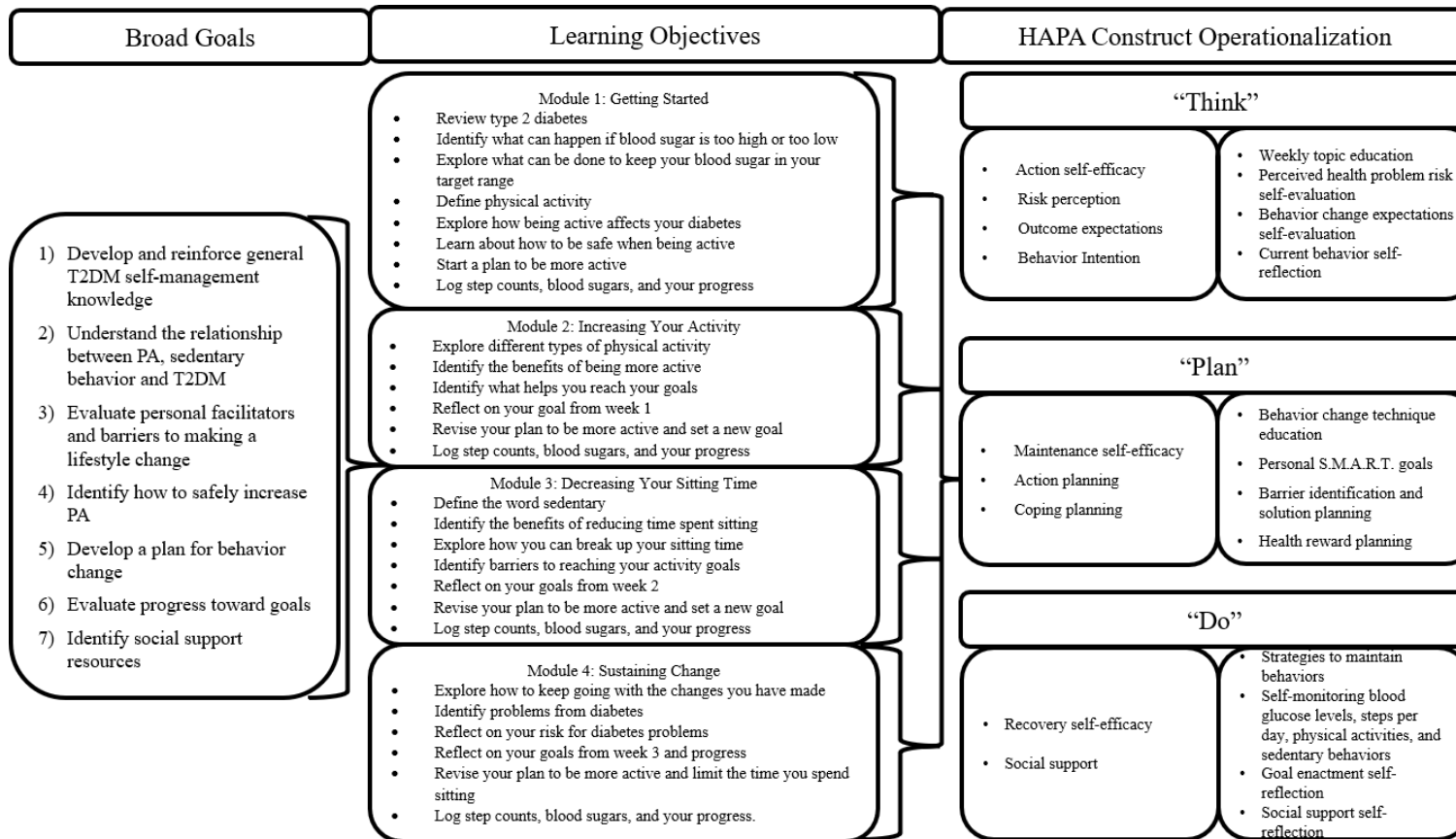
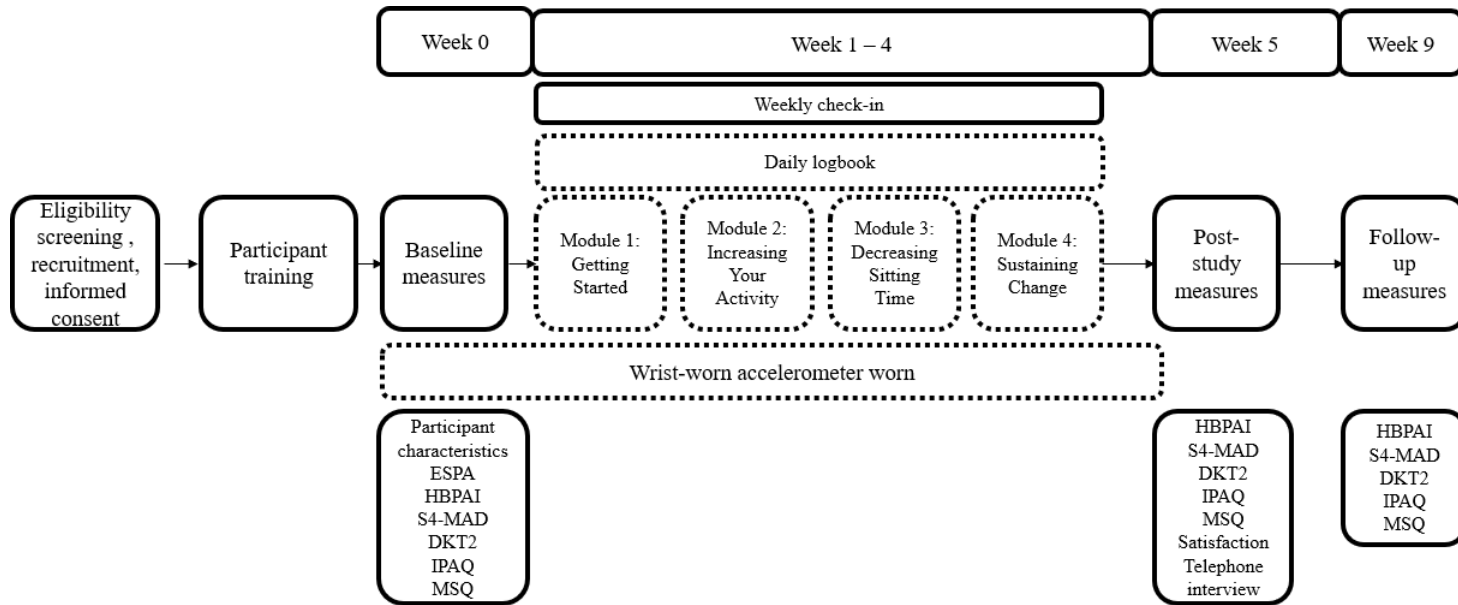


Figure 5

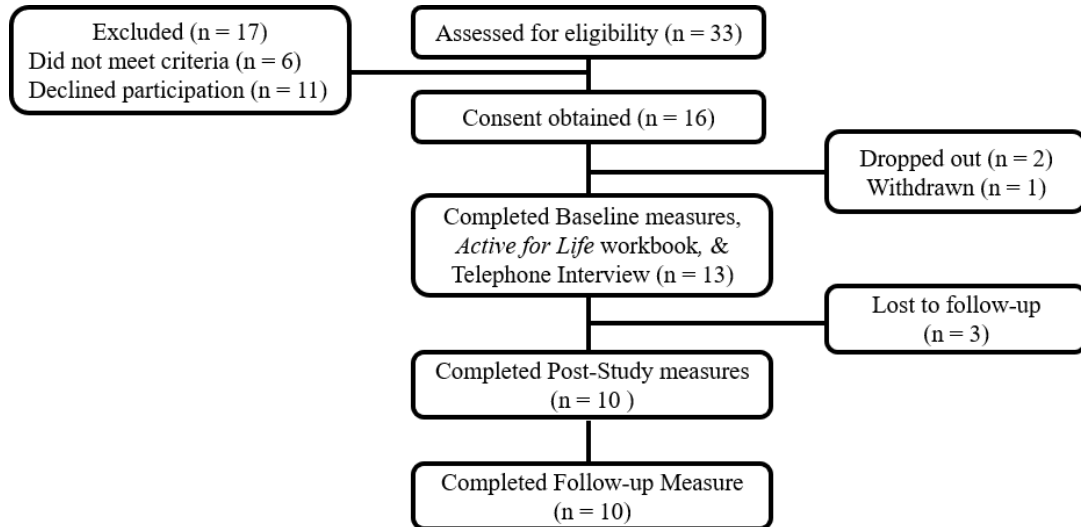
Overview of Study Procedures



Note. ESPA: Environmental Supports for Physical Activity; HBPAI: Health Action Process Approach Model Based Physical Activity Inventory; S4-MAD: Social Support Scale for Self-care in Middle Aged Adults with T2DM; DKT2: Revised Diabetes Knowledge Test; IPAQ: International Physical Activity Questionnaire; MSQ: Marshall Sitting Questionnaire

Figure 6

Participant Flow Through Study



CHAPTER FOUR: PART 2

ENGAGING RURAL POPULATIONS IN A TECHNOLOGY-BASED PHYSICAL ACTIVITY INTERVENTION

*As the primary author, my colleagues and I plan to submit the following for
publication*

A novel, 4-week educational and cognitive behavioral skill building physical activity (PA) and sedentary behavior change intervention was evaluated in a population of rural adults with Type 2 diabetes (T2DM). The intervention consists of an investigator developed *Active for Life* workbook and research-grade wrist-worn accelerometer (Actigraph GT9X-Link, Actigraph, LLC). The intervention was evaluated as a pilot study, with preliminary effects and acceptability, and succinct feasibility data reported in Chapter 4: Part 1. Due to the dearth of previously developed PA and sedentary behavior interventions for rural adults with T2DM, evaluation of feasibility is indicated to evaluate if study components can be used in a future fully powered intervention study and provide evidence to support refinement (Bowen et al., 2009; Eldridge et al., 2016). The following reports the findings of the *Active for Life* workbook, wrist-worn accelerometer, and study measure feasibility in a population on rural adults with T2DM.

Engaging Rural Populations in a Physical Activity Intervention

Rural adults most commonly participate in PA within their homes, neighborhoods, or community parks and trails; the most commonly performed activities include walking, gardening, and bicycling (Chrisman et al., 2015b). Attributes of rurality can influence an individuals' desire and ability to participate in PA. Unique personal, intrapersonal, environmental and policy features influence rural adults decision making

related to PA and sedentary behaviors. Midwestern rural adults surveyed identified competing personal priorities (i.e., work obligations, childcare), limited time, fatigue and tiredness, and a lack of motivation as barriers to increasing PA (Chrisman et al., 2015a; Jones et al., 2021; Miller et al., 2010). Social relationships can be both facilitators and barriers to increasing PA. Rural adults have described preferences for being active with a friend or having access to a supportive group of individuals as facilitators of PA (Chrisman et al., 2015b). Feelings of neighborhood safety and having destinations for PA (i.e., trails) may also facilitate PA in rural adults (Chrisman et al., 2015b). Conversely, stigma surrounding sharing T2DM diagnosis with family and peers related to concern of being perceived as chronically ill has been identified as a barrier to establishing social support systems to be more active (Bhattacharya et al., 2012). Community norms which are non-supportive of leading a physically active lifestyle in rural populations are an additional barrier to participating in PA (Jones et al., 2021). While characteristics of rural environments are geographically diverse, a lack of sidewalks, safety concerns related to roads, inadequate lighting, and limited accessible community resources to support PA have been identified (Chrisman et al., 2015b; Jones et al., 2021; Smalls et al., 2014). The influence of policy further impacts availability of environmental resources; Midwestern rural adults identified difficulties accessing public spaces and limited community planning (i.e., fewer parks and public recreation areas) as barriers to increasing PA (Chrisman et al., 2015b).

A limited number of interventions to increase PA and decrease sedentary behavior have been conducted in rural populations (Cleland et al., 2017), with even fewer conducted in rural adult populations with T2DM (Lepard et al., 2017). A meta-analysis of

PA and sedentary behavior interventions in rural adults identified no effects on PA or sedentary behavior (Cleland et al., 2017). However, at the individual study level greater effects were identified when objective measures of PA were included, versus when self-report measures alone were used (Cleland et al., 2017). Specific to rural populations with diabetes, interventions which included telehealth delivery methods, goal-setting and social support strategies, and tailored content demonstrated positive outcomes (Leopard et al., 2017). Additional research is needed to further understand rural adults with T2DM perspectives related to preferences and acceptability of PA and sedentary behavior interventions.

Challenges accessing, recruiting, and retaining rural populations are common in research (Nichols et al., 2021; Thurman & Harrison, 2020). Using strategies to enhance rural adults with T2DM engagement, recruitment and retention in PA and sedentary behavior interventions is integral to overcome barriers to enroll and retain adequate participants to detect changes in outcomes and identify findings which are generalizable to wider populations (Thurman & Harrison, 2020; Young et al., 2015). Engaging with rural communities to understand community needs and priority health concerns can improve engagement and intervention development. Establishing community partnerships and engaging community stakeholders is an effective strategy to engage rural adults, develop interventions tailored for rural adults, and improve intervention recruitment and retention rates (Young et al., 2015).

The Conceptual Framework of Feasibility Studies establishes evaluation of feasibility is warranted if uncertainty exists about the feasibility of a future randomized controlled trial (Eldridge et al., 2016). Feasibility studies can provide valuable evidence

when community partnerships need to be developed or maintained, there is little existing literature specific to the intervention, when little research has been conducted in the target population, or when a new setting is being utilized (Bowen et al., 2009). While several areas of focus exist relative to feasibility studies, the study reported here focused on evaluating intervention practicality and implementation in a population of rural adults with T2DM (Bowen et al., 2009). Practicality is defined as the extent the intervention can be carried out by participants; implementation is defined as the extent to which the intervention is successfully delivered to participants (Bowen et al., 2009).

Purpose

The purpose of this study was to evaluate the feasibility of a 4-week educational cognitive behavioral skill building PA and sedentary behavior change intervention guided by the Health Action Process Approach (HAPA) model in a population of rural adults with T2DM. A detailed evaluation of intervention components, the *Active for Life* workbook and wrist-worn accelerometer (Actigraph GT9X-Link), and study measures will be explored relative to feasibility in a population of rural adults with T2DM. Evaluation of detailed intervention feasibility findings will inform intervention refinement, prior to further evaluation as a fully powered randomized controlled trial aimed to increase PA and decrease sedentary behaviors in rural adults with T2DM.

Methods

Study Design, Setting, and Sample

The study used a quasi-experimental, one-group repeated measures design with semi-structured telephone interviews to a) determine feasibility and acceptability of the intervention within a population of rural adults with T2DM and (b) explore preliminary

intervention effects on HAPA model constructs, diabetes knowledge, PA, and sedentary behavior. The study received Institutional Review Board approval from the University of Missouri (IRB approval number 2063062).

Sixteen rural community-dwelling adults with T2DM were recruited from a Midwestern rural critical access hospital primary care clinic between November 2021 through February 2022. Enrolled participants met the following eligibility criteria: (1) diagnosed with T2DM, (2) rural community dwelling residents, (3) aged 18 – 75 years old, (4) able to speak, read, and write in English, (5) not exceeding 150 minutes of weekly moderate-to-vigorous PA, (6) able to increase PA without restrictions per their primary care provider risk assessment screening, and (7) had a primary care provider associated with the recruitment clinic. Participants were excluded if the following criteria were present (1) diagnosis of type 1 or gestational diabetes mellitus and (2) cognitive impairment. Cognitive impairment was evaluated using the Six-item Screen to Identify Cognitive Impairment Among Potential Subjects for Clinical Research; a three missed answer cut-point was applied to identify study eligibility (Callahan et al., 2002).

Recruitment and Enrollment

A collaborative partnership was developed with rural community stakeholders to develop the *Active for Life* workbook. Through the establishment of community partners, opportunities to collaborate with primary care providers at a Midwestern rural critical access hospital primary care clinic also arose. During the recruitment timeframe primary care providers displayed study flyers in the clinic and identified participants meeting basic eligibility criteria (i.e., diagnosed with T2DM, aged 18 – 75 years old, no PA restrictions, rural community-dwelling residents). The primary investigator was present

on-site to screen participants for eligibility and enroll them in the study if participants met eligibility criteria and volunteered to participate. Additionally, the study flyer was circulated as a Facebook advertisement.

Intervention

The intervention consisted of a 98-page, 8-inch x 11.5-inch color printed and spiral bound *Active for Life* workbook and a research-grade wrist-worn tri-axial accelerometer (Actigraph GT9X-Link, Actigraph, LLC). The *Active for Life* workbook was evaluated for clarity, readability, validation of concepts, and appropriateness for rural adults with T2DM by rural community stakeholders (rural primary care physician, certified diabetes educator, two community health department workers, and two community members with T2DM experiences) and health researchers with T2DM, patient education, rural health, and community based participatory method expertise. Workbook content is consistent with the Association of Diabetes Care and Education Specialists Curriculum (3rd Edition) and American Diabetes Association Clinician's Guide for PA (Association of Diabetes Care and Education Specialists [ADCES], 2021; Colberg et al., 2013). The *Active for Life* workbook is written at a 5th grade reading level, using plain, clear language; at minimum size 16 Arial font was used, white space was prioritized. The workbook included a cover page, an introduction which thanked participants for their participation in the study and provided a reminder of how to complete the workbook, table of contents, four modules, a logbook, and resources used. Tabs placed along the long edge of the workbook provided a quick reference for participants to access the weekly modules and logbook.

Figure 7 depicts *Active for Life* workbook broad goals and weekly module specific objectives and activities. The first module (Week 1 Module: Getting Started) focused on a review of T2DM, defined PA and established safety guidelines for increasing PA, and introduced creating an action plan. Activities within module one included self-reflecting on risk perception of common health problems and on how increasing PA and decreasing sedentary behaviors fit within the participants' lifestyle, and creating the action plan with one goal. The action plan consisted of establishing why the participants want to make a behavior change, setting S.M.A.R.T. (specific, measurable, attainable, realistic, timebound) goals, planning activities to fit the participants lifestyle, identifying three ways the plan can be adapted if setbacks arise, describing how to get back on track if a planned activity is missed, and identifying two sources of social support and one healthy reward.

The second module (Week 2 Module: Increasing Your Activity) focused on exploring different types and understanding the benefits of PA, self-reflecting on week one goals, and revising the action plan. Activities within module two included self-reflecting on how being more active will impact common health problems, on benefits and drawback of being more active, and on week one goals. The goal self-reflection included using a Visual Analog Scale to rate how participants perceived goal achievement, identify problems or issues that arose while enacting planned goals and activities, how problems were solved and sources of social support to help overcome problems, and a space to reflect on ideas for the current week. Next, participants identified one option to increase day-to-day activity and a second to increase aerobic

activity. Then, participants revised the action plan, setting two S.M.A.R.T. goals to increase PA.

The third module (Week 3 Module: Decreasing Your Sitting Time) focused on exploring sedentary behavior, understanding the benefits of breaking up sedentary time, self-reflecting on week two goals, and revising the action plan with three goals. Activities within module three included self-reflecting on how decreasing sedentary time will improve health problems, on when participants spend time sedentary, on benefits and drawbacks of decreasing sedentary time, and on week two goals. Next, participants identified one option to break up sedentary time during day-to-day activities and a second option to break up sedentary time in the evening. Then, participants revised the action plan, setting three S.M.A.R.T. goals, with two to increase PA and one to break up sedentary time.

The fourth module (Week 4 Module: Sustaining Change) focused on exploring long-term sustainability of behavior change, self-reflecting on diabetes health problems and on week three goals, and revising the action plan with three goals. Activities within module four included self-reflecting on the perceived risk of common health problems, on PA and sedentary behavior changes enacted in the past three weeks (i.e., a reflection on new activities, how sedentary behaviors have changed, how barriers are overcome, and strategies to sustain change), and on week three goals. Then participants revised the action plan with three S.M.A.R.T. goals.

The logbook included four sections, titled blood sugar, steps each day, track your activity, and sitting time. The blood sugar log included space to document blood glucose

levels for four weeks, at morning, mid-day, evening, and nighttime each day. The step count, PA, and sitting time logs included space to document daily for four weeks.

The wrist-worn accelerometer was worn on participants non-dominant wrist for the 4-week study duration, removing for bathing, swimming, showering, and charging the device. Participants were instructed to use the wrist-worn accelerometer to monitor steps per day. Steps per day were documented in the logbook of the *Active for Life* workbook.

Study Procedures

Participants received and were trained in the use of intervention materials after enrollment in the study during a face-to-face meeting. Participants were trained in the use of the wrist-worn accelerometer, including how and when to remove-reapply the device, what the symbols on the watch face indicated, and how to charge and calibrate the device. Participants were instructed to complete one workbook module per week and use the logbook section daily. Each week participants received a check-in message with a reminder to complete the weekly module and charge the wrist-worn accelerometer.

The study duration was nine weeks. Participants were assessed at baseline, after completion of the intervention (post-intervention at week 5), and four weeks later (follow-up at week 9). Figure 8 provides a longitudinal overview of study outcome measurement points. Participants were screened for cognitive impairment (Callahan et al., 2002) prior to enrollment. Once enrolled the Rapid Estimate of Adults Literacy in Medicine Short-Form was evaluated by the primary investigator (Arozullah et al., 2007). At baseline participants completed a demographic questionnaire, the Environmental Supports for PA (ESPA; Ainsworth et al., 2002), the Health Action Process Approach Based PA Inventory (HBPAI; Rohani et al., 2016), the Revised Diabetes Knowledge Test

(DKT2; Michigan Diabetes Research Center, 2015), International Physical Activity Questionnaire – Long Version (IPAQ-L; Craig et al., 2003), and the Marshall Sitting Questionnaire (MSQ; Marshall et al., 2010). Post-intervention participants completed the HBPAI, DKT2, IPAQ-L, MSQ, and an investigator developed Satisfaction questionnaire. At the follow-up measurement point, participants completed the HBPAI, DKT2, IPAQ-L, and MSQ. Feasibility was evaluated using data collected using a research log and from returned participant study materials. Acceptability was evaluated using post-intervention measures and telephone interviews.

Strategies to enhance participant retention included receiving intervention endorsement from primary care providers and discussing with participants' that the *Active for Life* workbook was developed with input from rural community stakeholders. Face-to-face screening and enrollment by the primary investigator facilitated development of rapport with participants. Additionally, participants received a weekly check-in message during the 4-week intervention and when additional study measures were collected. Participants received between \$5 and \$40 monetary compensation based on their time spent in the study.

Measurement of Feasibility

The feasibility of recruitment, retention, adherence to the intervention and study measures, time burden, and intervention safety were evaluated. Recruitment rates are defined as the number of participants enrolled/ number of participants approached. The length of time to recruit participants is defined as the number of days to reach target enrollment number of 15 participants. Recruitment challenges were obtained from telephone interviews and primary investigator field notes. Inclusiveness of eligibility

criteria are defined as the number of participants eligible/ number of patients at the recruitment clinic. Attrition rates are defined as the number of participants enrolled who completed baseline and post-study questionnaires/ number of participants enrolled. Reasons for attrition are obtained from follow-up interviews and primary investigator field notes.

The extent of workbook adherence is defined as the percentage of the workbook completed; 72 individual activities were identified in the workbook. The percentage of completed activities was defined as the number of activities completed/ number of activities in the workbook. Adherence to wrist-worn accelerometer use was measured objectively via the wear-time sensor of the Actigraph GT9X-Link (Actigraph, LLC). The extent of study measure completion was defined as the percent of measures completed; calculated as the number of measures completed/ total number of measures. Rates of missing data were calculated for each measurement tool. The time burden to complete the workbook, measures, and telephone interview were reported.

Adverse events or safety problems were monitored for the entirety of the study and reported to the Institutional Review Board within 24 hours of identification. Adverse events are quantified as the number of participants reporting an adverse event/ total number of participants.

Results

Recruitment

Thirty-three participants were approached for enrollment; of those, 16 were enrolled, resulting in a 48.5% recruitment rate. The targeted enrollment number of 15

participants was reached after 81 days. The sample of sixteen participants were recruited in 88 days.

Recruitment efforts presented several challenges. The process of primary care providers identifying potential participants using the electronic health record proved more difficult than anticipated. The rural primary care clinic electronic health record did not include features to sort patients by age, diagnosis, or location; therefore, the primary care providers had to individually review each scheduled patient encounter over a period of days to weeks to identify potential participants. The total number of potentially eligible participants at the primary care clinic was unable to be identified, due to an inability of primary care providers to create a report using the electronic health record. A winter COVID-19 surge presented significant barriers in participant recruitment. During a 15-day period the primary investigator was unable to return to the recruitment clinic due to high community COVID-19 levels. Upon return to the clinic, many potentially eligible participants attending routine clinic visits were subsequently diagnosed with COVID-19. Additionally, increased personal protective equipment guidelines and patient screening protocols impacted the primary care providers workload, decreasing available time to identify potential participants.

Social media recruitment was unsuccessful in this population, with no participants recruited from posted social media advertisements. Difficulties with Facebook security guidelines resulted in an inability to run the study advertisement, requiring an arduous verification process to reactive the page and advertise the study. Shortly after attempting to run an advertisement the page was deactivated. It was initially unclear why the page was deactivated; later, an email indicated page owner name verification was required.

Options were listed to submit documentation with name and date of birth or name and photo via government identification (ID) (i.e., driver's license, passport, birth certificate) or two forms of non-government ID (i.e., student card, refugee card, employment verification, diploma). Using a personal computer, a government ID was submitted following directions provided by Facebook; numerous attempts were unsuccessful. Only after using the Facebook mobile application, was the government ID accepted for verification; however, an attempt to run the advertisement was again non-successful.

Retention

Sixteen participants enrolled in the study. Thirteen participants completed the baseline measures, intervention, and participated in a post-intervention telephone interview about acceptability (81.3%). Ten participants completed all study data collection, which included the baseline measures, intervention, post-intervention telephone interview and measures, and follow-up measures (62.5%). The study attrition rate was 37.5%. See Figure 9 for a diagram of participant retention and attrition. Participants who dropped out of the study disenrolled during intervention weeks one and two. In follow-up discussion of why participants chose to leave the study, participants identified inadequate time to participate in the study due to work and family commitments:

“It’s just not something I can keep track of during my crazy schedule, I forget all about the handbook right away and have even forget to put the track watch on”

“I just don’t have the time right now”

Adherence to the Intervention

The median *Active for Life* workbook completion was $82.6 \pm 39.1\%$; completion ranged from 0.7% to 100% of the workbook. Specific to each workbook section, $88.9 \pm 36.3\%$ completed module one, $90.6 \pm 28\%$ completed module two, $85.3 \pm 34.5\%$ completed module three, $94.1 \pm 32.6\%$ completed module four, and $77.6 \pm 45.8\%$ completed the logbook. Table 15 reports activity specific completion of the workbook. Participants wore the wrist-worn accelerometer $82.2 \pm 10.3\%$ of the time; wear-time compliance ranged from 65.7% to 97.2%. Baseline measures were completed by 81.3% of participants; post-intervention and follow-up measures were completed by 62.5% of participants. Table 16 reports missing data rates from each measure by measurement point.

Time Burden

Participants self-reported spending 46 ± 22 minutes each week completing the weekly module and using the logbook. Self-reported time spent completing the workbook each week ranged from 15 to 75 minutes. Time spent completing each measure by measurement point is reported in Table 17. Telephone interviews lasted on average 10 ± 4 minutes, with the shortest interview lasting 4 minutes and the longest 17 minutes.

Safety

One adverse event was reported during the study, resulting in a 6.3% adverse event rate. After completing the intervention, a participant reported experiencing skin irritation at the site of the wrist-worn accelerometer. The skin irritation began shortly after wearing the device and worsened over the 4-week study timeframe. After removing the wrist-worn accelerometer the skin irritation resolved without treatment. While not

considered an adverse event, one participant was disenrolled due to safety concerns after multiple falls were reported during intervention week three. The falls were deemed unrelated to the intervention, but safety secondary to enrolling individuals with a high multimorbid disease burden should be considered.

Discussion

A detailed evaluation of intervention feasibility revealed four useful findings that will inform intervention refinement. First, recruiting rural adults with T2DM from primary care clinics with primary care provider referrals was a feasible means to recruit participants, yet challenges were encountered with both the electronic record and use of social media. Second, while participants were largely adherent to the *Active for Life* workbook and wrist-worn accelerometer areas for improvement were revealed. Third, the burden of completing study measures was examined and strategies were identified to improve completion of measures in future studies. Last, engaging community stakeholders during *Active for Life* workbook development to develop the intervention and establishing rapport with participants was integral to participant retention.

Recruitment

Recruiting rural adults with T2DM from a rural critical access hospital primary care clinic via primary care provider referral and flyers displayed in the clinic was a feasible recruitment strategy. Miyomoto et al. (2013) identified primary care provider referral as the most effective means to recruit rural adults with T2DM for intervention research studies, which is consistent with the present study findings. Additionally, collaborating with and placing flyers in local primary care clinics is identified as a strategy to engage rural adults for recruitment (Friedman et al., 2015; Thurman &

Harrison, 2020; Young et al., 2015). Establishing a presence within the recruitment community by engaging with community stakeholders was a key recruitment strategy, which is supported by findings in studies with rural adults with T2DM (Miyomoto et al., 2013). Additionally, the primary investigator who recruited participants was local to the recruitment community and had established relationships with community partners, which may have enhanced recruitment efforts (Miyomoto et al., 2013). Engaging community stakeholders and collaborating with individuals living locally for recruitment have demonstrated effectiveness in reaching hard to access rural populations (Thurman & Harrison, 2020). Maintaining flexibility and scheduling recruitment and enrollment around participants' planned routine clinic visits aided in reducing burdens associated with transportation or work requirements. Miyomoto et al. (2013) similarly described the importance of overcoming barriers related to a lack of transportation by implementing recruitment strategies which reduced travel associated burden.

Identifying eligible participants via electronic health record reports and the use of a social media-based advertisement were not the most effective recruitment strategies in this study. Streamlined and comprehensive identification of potential participants using the electronic health record requires technology with a feature-set to search for keywords through the electronic health record database. When the required features-set is absent, the task of identifying participants through electronic health records becomes cumbersome. Similar experiences were observed when clinics identified potential participants for a diabetes technology intervention; clinics with the capability to search electronic health record databases for potential participants efficiently identified eligible participants; however, when searching capabilities were absent it become more

burdensome to identify potential participants (Miyomoto et al., 2013). The use of social media as a simple and effective method to recruit individuals for research is gaining popularity; however this research study demonstrated barriers encountered using a social media recruitment strategy. Technical barriers increased recruitment strategy burden and potential privacy concerns were encountered. The cause of technical barriers when attempting to upload identification for verification using a personal computer is unknown; however, the need for technical proficiency to navigate social media-based recruitment strategies is revealed. A study on the use of social networking sites by healthcare providers for communication identified technical use challenges in those who infrequently used social media (Chan & Leung, 2018). When compared to in-person strategies, direct provider referral and contact via telephone, media advertising resulted in lower recruitment rates in rural populations (Young et al., 2015). One study engaged community gatekeepers to share recruitment materials via social media which was an effective strategy to reach potential participants (Thurman & Harrison, 2020). Differences observed between generic social media recruitment strategies and collaboration with community gatekeepers may be attributed to increased trust and interest in the research study due to endorsement by a trusted community member. Further research is needed to explore the benefits of community gatekeepers circulating recruitment materials via social media.

Additionally, while primary care provider referral was an effective recruitment strategy, Young et al. (2015) discussed the need to balance provider workload with recruitment. Utilizing recruitment strategies which reduce primary care provider burden are integral, to avoid providers feeling overwhelmed and balance recruitment needs with

workload. To further improve participant recruitment, a greater focus on community engagement to identify diverse community stakeholders, assessment of community needs and health priorities, and establishment of community presence to spread awareness of the research study should be sought.

Intervention Adherence

Active for Life Workbook Adherence

Overall, participants demonstrated moderate adherence to the *Active for Life* workbook; however, a greater interest for certain aspects of the workbook were identified. In a 12-week web-based PA intervention using a consumer-grade wearable device (wrist-worn activity tracker) for step count self-monitoring 82.5% of intervention participants completed more than half of the intervention content (Kooiman et al., 2018); the current study reported an 82.6% median workbook completion rate. Given similarities in behavior change techniques used between studies, it is possible that intervention delivery via a web-based platform or use of a consumer-grade wearable device to self-monitor PA was more appealing than a self-guided workbook to adults with T2DM. It is integral to first test intervention content and structure prior to developing a web-based or other telehealth intervention, as the intervention delivery strategy may confound the ability to identify the underlying influence of behavior change techniques on outcomes. While the weekly content was not described in great detail by Kooiman et al. (2018), differences in weekly content burden may have made the web-based PA intervention more appealing to participants. The present study delivered content over a 4-week timeframe, likely resulting in a greater weekly content burden, than the 12-week web-based PA intervention used by Kooiman et al. (2018).

Workbook module two (Increasing Your Activity) and module four (Sustaining Change) had the highest adherence rates, with module one (Getting Started) and module three (Decreasing Your Sitting Time) having lower adherence rates. Most individual activities within the workbook demonstrated high levels of adherence, except for a module one activity focused on identifying how behavior changes will fit into the participants' lifestyle. Longitudinally workbook adherence increased after module one, with the exception of activities related to sedentary behaviors. Within the Action Plan activities, items related to identifying why participants wanted to change behaviors, getting back on track after a slip-up, social support, and healthy rewards were the least often completed. Participants' reasons why they wanted to change behavior and strategies for overcoming slip-ups may not have varied greatly overtime, making completion of the same activity multiple times repetitive, thereby decreasing interest in completing the activities. Within personal reflection, reflecting on social support resources to help get back on track were the least frequently completed. Personal attributes of independence and self-sufficiency are valued by rural adults (Young et al., 2015). Activities related to social support resources and personal rewards may have been viewed as admitting to dependence or a lack of internal motivation, therefore decreasing adherence to the aforementioned workbook activities.

The logbook was the least frequently used workbook section which is inconsistent with findings from Connelly et al. (2017), who identified the logbook feature of a web-based PA intervention to be the most frequently used feature. The difference in findings may be attributed to logbook ease of use on a mobile application compared to other intervention components (i.e., educational modules, quizzes, etc.). Logbook activities

related to sitting time were the least complete. Lower adherence to the workbook module and logbook related to sedentary behavior indicate this content did not resonate as effectively as content related to T2DM or PA. Sedentary behaviors are associated with many passive behaviors (i.e., sitting, watching television, etc.), which may make recall of time spent sedentary more difficult as it is not perceived by study participants as a planned behavior. A recent evaluation of sedentary behaviors across United States adult populations identified 82% of leisure time is spent sedentary, with additional sedentary time accumulated across behavioral domains (Matthews et al., 2021). Combined, spending greater amounts of leisure time sedentary and difficulties recalling time spent sedentary may make identifying actionable goals difficult. While the blood sugar logbook section was utilized by the majority of participants, it is unknown how many or how frequently participants enrolled in the study were asked to self-monitor blood glucose levels by their primary care providers, which may have affected the blood sugar logbook completion rate.

Wrist-Worn Accelerometer Adherence

Objective measures of wrist-worn accelerometer wear-time compliance indicated that participants wore the accelerometer for 82.2% of the study duration. This is slightly lower than findings from Kooiman et al. (2018) which indicated that participants were 82.5% adherent to wearing the consumer-grade wearable device 75% of the time. Additionally, one participant experienced skin irritation at the wrist-worn accelerometer wear location. No additional reports of skin sensitivity to wrist-worn accelerometers specifically were identified in literature reviewed; however, given individuals with T2DM greater risk for skin problems it is important to further explore the wearability of

wrist-worn accelerometers in populations with T2DM. Consumer-grade wearable devices have been identified as effective at increasing PA, with greater effects observed when used with other behavior change techniques, and some are identified as accurately measuring PA and sedentary behaviors (Brickwood et al., 2019). Additionally, the consumer-focused design features of consumer-grade wearable devices may improve wear-time adherence, as compared to a research-grade device, which has limited patient-facing features. While participant preference between research-grade (Actigraph GT9X-Link) and consumer-grade wearable device was not explored, additional research is needed to understand if the wearable device influenced intervention adherence (i.e., *Active for Life* workbook).

Study Measure Completion

Most study participants completed baseline measures (81.3%), with 62.5% completing post-intervention and follow-up measures. The overall time burden to complete study measures may have influenced participants decision to complete additional measures, as the baseline measure took 57 minutes on average to complete. While post-intervention and follow-up measures required less time to complete, it could be beneficial to collect more baseline data in-person, to reduce the time spent completing baseline measures. A closer evaluation of study measures demonstrates trends in completion. Measures collected by the research investigator (i.e., REALM-SF and telephone interview) were completed 100% of the time, likely due to ease of completion. Additionally, the demographic questionnaire, ESPA, S4-MAD, DKT2, and satisfaction questionnaire demonstrated high completion rates across measurement points. Conversely, the HBPAI, IPAQ-L, and MSQ demonstrated lower completion rates at all

measurement points. When the length of time to complete study measures is compared, the HBPAI, IPAQ-L, and MSQ averaged 8 minutes or longer to complete, which is a longer average completion time than measures with higher completion rates. Anecdotally, participants annotated questions on returned measures about how to answer the HBPAI, indicating how to answer some questions was unclear to participants. To improve clarity, additional instructions about answering Likert style questions, formatting changes, and an example could be added. Both the IPAQ-L and MSQ require participants to recall PA and sedentary behaviors and report findings in days per week and hours and minutes per day. Like the HBPAI, instruction clarity and formatting changes may improve completion rates of the IPAQ-L and MSQ based on patterns of incomplete data observed.

Retention

Retention rates (62.5%) were higher than a community-based intervention in rural older adults (41.1%; Nichols et al., 2021), but lower than a self-monitoring PA intervention for adults with T2DM delivered via a web-based platform (91.7%; Kooiman et al., 2018). The *Active for Life* workbook was developed with community stakeholder input, using plain language at a 5th grade reading level. Miyomoto et al. (2013) identified the importance of developing study materials tailored for rural adults to engage study participants; the present study saw similar findings. Participants desire to improve their understanding of T2DM was identified as the most common reason for study enrollment in an intervention focused on diabetes self-management (Miyomoto et al., 2013). The education and cognitive behavioral skill building workbook in this study may have led to greater levels of participant engagement; that said, reasons for intervention engagement require further exploration to fully understand why participants chose to enroll. Face-to-

face recruitment strategies and regular check-ins with participants may have facilitated study retention. The benefits of developing rapport and establishing a trusting relationship in retaining rural participants has been described (Young et al., 2015). Additionally, regular participant follow-up has demonstrated the ability to improve retention (Young et al., 2015). Providing monetary compensation at the end of the study, based on the amount of time spent in the study, may have influenced some participants decision to complete the study.

While many facilitators to retain participants were in place, barriers to retention were identified. Measures of adherence to the *Active for Life* workbook and wrist-worn accelerometer provide insight into intervention features which participants may have deemed a barrier to study completion. Participant completion of the intervention, but lack of return of study measures provides further insights. Return of study measures may have been perceived as less important than completing the intervention; perceived personal or societal benefits have been associated with increased participant engagement (Young et al., 2015). The time commitment to both complete the intervention and time burden associated with study measures may have served as a barrier to study retention. Anticipated time commitments related to participating in research studies is identified as a barrier to participation in rural adults with T2DM (Miyomoto et al., 2013). Additionally, mailed questionnaires to be completed independently by participants may have been a barrier to retention. As identified by Nichols et al. (2021), participants may forget to complete and return study measures when required to complete measures independently, even when pre-paid postage is provided. The benefits of providing support and information upon request has been identified as a facilitator to completing

study measures in rural adult populations (Young et al., 2015). Reducing participant time burden to complete study measures and ensuring support is available may improve retention rates by addressing identified barriers to adherence.

Limitations

This study of feasibility of a PA and sedentary behavior intervention for rural adults with T2DM is not without limitations. Intervention feasibility was evaluated in a small, homogenous sample, which limits generalizability of feasibility findings to other populations. Limited information was collected related to participant comprehension of study measures; additional research is needed to understand Midwestern rural adults' perceptions and comprehension of PA and sedentary behavior measurement tools. Additionally, a single wrist-worn accelerometer was used for the study, limiting the ability to identify participant preference between consumer-grade and research-grade accelerometers for self-monitoring. The feasibility of conducting this study in a real-world setting where clinic staff facilitate participation is unknown and requires future investigation to evaluate intervention scalability.

Conclusions

The detailed evaluation of feasibility data provides valuable context to support intervention refinement, prior to conducting a fully powered study to evaluate intervention efficacy. Integration of detailed feasibility findings with intervention preliminary effects and acceptability will be discussed in Chapter 5. Recommendations for intervention refinement will be incorporated prior to further intervention evaluation.

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Table 15*Completion of Workbook by Activity*

	Activity	Percent	Number
Individual Activities	Mod. 1 Health Problem Risk Perception (n=13)		
	Complete	92.3	12
	Incomplete	7.7	1
	Mod. 1 Lifestyle Fit Behavior Change (n=13)		
	Complete	38.5	5
	Incomplete	61.5	8
	Mod. 2 Outcome Expectations PA (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 2 PROs and CONs (n=12)		
	Complete	83.3	10
	Incomplete	7.7	2
	Mod. 2 Daily Activity (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 2 Aerobic Activity (n=12)		
	Complete	75	9
	Incomplete	25	3
	Mod. 3 Outcome Expectations Sed. Behavior (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 3 Daily Sitting Time (n=12)		
	Complete	83.3	10
	Incomplete	7.7	2
	Mod 3. PROs and CONs (n=12)		
	Complete	75	9
	Incomplete	25	3
Mod. 3 Daily Sitting Time (n=12)			
Complete	66.7	8	
Incomplete	33.3	4	
Mod. 3 Evening Sitting Time (n=12)			
Complete	66.7	8	
Incomplete	33.3	4	
Mod. 4 Health Problem Risk Perception (n=11)			
Complete	81.8	9	
Incomplete	18.2	2	
Mod. 4 Reflect New Activities (n=11)			
Complete	90.9	10	
Incomplete	9.1	1	
Mod. 4 Reflect Decrease Sitting Time (n=11)			
Complete	90.9	10	
Incomplete	9.1	1	

	Mod. 4 Reflect Overcome Barriers (n=11)		
	Complete	81.8	9
	Incomplete	18.2	2
	Mod. 4 Reflect Lifestyle Strategy (n=11)		
	Complete	81.8	9
	Incomplete	18.2	2
Action Plan Activities	Mod. 1 Action Plan Why (n=13)		
	Complete	84.6	11
	Incomplete	15.4	2
	Mod. 2 Action Plan Why (n=12)		
	Complete	83.3	10
	Incomplete	7.7	2
	Mod. 3 Action Plan Why (n=12)		
	Complete	75	9
	Incomplete	25	3
	Mod. 4 Action Plan Why (n=11)		
	Complete	72.7	8
	Incomplete	27.3	3
	Mod. 1 Action Plan Goal (n=13)		
	Complete	76.9	10
	Incomplete	23.1	3
	Mod. 2 Action Plan Goal (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 3 Action Plan Goal (n=12)		
	Complete	58.3	7
	Incomplete	41.7	5
	Mod. 4 Action Plan Goal (n=11)		
	Complete	81.8	9
	Incomplete	18.2	2
	Mod. 1 Action Plan Planning (n=13)		
	Complete	61.5	8
	Incomplete	38.5	5
	Mod. 2 Action Plan Planning (n=12)		
Complete	83.3	10	
Incomplete	7.7	2	
Mod. 3 Action Plan Planning (n=12)			
Complete	58.3	7	
Incomplete	41.7	5	
Mod. 4 Action Plan Planning (n=11)			
Complete	72.7	8	
Incomplete	27.3	3	
Mod. 1 Action Plan Setbacks (n=13)			
Complete	69.2	9	
Incomplete	30.8	4	
Mod. 2 Action Plan Setbacks (n=12)			

Complete	83.3	10
Incomplete	7.7	2
Mod. 3 Action Plan Setbacks (n=12)		
Complete	58.3	7
Incomplete	41.7	5
Mod. 4 Action Plan Setbacks (n=11)		
Complete	54.5	6
Incomplete	45.5	5
Mod. 1 Action Plan Back on Track (n=13)		
Complete	69.2	9
Incomplete	30.8	4
Mod. 2 Action Plan Back on Track (n=12)		
Complete	75	9
Incomplete	25	3
Mod. 3 Action Plan Back on Track (n=12)		
Complete	50	6
Incomplete	50	6
Mod. 4 Action Plan Back on Track (n=11)		
Complete	45.5	5
Incomplete	54.5	6
Mod. 1 Action Plan Social Support (n=13)		
Complete	69.2	9
Incomplete	30.8	4
Mod. 2 Action Plan Social Support (n=12)		
Complete	75	9
Incomplete	25	3
Mod. 3 Action Plan Social Support (n=12)		
Complete	50	6
Incomplete	50	6
Mod. 4 Action Plan Social Support (n=11)		
Complete	63.6	7
Incomplete	36.4	4
Mod. 1 Action Plan Reward (n=13)		
Complete	61.5	8
Incomplete	38.5	5
Mod. 2 Action Plan Reward (n=12)		
Complete	66.7	8
Incomplete	33.3	4
Mod. 3 Action Plan Reward (n=12)		
Complete	41.7	5
Incomplete	58.3	7
Mod. 4 Action Plan Reward (n=11)		
Complete	45.5	5
Incomplete	54.5	6
Mod. 2 Reflect Visual Analog Scale (n=12)		
Complete	75	9

Weekly Reflection Activities	Incomplete	25	3
	Mod. 3 Reflect Visual Analog Scale (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 4 Reflect Visual Analog Scale (n=11)		
	Complete	90.9	10
	Incomplete	9.1	1
	Mod. 2 Reflect Goal Problems (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 3 Reflect Goal Problems (n=12)		
	Complete	91.7	11
	Incomplete	8.3	1
	Mod. 4 Reflect Goal Problems (n=11)		
	Complete	90.9	10
	Incomplete	9.1	1
	Mod. 2 Reflect Problem Solve (n=12)		
	Complete	83.3	10
	Incomplete	7.7	2
	Mod. 3 Reflect Problem Solve (n=12)		
	Complete	75	9
	Incomplete	25	3
	Mod. 4 Reflect Problem Solve (n=11)		
	Complete	72.7	8
	Incomplete	27.3	3
	Mod. 2 Reflect Support Help (n=12)		
	Complete	75	9
	Incomplete	25	3
	Mod. 3 Reflect Support Help (n=12)		
	Complete	58.3	7
	Incomplete	41.7	5
	Mod. 4 Reflect Support Help (n=11)		
	Complete	54.5	6
	Incomplete	45.5	5
	Mod. 2 Reflect Ideas (n=12)		
	Complete	83.3	10
	Incomplete	7.7	2
	Mod. 3 Reflect Ideas (n=12)		
	Complete	66.7	8
	Incomplete	33.3	4
	Mod. 4 Reflect Ideas (n=11)		
	Complete	72.7	8
	Incomplete	27.3	3
	Logbook: Blood Sugar (n=13)		
	Complete	69.2	9
	Incomplete	30.8	4

Logbook Activities	Logbook: Steps Week 1 (n=13)		
	Complete	69.2	9
	Incomplete	30.8	4
	Logbook: Steps Week 2 (n=12)		
	Complete	66.7	8
	Incomplete	33.3	4
	Logbook: Steps Week 3 (n=12)		
	Complete	66.7	8
	Incomplete	33.3	4
	Logbook: Steps Week 4 (n=11)		
	Complete	72.7	8
	Incomplete	27.3	3
	Logbook: PA Week 1 (n=13)		
	Complete	69.2	9
	Incomplete	30.8	4
	Logbook: PA Week 2 (n=12)		
	Complete	66.7	8
	Incomplete	33.3	4
	Logbook: PA Week 3 (n=12)		
	Complete	66.7	8
	Incomplete	33.3	4
	Logbook: PA Week 4 (n=11)		
	Complete	72.7	8
	Incomplete	27.3	3
	Logbook: Sitting Week 1 (n=13)		
	Complete	61.5	8
	Incomplete	38.5	5
	Logbook: Sitting Week 2 (n=12)		
	Complete	58.3	7
	Incomplete	41.7	5
	Logbook: Sitting Week 3 (n=12)		
	Complete	50	6
	Incomplete	50	6
	Logbook: Sitting Week 4 (n=11)		
	Complete	63.6	7
	Incomplete	36.4	4

Note. Mod.: Module; Sed: sedentary

Table 16*Missing Measures Data Rates by Measurement Point (n=13)*

Measure	Measurement Point	Completed			
		Mean Percent	SD	Percentage	Number
Demographic	Baseline	93	13.1	--	--
REALM-SF	Baseline (n=16)	100	--	--	--
ESPA	Baseline	100	--	--	--
HBPAI	Baseline	83.9	26	--	--
	Post-Intervention	88	17.2	--	--
	Follow-up	81.8	23.7	--	--
S4-MAD	Baseline	93.9	22.2	--	--
	Post-Intervention	100	--	--	--
	Follow-up	100	--	--	--
DKT2	Baseline	96.7	9.9	--	--
	Post-Intervention	92.1	14.9	--	--
	Follow-up	99.3	2.3	--	--
Satisfaction	Post-Intervention	100	--	--	--
IPAQ-L	Baseline				
	Completed	--	--	84.6	11
	Incomplete			15.4	2
	Post-Intervention				
	Completed	--	--	76.9	10
	Dropped Out			23.1	3
MSQ	Follow-up				
	Completed	--	--	76.9	10
	Dropped Out			23.1	3
	Baseline				
	Completed	--	--	76.9	10
	Incomplete			23.1	3
MSQ	Post-Intervention				
	Completed	--	--	76.9	10
	Dropped Out			23.1	3
	Follow-up				
	Completed	--	--	69.2	9
	Incomplete			7.7	1
	Dropped Out			23.1	3

Note. REALM-SF: Rapid Estimate of Adults Literacy in Medicine Short-Form; ESPA:

Environmental Supports for PA; HBPAI: Health Action Process Approach Model Based

Physical Activity Inventory; S4-MAD: Social Support Scale for Self-care in Middle

Aged Adults with T2DM; DKT2: Revised Diabetes Knowledge Test; IPAQ: International Physical Activity Questionnaire; MSQ: Marshall Sitting Questionnaire

Table 17*Time Spent Completing Measures by Measurement Point*

Measure	Measurement Point	Mean (minutes)	SD (minutes)	Range (minutes)
Total	Baseline ¹	56.7	33.2	14 – 115
	Post-Intervention ²	37.6	33	10 – 100
	Follow-up ²	28.2	19.3	8 – 70
Demographic	Baseline ¹	7	4	1 – 15
ESPA	Baseline ¹	4.8	2.8	1 – 10
HBPAI	Total	8.5	7.8	1.3 – 28.3
	Baseline ¹	8.4	6.5	2 – 25
	Post-Intervention ²	12	10.9	2 – 30
S4-MAD	Follow-up ²	8.6	8	2 – 30
	Total	3.2	2.7	.3 – 8.3
	Baseline ¹	3.9	3.3	1 – 10
DKT2	Post-Intervention ²	4.2	4.7	1 – 15
	Follow-up ²	2.8	1.9	1 – 5
	Total	4.7	2.6	1.7 – 10
IPAQ-L	Baseline ¹	6.7	3.6	3 – 15
	Post-Intervention ²	4.4	3.1	1 – 10
	Follow-up ²	5.3	3.7	2 – 10
MSQ	Total	8	4.4	2.3 – 18.3
	Baseline ¹	10.8	7.6	2 – 30
	Post-Intervention ²	8.9	8	2 – 30
Satisfaction	Follow-up ²	7.1	5.3	2 – 20
	Total	8.7	6	1.3 – 22
	Baseline ¹	19.3	18	1 – 56
Satisfaction	Post-Intervention ²	4.2	3.5	1 – 10
	Follow-up ²	4.5	3.7	1 – 10
	Satisfaction ²	4.8	6.4	1 – 20

Note. ¹: n=13; ²: n=10; REALM-SF: Rapid Estimate of Adults Literacy in Medicine

Short-Form; ESPA: Environmental Supports for PA; HBPAI: Health Action Process

Approach Model Based Physical Activity Inventory; S4-MAD: Social Support Scale for

Self-care in Middle Aged Adults with T2DM; DKT2: Revised Diabetes Knowledge Test;

IPAQ: International Physical Activity Questionnaire; MSQ: Marshall Sitting

Questionnaire

Figure 7

Active for Life Workbook Broad Goal and Module Specific Objectives and Activities

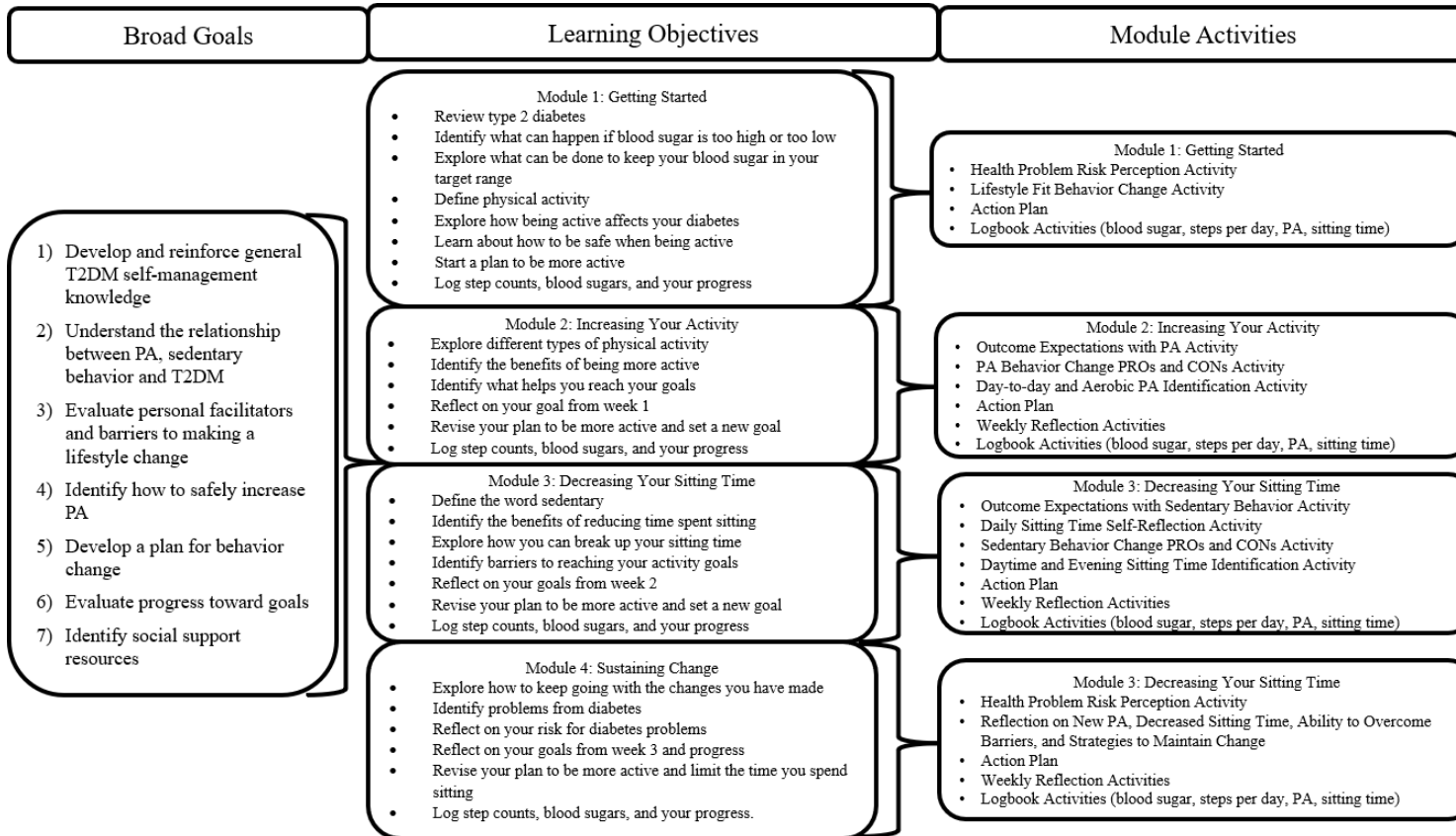
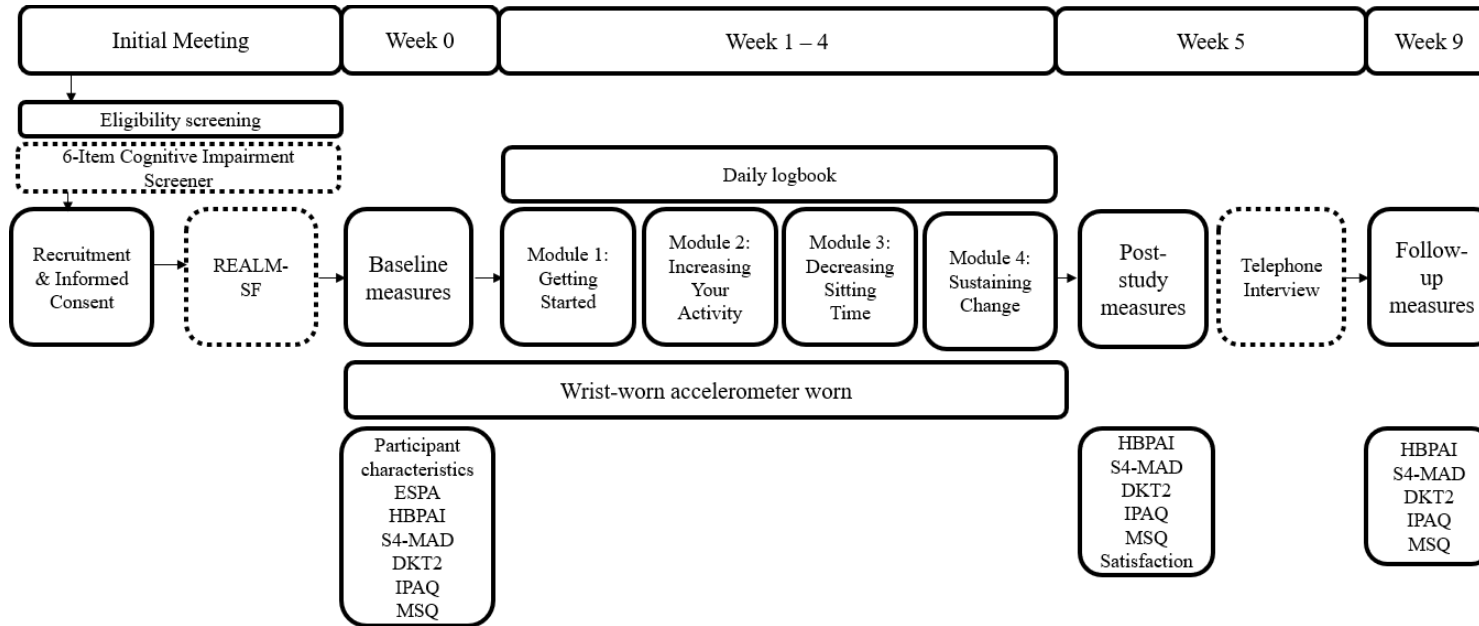


Figure 8

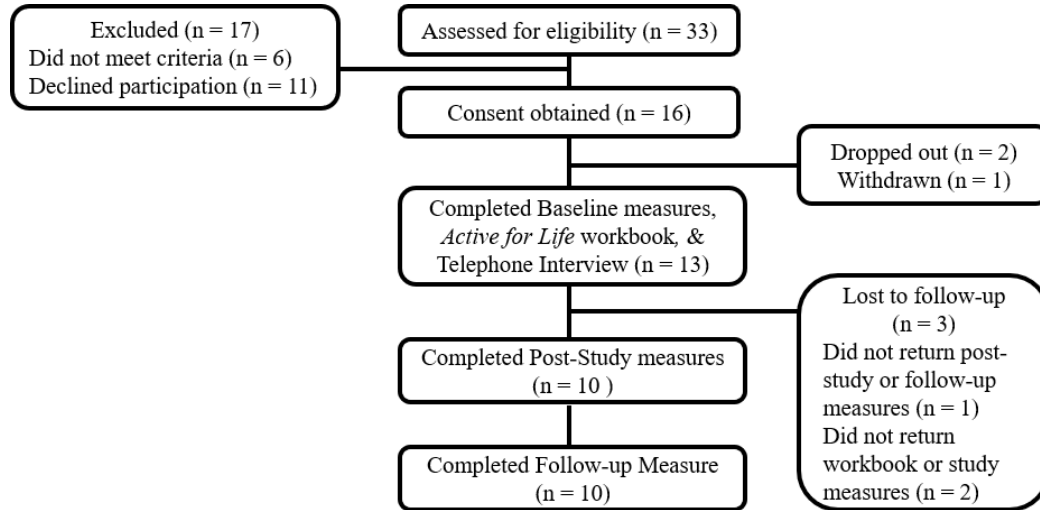
Longitudinal Overview of Study Outcome Attainment



Note. REALM-SF: Rapid Evaluation of Adult Literacy in Medicine: Short Form; ESPA: Environmental Supports for Physical Activity; HBPAI: Health Action Process Approach Model Based Physical Activity Inventory; S4-MAD: Social Support Scale for Self-care in Middle Aged Adults with T2DM; DKT2: Revised Diabetes Knowledge Test; IPAQ: International Physical Activity Questionnaire; MSQ: Marshall Sitting Questionnaire. Dotted lines indicate measures obtained by the primary investigator.

Figure 9

Participant Flow Through Study



CHAPTER FIVE

CONCLUSIONS

Type 2 diabetes (T2DM) produces a staggering burden on the health, resources, and well-being of rural individuals. With nearly 34.1 million adults affected, T2DM is a highly prevalent chronic disease which requires complex self-management activities to prevent and delay the onset of acute and chronic complications of diabetes (American Diabetes Association [ADA], 2022a; Centers for Disease Control and Prevention [CDC], 2020). Rural individuals are at increased risk for developing T2DM and face numerous barriers impeding access to health resources, including diabetes self-management education (Brown-Guion et al., 2013; Callaghan et al., 2020).

Diabetes self-management education aids individuals with T2DM in developing knowledge and skills to perform necessary self-management activities (ADA, 2022a). Diabetes self-management activities are inclusive of performing regular physical activity (PA), following a medical nutrition plan, adhering to prescribed medications, participating in daily-self and annual screening activities, smoking cessation, and managing psychosocial issues (ADA, 2022a). Increasing PA and reducing sedentary behaviors are foundational diabetes self-management activities, which lead to improvement in insulin resistance, glycemic control, blood pressure, and triglycerides (ADA, 2022a; Colberg et al., 2016). Despite compelling evidence and guidelines supporting the need to increase PA and reduce sedentary behaviors, adults with T2DM struggle to make lifestyle changes supporting behavior change.

Rural adults experience barriers in access to diabetes self-management and health resources and are influenced by aspects of rurality in relation to PA and sedentary

behaviors (Bolin et al., 2015; Brown-Guion et al., 2013). Limited access to primary care providers and diabetes specialists, financial constraints, and long travel distances and limited affordable public transportation effect accessibility of diabetes self-management and health resources in rural populations (Bolin et al., 2015; Ross et al., 2015). Telehealth has demonstrated the ability to improve access to health resources and diabetes outcomes in rural adults (ADA, 2022b; Lepard et al., 2015). Perceptions of diabetes and diabetes self-management activities influence rural adults use of available resources. Aspects of rurality, the built environment, and policy influence rural adults decision making surrounding integrating PA and sedentary behaviors into their lifestyle. Developing tailored interventions is integral to engage rural adults with T2DM in PA and sedentary behavior change interventions.

Physical activity and sedentary behavior interventions for adults with T2DM delivered using a website or mobile application can lead to increased PA, reductions in sedentary behaviors, and improved glycemic control (Connelly et al., 2013; Howland & Wakefield, 2021). Despite promising outcomes little research has been conducted in rural populations, sedentary behavior is rarely addressed as a unique construct, interventions lack theoretical underpinnings, and outcomes are not comprehensively evaluated (Howland & Wakefield, 2021). A critical need for the development and evaluation of theory driven mobile applications to increase PA and reduce sedentary behaviors in rural adults with T2DM exists. Rigorous development and evaluation of PA and sedentary behavior interventions for rural adults with T2DM are necessary to ensure appropriateness for rural adults, conceptual validity, understanding of the underlying mechanisms of behavior change, and comprehensive evaluation.

Dissertation Overview and Findings

This dissertation study focused on exploring the feasibility, acceptability, and preliminary effects of a 4-week educational and cognitive behavioral skill building PA and sedentary behavior change intervention guided by the Health Action Process Approach (HAPA) model on diabetes knowledge, PA, and sedentary behavior in rural adults with T2DM. As identified in Chapter 2, there is limited evidence supporting the use of PA and sedentary behavior interventions delivered via a website or mobile application in rural adults with T2DM (Howland & Wakefield, 2021). The following aims were proposed in the Chapter 3 research proposal: a) to evaluate the *feasibility and safety* of a HAPA model guided PA and sedentary behavior self-guided workbook, accelerometer, and study measures in rural adults with T2DM, and b) to evaluate the *acceptability* of a HAPA model guided PA and sedentary behavior self-guided workbook, accelerometer, and study measures in rural adults with T2DM.

Approach

A quasi-experimental, one-group repeated measures design study with semi-structured telephone interviews was conducted in a population of rural community dwelling adults with T2DM. Sixteen rural community dwelling adults with T2DM volunteered to participate and were enrolled. Participants were recruited from a Midwestern rural critical access hospital primary care clinic between November 2021 and February 2022. The study duration was nine weeks; participants completed the 4-week intervention consisting of a primary investigator developed *Active for Life* workbook and wrist-worn accelerometer (Actigraph GT9X-Link, Actigraph, LLC). Outcomes data were collected at baseline, post-intervention (week 5), and at a follow-up measurement point

(week 9) using valid and reliable measures of HAPA model constructs, diabetes knowledge, PA, and sedentary behaviors. A research log and returned participant materials were used to evaluate feasibility. Acceptability was evaluated using a post-intervention Satisfaction questionnaire and telephone interviews. Data were analyzed in the Statistical Package for Social Sciences Version 27 using descriptive statistics to summarize data, and the Wilcoxon Signed Rank and Friedman's test to evaluate preliminary intervention effects and calculate effect sizes.

Major Findings

Data analysis demonstrated the PA and sedentary behavior intervention for rural adults with T2DM resulted in non-significant increases in diabetes knowledge and PA, and reductions in sedentary behaviors. Both expected and unexpected findings were detected across variables measured. Measures of feasibility and acceptability were collected, which demonstrate effective recruitment and retention strategies for rural adults with T2DM, an overall feasible and acceptable intervention, and areas for intervention refinement. Major findings related to study outcomes are reported below.

Preliminary Intervention Effects on Outcomes

Several constructs of the Health Action Process Approach model demonstrated increases in participant perception post-intervention. Constructs of behavioral intention ($\chi^2_2 = 1.18, p = .55$), maintenance self-efficacy ($\chi^2_2 = 1.08, p = .58$), planning ($\chi^2_2 = .21, p = .90$), recovery self-efficacy ($\chi^2_2 = 2.00, p = .37$), and social support ($\chi^2_2 = .84, p = .67$) reflected expected non-significant increases at the post-intervention measurement point. At the follow-up measurement point, participants perceived ability to plan for PA continued to increase, with perceptions related to maintenance self-efficacy and social

support decreasing at the follow-up measurement point to levels greater than baseline. Unexpectedly, model constructs of action self-efficacy ($\chi^2_2 = .06, p = .97$), risk perception ($\chi^2_2 = .42, p = .81$), and outcome expectations ($\chi^2_2 = 1.36, p = .51$) decreased at the post-intervention measurement point, with action self-efficacy increasing to a level similar to baseline at the follow-up point and outcome expectations increasing to a level below baseline at the follow-up measurement points. Small, non-significant effect sizes were detected across measurement points for HAPA model constructs.

As expected, after receipt of the intervention diabetes knowledge increased across measurement points ($\chi^2_2 = 1.93, p = .38$); small effect sizes were detected. However, high baseline levels of diabetes knowledge were not anticipated, as diabetes health resources are limited within the rural community participants were recruited from. This may have resulted in a ceiling effect, as observed by small increases in diabetes knowledge across measurement points. Participants sampled had lived with T2DM for 10 years on average, which may have resulted in accumulation of significant diabetes knowledge over time, as a result of repeated exposure to the health care setting and personal experience with self-management.

Receipt of the intervention resulted in increased self-reported PA across activity intensity levels and domains, which are expected findings. A significant, moderate effect size was detected between baseline and post-intervention measurement points for self-reported leisure time PA ($r = .48, p = .04$). Work related PA increased across measurement points ($\chi^2_2 = 3.00, p = .22$). Total PA ($\chi^2_2 = 1.56, p = .46$) and moderate intensity ($\chi^2_2 = .33, p = .85$), and domain specific household ($\chi^2_2 = .29, p = .87$) and leisure time ($\chi^2_2 = 5.06, p = .08$) PA increased at the post-intervention measurement

point, then decreased at the follow-up measurement point to a level higher than baseline. Walking ($\chi^2_2 = 1.92, p = .38$) and vigorous ($\chi^2_2 = 4.00, p = .14$) intensity, and travel ($\chi^2_2 = .08, p = .96$) domain specific PA increased post-intervention, then decreased to a level below baseline at the follow-up measurement point. Moderate, non-significant effect sizes were detected after receipt of the intervention for self-reported total PA, moderate and vigorous intensity PA, and within the work and household domains. Objectively measured PA reflects similar non-significant increases in steps per week ($z = -.53, p = .59$), and time spent performing light ($z = -.18, p = .86$) and moderate ($z = -.06, p = .95$) intensity PA; small effect sizes were detected.

Reductions in sedentary behavior were observed after receipt of the intervention across total ($\chi^2_2 = 2.30, p = .32$), weekday ($\chi^2_2 = 2.77, p = .25$), weekend day ($\chi^2_2 = 1.24, p = .54$) and work-related, computer use ($\chi^2_2 = 3.71, p = .16$), television watching ($\chi^2_2 = 5.73, p = .06$), and leisure-time domains ($\chi^2_2 = 2.53, p = .28$). Decreases in sedentary behaviors were not maintained at the follow-up point. Weekday, computer use, and leisure-time sedentary behaviors remained lower than baseline at the follow-up measurement point. Large effect sizes were detected between baseline and post-intervention for reductions in computer-use ($r = .51, p = .11$) and television watching ($r = .59, p = .06$) sedentary behavior domains. However, at the follow-up point, a large effect size was detected relative to increased computer-use ($r = .50, p = .08$) and a moderate effect size was detected for increased television watching ($r = .39, p = .23$). Travel related sedentary behavior increased across measurement points ($\chi^2_2 = 1.29, p = .53$). Unexpectedly, when measured objectively, the amount of time spent sedentary, and number of sedentary bouts increased from baseline to post-intervention measurement

points. While a decrease in the percentage of objectively measured time spent sedentary was observed, it is likely the result of displacement due to increased time spent at a moderate intensity activity level.

Intervention Feasibility and Acceptability

The majority of participants reported high levels of satisfaction with the *Active for Life* workbook (90%, module 1 and 2; 80%, module 3, 4, and logbook) and wrist-worn accelerometer (90%). Fewer participants indicated interest in continuing to use the workbook (50%) than the wrist-worn accelerometer (80%). Seventy percent of participants identified the intervention as appropriate for rural adults with T2DM.

Analysis of adherence to the *Active for Life* workbook demonstrated an 82.6% median completion of the workbook, with modules 2 and 4 demonstrating the highest completion rates. Detailed analysis of workbook activities demonstrated participant preferences within the Action Planning activity, with participants demonstrating lower completion rates of activities identifying why participants' want to make a behavior change, how to get back on track after a slip-up, social support resources, and healthy rewards. The logbook section related to sitting time demonstrated the lowest completion rate. On average, participants spent 46 weekly minutes completing the workbook. Participants were adherent to wearing the wrist-worn accelerometer; with an 82.2% wear-time compliance observed. One participant experienced an adverse event related to the wrist-worn accelerometer; developing skin-irritation at the wear location of the accelerometer.

Completion of study self-report measures was highest at baseline (81.3%), then decreased at post-intervention and follow-up (62.5%) measurement points. Average

completion times by measurement points are as follows, baseline 57 minutes, post-intervention 38 minutes, and follow-up 28 minutes. Differences in measure completion rates were observed; the HAPA Based PA Inventory, International Physical Activity Questionnaire – Long Version, and Marshall Sitting Questionnaire demonstrating consistently lower completion rates across time and greater time burdens for completion. All participants who completed the intervention participated in a post-intervention telephone interview, which lasted for 10 minutes on average.

Upon analysis of telephone interviews, four themes (workbook, watch, and survey features; short-and-long term behavior change outcomes; facilitators and barriers of behavior change; rural influence) with six subthemes were identified. Features which engaged participants in use of the *Active for Life* workbook included finding the workbook easy to use, interesting, and practical. Participants described the wrist-worn accelerometer as easy to use and charge. The 4-week study length was acceptable to participants. Features identified as barriers to intervention engagement included finding some workbook activities repetitive and usability issues with the wrist-worn accelerometer (i.e., sudden power failure, not tracking all steps taken, difficulty seeing the watch face, skin irritation). Participants identified short-term increases in PA, reductions in sedentary behaviors, and improvement in general wellness (i.e., improved sleep, increased energy, weight loss). Additionally, participants described long-term behavior changes relative to continued self-monitoring and planning behaviors. Factors which facilitated behavior change included increased motivation and awareness, and the development of goal setting, planning, setting alternative plans, self-monitoring skills, and increased T2DM knowledge. Participants described barriers to behavior change as

living a sedentary lifestyle, difficulties breaking long-standing habits, the influences of weather, holidays and COVID-19, fear of failure, and difficulties self-managing multiple chronic diseases. Participants described increased interest in performing PA within their homes, describing limited options for outdoor activities and a disinterest in participating in PA in a group setting.

Recruitment strategies demonstrated the feasibility of recruiting rural adults with T2DM from a rural critical access hospital primary care clinic setting. Of patients approached for recruitment, 48.5% were eligible and volunteered for study enrollment. Recruitment barriers were identified, related to challenges identifying potential participants using the electronic health record, a COVID-19 surge, and use of social media advertisements. Retention strategies resulted in 81.3% of participants completing the intervention and post-intervention telephone interview, and 62.5% of participations completing the study. A 37.5% attrition rate was identified, with two participants dropping out due to work and family commitments, one participant withdrawn due to safety concerns, one participant not returning post-intervention and follow-up measures, and two participants not returning any study materials.

Discussion

The present study demonstrated strengths in engaging community partners and stakeholders to develop a novel PA and sedentary behavior change intervention and recruit rural community dwelling adults with T2DM, integration of theoretical concepts from the HAPA model to develop a theory guided intervention, and use of a comprehensive evaluation strategy. Engaging community stakeholders during *Active for Life* workbook development was essential to developing an intervention tailored for rural

adults and establishing relationships with community partners which facilitated recruitment of a hard-to-reach population. The majority of study participants indicated the intervention was appropriate for rural adults with T2DM. Collaborating with community partners, rural critical access hospital primary care clinic providers, provided access to a population of vulnerable rural adults. Rural adults have been identified as a hard-to-reach population (Thurman & Harrison, 2020). A critical first step in recruiting rural individuals, is obtaining access to the target population. Established relationships within the community and engagement with community stakeholders to develop the *Active for Life* workbook led to the development of rapport with recruitment partners.

Recruitment and Retention

Further, engagement with community partners and stakeholders supported participant recruitment and retention. Primary care provider referral has been identified as an effective strategy to recruit rural individuals with T2DM (Miyomoto et al., 2013). Endorsement from rural primary care providers provided an invaluable bridge to begin establishing rapport with potential participants. Including recruitment strategies which reduced participant burden, including flexible recruitment times and screening participants for eligibility at the primary care clinic, were essential to overcome participant barriers related to accessing the research study (Miyomoto et al., 2013). The use of face-to-face recruitment, which allowed time to develop rapport with potential participants aided in recruitment and retention. Establishing a trusting relationship with rural adults can aid in overcoming recruitment barriers related to distrust in outsiders and facilitate intervention engagement (Young et al., 2015). Additionally, checking in with participants and offering monetary compensation may have supported retention.

This study led to the identification of barriers to recruitment and retention in rural adults with T2DM. Identifying participants via primary care providers' screening electronic health records to identify potential participants was not a feasible recruitment strategy. Additionally, a COVID-19 surge limited the ability to recruit participants. Using social media to recruit rural adults with T2DM proved not to be a valuable use of resources. Findings observed are similar to those described when recruiting rural adults with T2DM for a diabetes self-management education intervention; electronic health record screening and social media advertisements were not the most effective recruitment strategies used (Miyomoto et al., 2013). While the intervention was identified as acceptable, observed trends in adherence to workbook and survey completion may reveal areas for refinement which influenced retention.

Integration of Theoretical Concepts

The full operationalization of theoretical concepts of the HAPA model provides a critical framework for intervention development and future evaluation of efficacy and transition to a telehealth delivery platform. There is limited full integration of theoretical concepts within existing web-and-mobile phone-based PA and sedentary behavior interventions for adults with T2DM (Howland & Wakefield, 2021). Integration of all theoretical constructs as intervention mediators strengthens the intervention design and provides a strong framework for evaluation of the resultant study outcomes in the context of underlying behavior change mechanisms (Prestwich et al., 2015). Additionally, recent calls have been issued identifying the need to develop, validate, and disseminate evidence based mobile applications and patient outcomes data, further supporting the need to use innovative methodology to rigorously develop and evaluate interventions (Fleming et al.,

2020). This study represents the first steps in developing a conceptually sound mobile application to increase PA and reduce sedentary behaviors in rural adults with T2DM.

Comprehensive Outcome Evaluation

The studies' use of longitudinal data collection and comprehensive evaluation of theoretical constructs, diabetes knowledge, PA, and sedentary behavior are evidence of methodological study strengths. The evaluation of baseline and post-intervention outcomes provides evidence of preliminary intervention effects, allowing for effect size calculations necessary for future research. The inclusion of a one-month follow-up measurement point provides evidence of the long-term sustainability of changes in behavior. In the future, it would be beneficial to include follow-up measurement points 6-months to 1-year post-intervention, to further explore intervention sustainability. Evaluation of self-reported and objectively measured PA and sedentary behaviors provides evidence of behavioral domain changes and accurate measurement of activities. The selection of measures with adequate construct validity for domains of PA and sedentary behavior reduced threats to validity. Less frequently are both self-report and objective measures and PA and sedentary behavior measurement tools used, making it difficult to interpret study outcomes due to unknown bias associated with under-and-over reporting and construct validity (Howland & Wakefield, 2021; Prince et al., 2008). Additional strategies and further intervention refinement are necessary to improve participation retention; thereby reducing threats to internal validity associated with attrition.

Evidence of Preliminary Effects

This study provides preliminary evidence of intervention effects and supports the future refinement and efficacy evaluation as a randomized controlled trial. Improvements in diabetes knowledge, increases across activity intensity levels and domains of PA, and reductions in sedentary behaviors support further evaluation. Significant moderate effect sizes detected relative to leisure time PA and large effect sizes detected relative to computer use and television watching sedentary behavior domains demonstrate the potential for the intervention to address a significant health problem. A recent national survey of sedentary behavior in United States adults identified the greatest amount of time spent sedentary occurs within work and leisure time domains (Matthews et al., 2021). Displacing leisure time spent sedentary with any intensity of activity has the potential to improve health outcomes in rural adults with T2DM. While nominal increases in diabetes knowledge were observed, the intervention has the potential to improve diabetes knowledge in populations with limited access to diabetes health resources.

Evidence to Support Intervention Refinement

Evidence to support refinement of the intervention were collected, including identifying effective recruitment strategies, comprehensively evaluating the *Active for Life* workbook, wrist-worn accelerometer, and study measures, and evaluating barriers and facilitators of participant retention. Trends in intervention adherence and participant interviews revealed areas for workbook improvement. Workbook module 1 demonstrated a low adherence; participants interviewed indicated difficulty with initial motivation which improved as confidence was gained. Additionally, an individual activity within

module 1 demonstrated very low adherence rates. Replacement of the individual activity with an activity to increase confidence (operationalized action self-efficacy) may improve adherence to workbook module 1. Workbook module 3 also demonstrated low adherence, with participants describing difficulty recalling time spent sedentary, barriers related to rurality, and difficulty breaking sedentary habits. Participants identified using television commercials as a cue to break up time spent sedentary as a key behavior change technique. Additional examples of how to break up time spent sedentary by making small lifestyle changes and using cues may improve participant adherence and the ability to enact behavior change. Participants reflected on preferences to have a visible logbook; future workbook iterations could include a removable logbook section that could be displayed similarly to a calendar.

While participants described satisfaction with the wrist-worn accelerometer, safety concerns and barriers to use provide evidence to support exploring the use of a consumer-grade wrist-worn accelerometer for future study iterations. Consumer-grade wearable devices may improve adherence due to a focus on integrating patient-facing technology, with improved battery features, display screens, and technology support. Additionally, the use of a consumer-grade wearable device may improve long-term behavior change by supporting self-monitoring after completion of the intervention (Brickwood et al., 2019).

Trends in completion of study measures provide evidence of the need to reduce burden and provide participants with additional support. Additional research is needed to evaluate participant comprehension and ability to complete study measures. Iteratively integrating intervention revisions based on participant feedback may improve study

retention. Other strategies to improve retention, such as more frequent check-ins for the study length, reducing the time burden to complete the intervention and study measures, and collecting study measures in-person or over the telephone may improve participant retention in future studies.

Limitations

While several strengths were identified, study limitations exist. The study was conducted in a small, homogenous sample of rural adults with T2DM, which limits the generalizability of study findings. Obtaining the study sample from a rural critical access hospital primary care clinic excluded individuals who do not have access to healthcare, as they were not members of the accessible population. The primary investigator's membership within the recruitment community and pre-existing relationships with community partners may have influenced the establishment of community partnerships, and recruitment and retention of participants. Recall bias or ceiling effects may have affected study findings related to diabetes knowledge. Participants completed the Revised Diabetes Knowledge Test three times within nine weeks; completing the measures multiple times may have led to improvements in diabetes knowledge. Additionally, participants entered the study with greater baseline knowledge of diabetes than anticipated. Participant comprehension of questions asked on study measures was not evaluated. Low adherence to completing identified study measures may indicate poor comprehension of questions asked; additional research is needed to ensure identified study measures are appropriate for rural adults with T2DM. While telephone interviews reduced participant burden, researchers may have missed non-verbal cues, influencing the ability to analyze interview data. Preferences between research-grade and consumer-

grade wrist-worn accelerometers were not evaluated; therefore, we are unable to determine if device adherence was related to the specific wrist-worn accelerometer used or all wrist-worn accelerometers in general. No evaluation of dose-specific response was conducted; future studies should evaluate the dose-specific intervention response to identify intervention length with the least participant burden.

Future Research

The dissertation research study (Chapter 4) and integrative review (Chapter 2) identified gaps in the literature widening health disparities for rural adults with T2DM, provided evidence of preliminary effects of a theory guided PA and sedentary behavior intervention, and highlighted areas for intervention refinement. Chapter 2 demonstrated the need to rigorously develop and evaluate PA and sedentary behavior web-and-mobile phone-based interventions for rural adults with T2DM. Chapter 4 represents a preliminary step in the development of a theory guided PA and sedentary behavior mobile application intervention. While the dissertation study (Chapter 4) provided evidence of preliminary effects of the intervention on constructs of the HAPA model, diabetes knowledge, PA, and sedentary behavior, collected feasibility and acceptability data provided evidence of the need for intervention refinement prior to additional testing.

After intervention refinement, future research is needed to establish intervention efficacy and evaluate mediators of behavior change. In future studies, evaluating the intervention as a randomized controlled trial will provide evidence of efficacy on identified outcomes and explore the underlying mechanisms of behavior change. To create a parsimonious intervention which produces intended outcomes while reducing participant burden, the underlying mechanisms of behavior change must be identified.

Once the intervention content and underlying mechanisms of behavior change are evaluated and efficacy is determined, the intervention will be transitioned to a mobile application. Intervention delivery as a mobile application can help to overcome barriers related to lack of access to diabetes and health resources, by reaching a diverse group of vulnerable rural adults. Additional usability and efficacy testing will be required of the intervention as a mobile application.

Exploration of intervention scalability is necessary during development and efficacy testing. Little literature exists describing the effects of implementing telehealth interventions on health care provider workloads. Many interventions are developed and rigorously evaluated, but translation to real-world clinical settings is limited due to implementation barriers not identified during intervention development. Further research exploring health care provider perceptions and attitudes of mobile applications, wearable devices for self-monitoring, and the influence of provider workload are needed to gain knowledge about the translation of telehealth intervention to real-world settings.

An additional takeaway from this dissertation study regards development of a comprehensive understanding of the influence of rurality of PA and sedentary behaviors in adults with T2DM. Extant literature has been identified regarding the influence of rurality of PA, with a limited focus on sedentary behaviors. However, little research has been conducted exploring the intersectionality of rurality, PA, sedentary behaviors, and T2DM. Given, the known prevalence of T2DM and multimorbidity in rural populations, higher rates of sedentary behaviors, and influence of rurality on PA preferences it is imperative to further explore these topics to address a significant health problem. Gaining deeper insights into identified concepts will aid in developing interventions which

address multiple levels of health behavior change barriers. Additionally, exploration of the effects of multimorbid symptom burden on the performance of T2DM self-management behaviors, including increasing PA and reducing sedentary behaviors, is necessary to develop interventions which produce sustainable lifestyle changes.

In conclusion, this dissertation identified gaps in the literature which supported the development and preliminary evaluation of a novel 4-week cognitive behavioral skill development, HAPA model guided, intervention to increase PA and reduce sedentary behaviors in rural adults with T2DM. Additional evidence to support intervention refinement to improve appropriateness for rural adults was identified. Though findings are preliminary, they are promising and set the foundation for future research culminating in the development of a mobile application for rural adults with T2DM. With future research and the transition of evidence to clinical settings, health disparities in a vulnerable population of rural adults with T2DM could be improved, resulting in positive health outcomes and reductions in chronic disease burden.

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VITA

Chelsea R. Howland is from southern Illinois and was raised by her mother who was a registered nurse and father who was a trade pipefitter and licensed plumber. She has a brother who is a journeyman precision machinist and farmer. She received her Bachelor of Science in Nursing and Master of Science in Nursing Education from Southern Illinois University Edwardsville in 2012 and 2016, respectively. She has over ten years of professional nursing experience, with six years of bedside practice in adult medical/surgical, emergency medicine, and critical care nursing. While practicing at the bedside she served as a member of the Alton Memorial Hospital Diabetes Resource Team and chaired the Professional Practice Council. She has worked as nursing faculty at Southern Illinois University Edwardsville School of Nursing since 2016, specializing in adult acute care and critical care nursing undergraduate education. Through personal experiences, living in a rural community with a father with diabetes, and professional experiences, providing care to numerous individuals afflicted by diabetes and multimorbid chronic disease, she chose to pursue her doctoral degree in 2018 at the University of Missouri-Columbia Sinclair School of Nursing. During her doctoral program she successfully had her dissertation proposal funded by the Toni and Jim Sullivan Endowed Research Fund for PhD Students and the Sigma Epsilon Eta Chapter Dissertation/Evidence-Based Practice Research Grant. She currently resides in Brighton, Illinois with her husband who works in landscaping. Chelsea was awarded a Post-doctoral Scholar position at the University of Iowa, College of Nursing, which she will begin in the fall of 2022.