Title: Veterans with Diabetes Mellitus: Improving Physical Activity & Participation

NCT02268916

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Objective

Short term objective: Among a small group of veterans with diabetes, we aim to test the efficacy of an individually tailored lifestyle modification intervention based on objectively assessed physical activity patterns and associated contextual environment in a pilot randomized controlled trial.

Specific Aims

In veterans aged ≥ 60 years with diabetes, the specific aims are:

AIM 1. To examine how PA relates to the contextual environment and *social participation* (i.e., ability to participate in daily life activities and satisfaction with participation).

Hypothesis 1: Lower levels of weekly and daily PA will be associated with a greater number of physical and social environmental barriers and less social participation.

AIM 2. To test the efficacy of an individually tailored lifestyle modification PA intervention based on objectively assessed PA patterns and associated contextual environment in a pilot randomized controlled trial.

Hypothesis 2a: At the end of 6 months, individuals in the intervention group will have increased PA compared to the wait-list control group.

Hypothesis 2b: At the end of 6 months, individuals in the intervention group will have improved *social participation* compared to the wait-list control group.

AIM 3: To further refine the intervention in preparation of a larger trial and to disseminate the intervention, we will conduct post-intervention interviews to assess the subject experience of the intervention.

PHYSICAL ACTIVITY INTERVENTIONS FOR ADULTS WITH DIABETES NEED IMPROVEMENT

Regular physical activities benefit diabetes-related clinical outcomes, particularly older adults

Type 2 diabetes is a prevalent and debilitating chronic disease that disproportionally affects middle-aged and older adults; 13% of adults aged 45-64 years and 27% of adults aged ≥65 years had diabetes in 2010.[1] The prevalence of veterans with diabetes is similarly high, and is increasing: 6.7% in 1998 (~490,000 veterans) and 19.6% in 2000 (~740,000 veterans);an incidence estimated to be 2% per year.[2]

Diabetes is a major cause of heart disease and stroke, and is the seventh leading cause of death in the U.S.[1] Older persons with diabetes have higher rates of premature death, functional disability, and coexisting illnesses such as hypertension, coronary heart disease, and stroke[3,4] than those without diabetes. Older adults with diabetes are at greater risk than other older persons to have common geriatric conditions, such as depression,[5] cognitive impairment,[6] falls,[6] and pain,[7] which are associated with physical disability.[8]

The health benefit of regular physical activities (PA) among patients with diabetes is well recognized. It includes improvement of glycemic control and the risk of macrovascular and microvascular complications, such as cardiovascular disease, retinopathy, and nephropathy.[9] In fact, the American Diabetes Association recommends that clinicians counsel patients with diabetes to increase PA to at least 150 minutes of moderate activity (e.g., walking) per week, in addition to weight loss of 5-10% of body weight.[10] Older adults may particularly benefit from regular PA. Studies have demonstrated PA-associated improvements in physical function disability, cognitive function, better quality of life, and less depression. [9]

Contextual environments are one of the barriers to PA

Regular PA may prevent or delay diabetes and its complications; yet, over 60% of adults with type 2 diabetes are not physically active.[11] Older adults are especially likely to be sedentary; only 12% of adults aged 75 or older engage in 30 minutes of moderate PA 5 or more days per week, and 65% report no leisure PA.[12] A wide array of different PA intervention approaches currently exist, but no single intervention led to consistent positive results,[12] and many of older adults with chronic medical conditions and geriatric conditions were not included in current PA interventions.[12,13,14]

Table 1.[15-17] Internal Barriers	External Barriers (contextual environment)
1. Poor health 2. Exercise is not motivating 3. Emotions 4. Lack of knowledge to exercise 5. Lack of awareness of being inactive	1. Lack of social support 2. Lack of facilities for exercise 3. Religious and cultural barriers 4. Weather

Table 2.[16-18] Internal Motivators	External Motivators (contextual environment)
1. Pleasure from exercise 2. Positive attitude toward exercise 3. Health 4. Enhanced self-regulatory skills	1. Tools for monitoring own exercise 2. Social support and encouragement

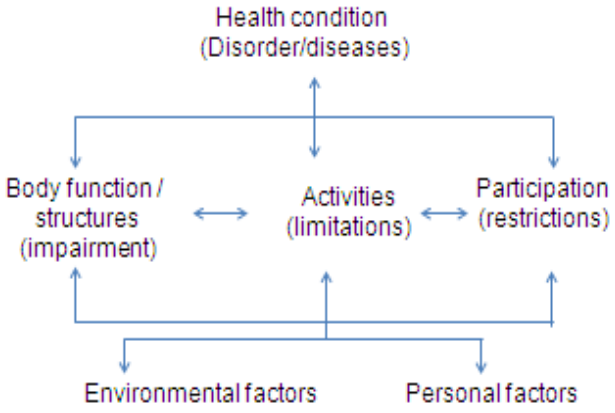
As summarized in Tables 1 and 2, the barriers and motivators of PA can be broadly described as internal and external factors.[15 18] The internal factors are influenced by the individual's own decision-making, whereas the external factors involve an individual's contextual environment, both social and physical environment unique for the individual, and are factors that are independent of an individual's decision-making. As Conn et al.[12] concluded, there is a need for future PA interventions to improve upon study designs, examine the impact of contextual environment, to include adults with chronic medical conditions and are older, and examine standardized lifestyle activity recommendations. To address this gap in the literature, the proposed lifestyle intervention will target older adults with at least one chronic condition, aged ≥ 60 years, and the intervention will be standardized and tailored according to the individual's baseline PA pattern and contextual environment.

THEORIES AND CONCEPTUAL MODEL FOR THE INTERVENTION

The ICF model is the basis of the lifestyle intervention

The World Health Organization developed the International Classification of Functioning, Disability and Health (ICF) model as a framework on health and disability. The ICF model shows the interaction between individual health status and life situation (**Figure 1**).[19,20] Based on the ICF model, individual functioning occurs at 3 broad levels: body function/structure, activity, and participation. *Bodily function/structure* refers to specific detailed functional abilities and impairments (e.g., visual impairment); *Activities* are what people can do inherently without assistance or barriers or function at an individual's level (e.g., able to run a mile); ***Participation*** refers to functioning taking into account the impact of barriers and facilitators in the environment, or functioning as a result of the interaction between the individual and his/her contextual environment.[20]

Figure 1.
ICF components and their relationships

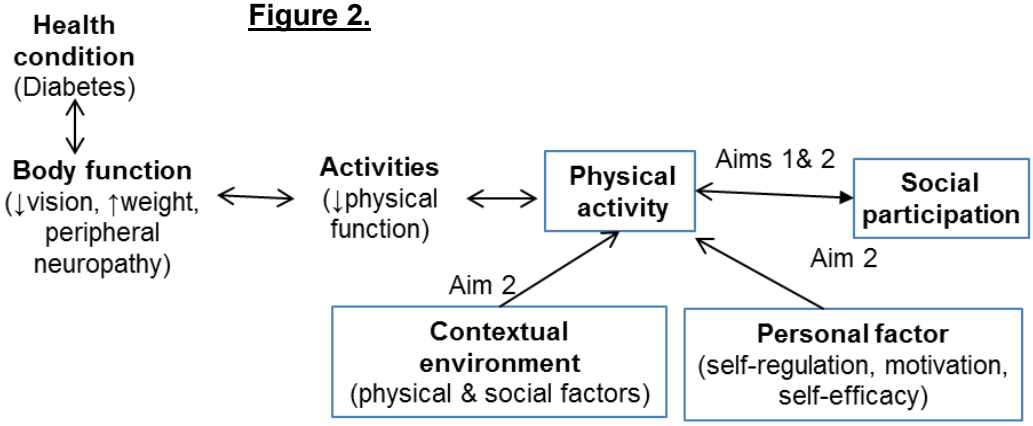


The dynamic interactions of the various PA barriers and facilitators among diabetic patients can easily be described by the ICF model (**Figure 2**). Older adults with diabetes, as previously shown, have numerous barriers similar to those described by the ICF models interact to limit their participation. An example is that a person's with diabetic neuropathy (i.e., *body function impairment*) has difficulty walking 100 feet (i.e., *activities*), but still completed a in a 5K walk (i.e., *participation*) to raise funds for breast cancer research because her co-workers are walking with her (contextual environment).

Social participation is a meaningful and measurable outcome for PA interventions involving older adults

Social participation, the focus of the proposed project, is one of the main outcomes of rehabilitation and a common intervention goal of many health professionals.[21] It is an important modifiable variable that influences community living and has been associated with health, mortality,[22] morbidity,[23] and quality of life.[21,24] Participation has been shown to decrease in normal aging,[25] be more restricted by disabilities in old age[26] and

Figure 2.



not be totally explained by activity level.[25,27] *Social participation* is defined in terms of the level of accomplishment in daily activities and social roles, therefore it's reasonable to believe that interventions affecting one's daily activities (i.e., lifestyle intervention) will affect social participation, as proposed in this research (Figure 2). For the proposed project, the terms *social participation* and *participation* will be used interchangeably.

We will assess *participation* using the validated questionnaires developed by the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS questionnaires were developed and tested in older adult population with available population mean and standard deviation. *Social participation* overlaps with *Social Health* in the PROMIS domains,[28] and is defined by 2 subdomains per PROMIS workgroup: *ability to participate and satisfaction with participation*.

A*bility to participate* is most consistent with participation restrictions, which occurred when "problems an individual may experience in involvement in life situations" arise.[20] Participation restriction includes problems experienced in social interaction, employment, using transportation and community, social and civic life. Older adults with diabetes are likely to have *participation restrictions* due to their risk for disabilities, [28] and the necessity to organize and plan meals and snacks.[29] Furthermore, older adults are more likely to have participation restrictions if they have a history of falls or at risk for falls.[30]

Satisfaction with participation, on the other hand, is most consistent with quality of life.[24] *Satisfaction with participation* is closely related to personal goals and priorities and might better reflect an individual's perception of his/her optimal participation level.[31] Well-adapted individuals might be satisfied with their *participation* level even if it is restricted,[32,33] Individuals with health conditions that affect functioning such as stroke and traumatic brain injury report participation outcomes at the societal level to be more important than outcomes at physiological or individual level of functioning.[34] Satisfaction with participation among older adults with chronic diseases such as diabetes has not been investigated.

Social participation may be improved through lifestyle-based PA interventions involving contextual environment

According to the ICF model, environmental factors are critically important in the *participation* of an individual (Figure 1), and should be targeted in health interventions.[35] Environmental factors may act as facilitators or barriers for participation among community-dwelling older adults; it's unclear if these factors may have similar effect on *social participation* and PA among veterans with diabetes (**Figure 2**).

An individual's environment, social and physical, can affect social and PA participation. Social isolation was found to be associated with less PA among patients with mental illness through accelerometer-assisted assessment.[36] Supportive social environment may ameliorate the negative effect of physical environment among older adults. [31] On the other hand, older adults with the greatest physical limitations perceived the environment to have more impact on their *participation* than those with less physical limitations. Thus, it's logical that lifestyle-base PA intervention to improve the ability to function (i.e., more PA) within the environment or reduce physical limitations, may improve *participation* as proposed in the current project.

In fact, despite the paucity of studies assessing participation outcomes, PA interventions to prevent falls among older adults have been shown to improve *participation*.[30] The effect size of PA interventions on *participation* was small (standardized mean difference = 0.16). However, when PA was delivered as one component of the intervention, not just the single intervention, the effects were larger. This finding is consistent with the ICF model, where *participation* is the result of interactions with physical and social factors. PA interventions incorporating the multiple components of ICF models such as the contextual environment will likely lead to greater improvement in social *participation*.

Given the importance of contextual environment in *social participation* [21] and PA interventions, we decided to use the Measure of the Quality of the Environment (MQE) version 2.0[37] for the proposed study. MQE is one of the most comprehensive questionnaires of self-perceived physical and social environment, and has been widely used in *participation* research. It assesses both the number of environment barriers/facilitators and individuals' perception of how the environment affects them. We were unable to identify any diabetes-specific questionnaires assessing this level of detail environmental information,

TAILORED LIFESYTLE INTERVENTIONS ARE NEEDED TO INCREASE PA PARTICIPATION

Tailored lifestyle PA interventions are indicated for older adults with diabetes

The 2010 position statements from American College of Sports Medicine (ACSM) and American Diabetes Association (ADA) recommend that programs promoting PA should focus on developing self-efficacy and fostering social support, and that encouraging mild or moderate PA may be most beneficial to adoption and maintenance of regular PA participation.[38] Although greater and more intense PA is generally beneficial for older adults, such activities may also increase injury risk.[39-41] Additionally, older adults with diabetes are heterogeneous regarding their physical function status and co-morbidities (see Work Accomplished), so the same single PA goal of requiring one to perform moderate to vigorous exercise for 150 minutes per week would be impractical for many patients and difficult to adhere to in long-term. For adults with multiple co-morbidities, the burden of just managing their diseases is already overwhelming, [42] leaving limited time to participate in other activities. Therefore, individually tailored PA interventions based on the person's health status, daily routines, and physical function capabilities may be more practical.

Recent studies have found that levels of PA lower than previously recommended for cardiorespiratory conditioning (e.g., below 50% VO_{2max}) also enhance glucose tolerance, improve coronary risk factor profile, and reduce cardiovascular-related mortality.[43] Furthermore, patients with lower baseline PA status are likely to experience greater health benefit with a given increase in PA, usually with longer and /or more frequent exercise sessions.[44] Thus, adults with diabetes may be best served with exercise of lower intensity but longer duration and/or more frequent.

Tailoring based on PA patterns and contextual environment may improve PA and social participation

Tailored lifestyle intervention based on individuals' patterns of PA is promising for older adults, although has not been tested in older veterans with diabetes. Gardiner et al.[45] provided counseling for older adults aged ≥60 years based on their patterns of sedentary time and PA obtained from an accelerometer, and was successful at reducing sedentary time (3.2% reduction). The study was a pre-post study with no controlled group, so efficacy of the intervention can't be assessed. The participants were relatively thin, the authors did not disclose information on co-morbidity and physical function, and social participation was not assessed.

Dr. Murphy's group has developed a standardized protocol of lifestyle tailoring based on a combination of PA patterns and momentary symptoms of pain and fatigue. This protocol was shown to be feasible in a sample of veterans with osteoarthritis,[46] and is currently being tested among veterans with chronic low back pain receiving their care at the VA Ann Arbor Healthcare System. Veterans with osteoarthritis or low back pain are usually limited in PA because of their symptoms of pain or fatigue. Based on their individual patterns of PA and pain or fatigue, Dr. Murphy's group counseled participants to increase their PA while avoiding too much pain or fatigue. This ecological momentary assessment (EMA) of symptoms of pain or fatigue was obtained through the assistance of an accelerometer similar to the one to be used in the proposed study.

EMA is a field-based method to reliably obtain immediate-recalled data, as opposed to delayed recall, in natural settings. It is a powerful tool that allows researchers to identify opportunities to impact health behaviors. For example, Dr. Murphy's group asked the participants to wear an accelerometer that recorded their PA in small epochs and also prompted them several times a day to record their symptoms. Based on this information, they were able to link the PA (i.e., more active, less active) with symptoms (i.e., pain). Then, participants can be counseled to pace their PA by balancing activities with rest, so that they can maintain PA on a regular basis without exacerbation of symptoms.[46,47]

The proposed study will adapt the protocols from Gardiner et al.[45] and Dr. Murphy's group[46] to tailor the lifestyle intervention based on the individual veteran's baseline PA pattern and the contextual environment associated with the activities. A trained occupational therapist (OT) will teach the veterans strategies to increase their PA while adapting to their environment. Through this intervention, the goal is for the veteran to

increase PA and social participation. This method of tailoring is likely to be effective in diabetic veterans because previous studies already shown that tailoring based on PA patterns may improve PA, and with the addition of environment information, a common factor that can influence both PA and social participation, our intervention is likely to improve both PA and social participation. OTs are ideal candidates to deliver the intervention, as they are professionally trained to use strategies to promote the capacity of individuals to participate in satisfying daily activities by addressing the individual's capacity to perform and the activity being performed while adapting to the environment in which the activity is performed.[48]

Self-regulation theory forms the basis of the proposed lifestyle intervention

In order to effectively improve an individual's participation in PA, we operationalized the steps of self-regulation based on the social cognitive theory - one of the most promising health behavior theories for lifestyle-based PA interventions.[12] Self-regulation is the process by which an individual learn strategies in attempt to control personal, behavioral and environmental factors to manage a health condition such as diabetes or lack of exercise.[49,50] According to the process of self-regulation, the individual will first observe [*self-observation]* his/her condition*,* then make judgments based on observation [*self-evaluation*], and react appropriately to achieve personal goals by changing one's own behavior [*self-reaction*]. In fact, many physically inactive adults were unaware that they are in fact inactive,[17] suggesting that informing the individuals of their actual activity level through objective measurement should be the first important step in any PA interventions; our proposed intervention will begin by informing the participants their actual PA level. These adults (aged ≥ 60 years) also prioritized social engagement to be more important (and enjoyable) than PA, suggesting that PA interventions targeting them should also assess their social participation as a potential motivator and outcome. [**Aims 1 and 2**]

To operationalize steps of self-regulation in the proposed project, we will first use an accelerometer and logbook to assess an individual's PA pattern and contextual environment in the home environment [**AIM 1**] to enhance his/her *observation* of PA (or lack of PA). We will then teach the individual to *self-evaluate* their PA and social participation level and to identify available opportunities to increase PA and social participation. Following this, the trained OT will teach each individual various strategies to *modify his/her lifestyle* to improve PA. Based on the interaction between *participation* and environment as described in the ICF model, we believe this intervention will not only increase PA but also improve *social participation* [**AIM 2**].

In order to best tailor the intervention for individual veterans, the proposed CDA will integrate environmental, personal, and behavioral factors[49,51] into the intervention through a standardized protocol. The contextual environment such as cars and computers can be a "motivator" or "facilitator" on PA behavior, and thus will be systematically assessed. Personal (self) influences, which include prior knowledge, self-efficacy beliefs, goals or intentions, will be addressed. A goal is more influential and motivating to change behavior if it has a more closely held value and is salient for the individual. As discussed above, the goals to reverse or improve illness or disability are often not achievable in a short time; however, goals such as improvement of *social participation* may be more attainable, therefore, motivating for older adults. For example, it may be more difficult to lose 10% body weight through dieting than to add an hour of play time with the grandkids.

In conclusion, as behavior is a function of the person and the person's environment,[52] PA interventions targeting adults who are older and have chronic diseases, whom often have concurrent physical disabilities, may best be approached through a tailored lifestyle intervention based on the individual's environment to optimally impact participation.

PRELIMINARY STUDIES

Work Accomplished

1. Older adults with diabetes have worse physical function limitations and more co-morbidities than those without diabetes or with pre-diabetes.[58]

We performed a cross-sectional analysis of 5,991 respondents aged ≥53 years from the 2006 wave of the Health and Retirement Study, a nationally representative health survey. All respondents reported physical function limitations and co-morbidities (chronic diseases and geriatric conditions). We found 21% of respondents had diabetes, and they had the highest prevalence of co-morbidities and physical function limitations, followed by those with prediabetes, then normoglycemia ($p<0.05$). Among diabetic respondents, 48% had mobility limitations (walking several blocks and /or climbing a flight of stairs), and 69% had lower

extremity limitations (getting up from a chair and /or stooping/kneeling/crouching). Compared to respondents without diabetes, respondents with diabetes had higher odds of having functional limitations affecting mobility and lower extremity functioning (OR=2.13 – 2.92, all p<0.01).

➔ Co-morbidities and physical function limitations are prevalent among middle-aged and older adults with diabetes. Effective lifestyle interventions for diabetic patients must accommodate physical function limitations. These findings support our intervention approach to use tailoring to accommodate their pre-existing co-morbidities and functional limitations.

2. Sedentary older adults with diabetes are more likely to participate in PA involving daily life routines than other types of PA (Lee P, Blaum C, Alexander N; Poster *presentation at the Annual Meeting of the Gerontological Society of America, 2013*)

Using a cohort of sedentary adult aged 60-85 with diabetes (n=115) enrolled in a PA enhancement trial, we analyzed what types of self-reported PA, as per Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire, did they participated in 4 weeks prior to enrolling in the study. Latent class modeling was fitted, after excluding items such as basketball, soccer, racquetball, running, where <5 respondents reported to have participated in. We were able to classify the respondents into 3 classes: 60% almost exclusively participated in activities involving daily life routines, and the other 40% participated in some activities involving volitional PA such as walking for exercise, stretching, or strength training. Individuals were more likely to participate in activities involving daily life routines than other types of physical activities (all p<0.05).

➔ This study provides support for the proposed intervention to incorporate PA into an individual's daily life routines.

3. Diabetes is associated with poor mobility and less physical activity in symptomatic osteoarthritis patients (*Lee P, Alexander N, Murphy S; Poster presented at the Annual Meeting of the Gerontological Society of America, 2013*)

We analyzed data from participants recruited for a life-style intervention trial by Dr. Murphy's group: community-living adults aged ≥65 years with mild to moderately painful knee or hip OA and fatigue. We assessed mobility by using Six-minute Walk distance (6MW; feet) and PA by using a wrist-worn accelerometer (Actiwatch) over 7 days (average count/day). Linear regression models were performed to examine the contribution of diabetes, age, body mass index, pain, and self-reported disability on mobility and on PA.
We found that diabetic participants (n=20, mean age 72) were more obese than non-diabetic participants (n=147, mean age 72). Diabetic participants had shorter 6MW distance (β= -131.87, p=0.03), adjusting for age, BMI, pain and disability. They were less physically active, adjusting for age and BMI (β=-55.78, p=0.03).

➔ Diabetes can be a barrier to PA among adults with OA, and adults with OA and diabetes need additional support to participate in PA. This study confirms that it's feasible to use Actiwatch to assess PA among older adults with diabetes, that these participants are able to use the Actiwatch and logbooks to record their momentary symptoms of fatigue and activities, which are key components of the proposed CDA. The acceptance of this study protocol among the participants also supports the proposed intervention.

4. Geriatric conditions, which are associated with physical disability, begin to develop in middle-aged adults with diabetes.[59]

We performed a follow-up analysis of data from Health and Retirement Study waves 2004 and 2006, including respondents aged ≥ 51 years in 2004 (n=18,908). We examined the prevalence and two-year cumulative incidence of eight geriatric conditions (cognitive impairment, falls, incontinence, poor nutrition, dizziness, vision impairment, hearing impairment, pain) and their association with diabetes. We found that adults with diabetes, compared to those without, had increased prevalence and incidence of geriatric conditions across the age spectrum (p<.01 for all ages through 75-79 years old). Diabetes was associated with the two-year cumulative incidence of acquiring new geriatric conditions (OR= 1.7, 95%CI 1.3-2.2).

➔ Middle-aged adults, as well as older adults with diabetes are at increased risk for the development of geriatric conditions, which contribute substantially to their complex health status. These findings provided support for our study to include middle-aged veterans, and tailor our intervention to accommodate their complex health conditions and the contextual environment (physical and social).

METHODS

Study Design
This is a randomized-controlled trial to test the efficacy of a tailored lifestyle-based PA intervention, among veterans aged ≥ 60 years with diabetes. The study will compare the intervention group with a wait-list control group (**AIM 2**), where **AIM 1** will assess the baseline information for both the intervention group and wait-list control group, and **AIM 3** will assess the subjects' experience of the intervention to prepare for a larger randomized trial in the future.

SAMPLE SIZE: N=70

Recruitment
Setting:
The study will take place at the main campus of VA Ann Arbor Health System, located in Ann Arbor, which serves nearly 57,000 Veterans living in a 15-county area of Michigan and northwest Ohio (fiscal year 2011). More than 455,000 outpatient visits were made at VAAAHS in fiscal year 2011. According to national VHA data, at least 16% veterans are expected to have diabetes and more than 70% of veterans are either overweight or obese; obesity is a single major risk factor for diabetes.[60] According to CDC estimates, 27% of adults aged ≥65 have diabetes;[1] thus, similar number of veterans with diabetes is expected.. We will primarily recruit subjects from 4 resources:

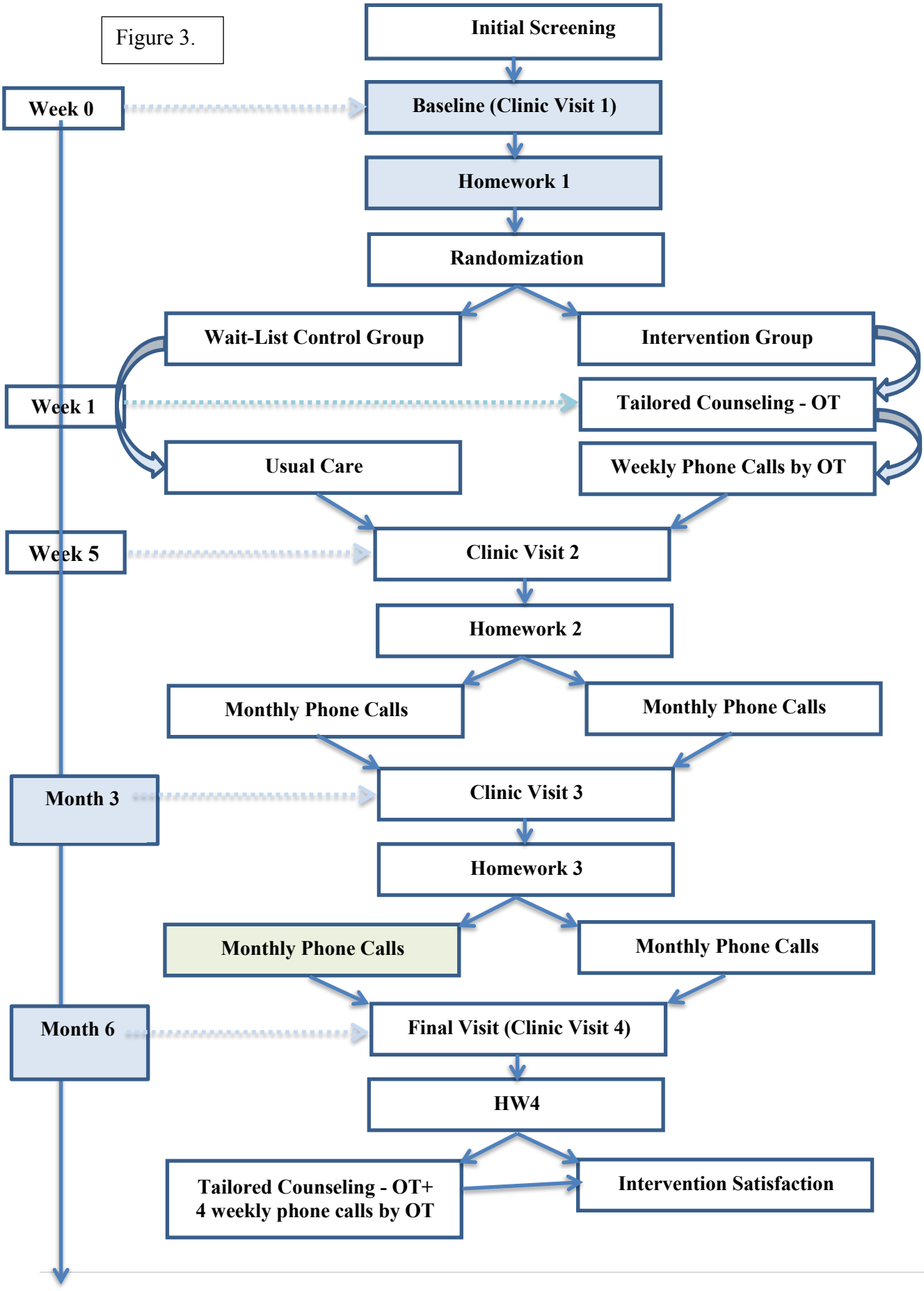
1. Referrals from VA health providers, including primary care providers, geriatricians, endocrinologists, and other subspecialist who care for diabetic patients.
2. Direct advertisement through local newspaper and at the VA for potential subjects.
3. Referrals from the VA Ann Arbor MOVE! program. The MOVE! program in VA Ann Arbor provided care for 710 veterans in 2010, with 490 of them as first time participants in MOVE! program;[61] 50% of the MOVE! participants have diabetes.[62]
4. We will obtain VA Institutional Review Board's approval to screen for diabetic patients using the VA electronic medical record. After identifying potential subjects, we will contact their primary providers for approval to recruit these patients.

Sample:
We will recruit approximately 70 veterans who have known diabetes and are aged ≥60 years. Subjects will be recruited based on their self-reported diabetes diagnosis. After identifying potential subjects, we will send them introductory letters describing the study, including an opt-out postcard for them to mail back. If we do not receive the opt-out postcard after 2 weeks, then we will contact the veterans by phone to confirm their interest in participating in the study and to screen for eligibility.

Eligibility
Inclusion Criteria

- Aged ≥60 years
- Diagnosis of diabetes mellitus, type 2 (or adult-onset) (self-reported or per medical record)
- At least 5/6 on 6-item cognitive screening test on the phone
- Ability to reliably operate the Actiwatch accelerometer
- Community-living (i.e., not nursing home resident)
- Ambulatory either with or without an assistive device
- English-speaking
- Competent to provide inform consent
- Sedentary (<150min moderate activity in a week)

Figure 3.


Initial Screening
Week 0
Baseline (Clinic Visit 1)
Homework 1
Randomization
Wait-List Control Group
Intervention Group
Week 1
Tailored Counseling - OT
Usual Care
Weekly Phone Calls by OT
Week 5
Clinic Visit 2
Homework 2
Monthly Phone Calls
Monthly Phone Calls
Month 3
Clinic Visit 3
Homework 3
Monthly Phone Calls
Monthly Phone Calls
Month 6
Final Visit (Clinic Visit 4)
HW4
Tailored Counseling - OT+
4 weekly phone calls by OT
Intervention Satisfaction

Exclusion Criteria

- Medically unstable in which exercise would be contraindicated (e.g., previous severe symptomatic hypoglycemia, decompensated congestive heart failure, severe anemia, severe aortic stenosis, unmanaged thyroid dysfunction, etc.)
- Self-reported illness or conditions that impair cooperation with the study team or ability to complete study procedures
- Hospitalization within last 6 months for any reason
- 2 or more days of complete bed rest within the last month
- Limb hemiplegia or amputation
- Replacement of any hip or knee joint within the last 6 months
- Current attendance in a PA program
- Work involves shift schedule
- Heart attack within past month
- Parkinson's disease

PARTICIPANT TIMELINE

Figure 3 describes the study flow. After potential subjects are identified based on inclusion and exclusion criteria, they will be asked to complete a number of questionnaires to obtain baseline information on PA, social participation and contextual environment. They will then be taught to wear a wrist-worn accelerometer for 7 days to monitor home activities. Subjects who successfully completed the baseline 7-day home monitoring will be randomized into 2 arms: intervention or wait- list control groups. The intervention group will receive the tailored PA report in a one-hour counseling session, followed by weekly phone calls for 4 weeks by the same occupational therapist. This will be followed by monthly phone calls by research assistants until the end of the study.

The wait-list control group will receive monthly phone calls to discuss about their health status but not PA-related issues. These monthly phone calls are necessary to maintain the subjects' interest in staying in the trial. The wait-list control will receive the tailored PA pattern report and the counseling intervention at the end of the study.

Both arms of the study will have post-intervention assessment at 5 weeks after randomization and final outcomes assessment 6 months after randomization. Each outcomes assessment involves surveys, physical function assessment, and a 7-day home monitoring period. After the 6-month assessment, we will interview participants who completed the intervention to assess their experience for the purpose of improving the intervention in the future.

Research Procedures

Baseline data collection: Aim 1

If potential participants meet the inclusion and exclusion criteria based on phone screening, then they will be invited for baseline evaluation. Baseline data collection will be completed in 4 steps from 3 sources: accelerometer-generated PA patterns, the ecological momentary assessment (EMA) of contextual environment, and survey data. We estimate the time to complete baseline assessment will be 1.5 - 2 hours.

1. After participants complete the screening and informed consent, a trained research assistant will assess their physical performance, which includes the Six-Minute Walk Test [64] and Timed Up and Go Test [65].
2. The research assistant (RA) will guide the participants to complete a packet of survey questions. The questionnaires will ask about demographics, co-morbidities, physical activity (self-reported), *social participation,* their perception of the influence of contextual environment (physical and social environment) on daily lives, and potential barriers and facilitators of diabetes care.
3. The RA will direct the participants to complete a standardized education module, where they will learn to use the wrist-worn accelerometer to rate their response to pre-determined questions using a numerical

rating scale and entering responses, and to record addition information on activities and /or barriers or facilitators to PA in an accompanying logbook. Dr. Murphy's group has already refined this education module to teach older veterans with osteoarthritis and low back pain to use a similar accelerometer and logbook to obtain data on PA and symptoms. We will adapt Dr. Murphy's education module for this study.

The accelerometers are designed for assessment of PA patterns over time and will be worn by each participant in their home environment for 7 continuous days (allowing capture of data on both weekdays and weekends). At five pre-determined times throughout the day, the accelerometers will prompt the participants to enter responses to 3 pre-determined questions to assess their perception of the contextual environment on their ability to participate in PA and social activities (i.e., momentary assessment of the environment). Based on experience by Dr. Murphy's group, we will set the accelerometer alarm at wake up time, 11am, 3pm, 7pm, and before bedtime. Time for waking up and going to bed will be individualized for each participant. Each participant will know when their accelerometer alarm will go off. This will help the participant to pay attention to the alarm.

- Participants will become familiar with an accompanying logbook, in which participants will record the exact environment and activities they were involved in at two-hour intervals (See Appendix for the mock Activity Log).The logbook provides supplementary data that are important for the tailoring intervention, and also serves to cross-validate the items entered in the accelerometer. The logbook will be used as a back-up if there are missing data from the accelerometer.
- During this teaching module, participants are given the opportunity to practice rating their environment and using the accelerometer's input button to record the information. If, for some reason, participants fail the learning module (e.g., inability to press the input button) they will be excluded. Although we have not encountered exclusion for this reason in any of our past studies, this reporting is central to the tailoring portion of the intervention and therefore is an important criterion for study inclusion.
- This education module will take approximately 40 minutes per veteran. Participants will leave the session with a list of the questions they need to answer and examples of activities, potential barriers or facilitators to PA.

4. Participants will then wear the accelerometer and complete their logbooks for a 7-day home monitoring period and then return the materials to the study team via a postage-paid mailing envelope. At that time, Aim 1 portion of the study (or baseline data collection) will end.

Randomization

Randomization was done upon enrollment. Once participants completed baseline data collection successfully, they will be automatically assigned into intervention or wait-list control group. To ensure that both groups have same number of participants, and avoid investigator bias and confounding, we will randomize by simple randomization.[66] Once randomized, all participants who are assigned to the intervention group will be scheduled for a one-on-one counseling session. Individuals who are assigned to the wait-list control group will be notified that they are enrolled in the study but that they will not be able to start the active intervention for 6 months.

Intervention to be delivered for intervention group

Intervention is tailored based on each individual participant's baseline objectively measured PA pattern (i.e., not active for all day or only active at certain periods of the day), and ecological momentary assessment of the participant's contextual environment. Together these data inform the therapist what types of activities are most likely to be performed by the participants and when is a good opportunity to increase or add PA. The strategies to increase PA will take into account of each individual's self-reported barriers of PA.

An occupational therapist (OT) will deliver the intervention; this OT will have underwent training by Dr. Murphy's group to deliver standardized lifestyle-based PA intervention using accelerometer –measured PA patterns. Dr. Murphy's group has already established standardized training protocol for OT to deliver this type of tailoring intervention. Additionally, as discussed in the Background, OT's approaches to lifestyle intervention are most befitting for this population (older, high risk for disability, sedentary, restricted by their environment, etc.). In the future, we will test the intervention delivery through other trained providers such as a nurse educator. For the study, the participant will meet with an OT for a one-hour session for the following activities:

1. Brief presentation on the benefits of PA and how to safely perform PA at an older age and with diabetes. Each participant will leave the session with a National Institute of Aging exercise workbook[67] and tips to exercise safely with diabetes.[68]
2. The OT will review the baseline PA pattern report determined from the home monitoring period. This report is prepared before the counseling session. It also summarizes the participant's self-reported perception of the environment, his/her daily activities and the associated context. The OT will help the participant to correlate the level of PA with potential barriers associated with PA at that moment. For example, being alone may be associated with few activities, but attending church is associated with more activities. The OT will focus on periods where the relationship between PA and an identifiable and modifiable barrier is most salient. (See Appendix for a mock Baseline Physical Activity Report)
3. Based on the baseline PA report, the OT will teach the study participant potential strategies to incorporate PA into daily life routines. These strategies will accommodate for the individual physical and social environment and health barriers. Generic strategies from Gardiner et al.[45] will be adapted to reduce sedentary time and increase PA, with particular emphasis in activities involving the social environment (See Appendix for a sample of Strategies to Increase Physical Activity) . Participants will identify strategies specific to their circumstances, and will leave the session with a list of these strategies. For example: A participant's home monitoring report shows an hour of inactivity on Monday. The logbook shows that he accompanied his wife to her medical appointment and arrived 30 minutes early. The OT may recommend: "Instead of sitting in the lobby for half hour to wait for the doctor, you (maybe your wife too), can walk around the clinic while waiting. In fact, many clinics also have stair cases, so you may want to use the opportunity to walk up and down a flight of stairs a few times while waiting."
4. The OT will conclude the session by helping the participant to set a realistic goal to increase PA, and to operationalize the 3 steps of self-regulation using a PA tracker worksheet similar to the one used for baseline activity assessment (See Appendix for an example of a Physical Activity Worksheet). The participant will be encouraged to complete the worksheet daily or at least 4 times a week. The key components of the worksheet include a weekly PA goal, daily PA tracker, weekly self-evaluation of achievement of the goal, goals for next week, and description of strategies to achieve the goal. Completion of the worksheet is important for the participant to be self-observant, so that they can evaluate if the previously set goal has been reached. Then the participant can self-react by increasing his/her activities, using the strategies provided to them during the counseling session.
5. After the face-to-face session, the same OT will make weekly phone calls to the participants for 4 weeks (See Appendix for a Flowchart of the Phone Call). The OT will already have been trained by Dr. Murphy's group to make these phone calls following the flowchart, demonstrated an understanding of the program, learned to address the various actions on the flowchart (i.e., how to probe for barriers, how to help with problem solving, etc.), and how to respond to participants' various questions. The OT will ask the participant questions based on their response to the PA worksheet as described above. Then, using the answers to the PA worksheet as a guide, the OT will review with participants the steps of the self-regulation, provide positive reinforcement, assess progress in achieving PA goals, problem solve barriers, and discuss changes in medications and health status. Each phone call will last approximately 30 minutes. This completes the intervention phase of the study.

Wait-list control group

This group will participate in all outcome assessments as the intervention group at baseline, post-intervention, and 3-months and final assessments. After the 6-month final assessment, these participants will receive their baseline activity summary reports and the counseling that the intervention group had received.

Post-intervention assessment

Post-intervention assessment will be done 5 weeks after randomization to assess if the intense intervention (counseling and weekly phone calls) had an immediate impact on the study participants. Potential participant drop outs are expected at the 6-month follow-up. Therefore, information obtained at the post-intervention assessment will be helpful in determining the impact of the intervention. All participants in the intervention group and wait-list control group will be assessed for all outcomes, including the 7-day home monitoring.

After the post-intervention assessment, a RA will contact all participants monthly until the 6-month final assessment to discuss changes in medications and health status. PA issues will not be discussed. The goals of these phone calls are to obtain updated health information and maintain the participants' interest in remaining in the trial.

Measures

Primary outcomes:

a) Physical activity will be assessed using data from *Actiwatch Score* and a validated survey – Community Healthy Activities Model Program for Seniors (CHAMPS).[71] These two measurements complement each other as Actiwatch provides patterns of PA each day, whereas the CHAMPS provides measures of total PA and PA of moderate or greater intensity.

Table 3. Timetable for assessment

	Baseline	Post-intervention	During the intervention	3 and 6 months
Primary Outcomes (PA and social participation)	X	X		X
Secondary Outcomes				
-functional status	X	X		X
-biomarkers	X			X
-quality of life	X	X		X
-intervention feedback				X (6-months)
-participant retention		X		
-adverse events		X	X	X
Medications	X			X
Co-variates	X			GDS

1. Physical activity will be objectively measured by Actiwatch that measures changes in acceleration. We have chosen a wrist-worn accelerometer (Actiwatch Score, Phillips Respironics-Mini Mitter Co, Bend OR; see Figure 4) to measure the PA because it is the only device that allows concurrent reporting of momentary activity data and measurement of PA. Waist-worn accelerometers that are cheaper do not allow momentary activity reporting. It is not meant to provide feedback to the participant (as a pedometer); it is a clinical tool in which information is synthesized for the intervention as described in our study.

Figure 4.

The wrist-worn accelerometer will be mounted on each participant's non-dominant wrist. Although it is worn on the wrist, it is highly associated with whole-body movement.[72,73] Changes in acceleration are recorded as activity counts and saved every 15 seconds. Higher activity counts reflect participation in higher intensity activities.[74,75] Actiwatch has been shown to have excellent reliability between units (r= .98) and has established preliminary criterion validity among a sample of chronic pain patients.[76] Three main PA measurements are derived from the Actiwatch: 1) average activity counts/minute reflects average level of PA over a specified time period; 2) peak PA (largest daily activity count averaged over 7 days) is a measure of daily activity intensity; and 3) total PA is the 7-day cumulative activity score at times when a person was deemed awake and excluding missing data that occurred from temporary removal of the Actiwatch. We will look at average activity counts and total activity counts that occur: 1) in different context, 2) over each day, and 3) over the 7 day period. Because participants wear the accelerometer continuously for 7 days, it is necessary to establish participants' wake-up and bedtimes. A previously-established algorithm will be used to corroborate participant-report of wake and bedtimes with the objective measures.

2. Physical activity will also be self-reported by having the study participants completing the *Community Healthy Activities Model Program for Seniors (CHAMPS)* questionnaire.[71] CHAMPS is a self-administered questionnaire developed for underactive populations and tested primarily among older adults. The questionnaire included 41 items, asking the respondent to report the participation in specific activities that older adults are likely to engage in. The responses are "YES" or "NO" to an activity, and if "YES", then the

number of times per week and total hours per week of activity participation. From the questionnaire, we can derive measures of frequency per week and estimated caloric expenditure per week in PA. For both frequency and caloric expenditure, two measures can be derived based on: 1) PA of moderate or greater intensity (MET value ≥3.0), and 2) all specified PA that included activities of light intensity in addition to moderate and greater. The 6-month reliability coefficients for total and moderate-intensity activities were 0.66 and 0.76, respectively.[71]

b) Social participation will be measured from the 2 sources *(Please see Appendix for questionnaire):* Social participation will be measured at each assessment point using validated questionnaires from the Patient-Reported Outcomes Measurement Information System (PROMIS) assessment center.[77] Together, these questions (51 items) assess two subdomains of social participation - *ability to participate* and *satisfaction with participation.*[78] Each set of the questionnaire can be administered independently and have been validated and standardized with a population mean of 50 and standard deviation 10. PROMIS assessment center also offers shorter versions of social participation questionnaires.

PROMIS is a NIH initiated multicenter cooperative group who builds and validates common, accessible item banks to measure key symptoms and health concepts applicable to a range of chronic conditions, enabling efficient and interpretable clinical trial and clinical practice applications of patient-reported outcomes. These patient-reported outcomes are built on the WHO framework of physical, mental, and social health, and social participation is one of the key domains included in PROMIS items. The item banks all underwent rigorous psychometric evaluation, and are broadly available for use in clinical research and clinical practice.

1. Satisfaction with participation, the subdomain of social participation most consistent with quality of life, will be additionally investigated to see if it fluctuates daily and if it is associated with daily PA level. We will adapt three questions from the PROMIS item bank and ask the participants to record their ratings (1-5) into the logbook daily during the 7-day home monitoring periods: "I am satisfied with my current level of social activity; I am satisfied with my ability to perform my daily routines; and I am satisfied with my ability to do leisure activities."

Secondary outcomes:

a) **Functional status** will be assessed by 2 physical performance measurements and 1 self-reported physical function status, all commonly used and validated. Changes in these 3 measurements may be clinical meaningful to predict fall risks, ability to live independently and mortality.[79,80] Based on the study enrollment criteria, we do not anticipate any participants to have limitations in instrumental or basic activity of daily living, so these basic functions will not be assessed to minimize their burden.

1. The Six- Minute Walk Test [64] – A participant will be instructed to walk at his/her usual pace for six minutes and distance covered in feet is recorded.
2. Timed Up and Go Test [65] – A participant will be timed (in seconds) when get up from sitting in a chair, walk 3 meters, turn around, and walk back to sit down.
3. Comfortable gait speed in 10 meter walking.
4. Rosow, Breslau and Nagi activities[81-84] – Self-reported ability to run a mile, walk 1 or several blocks, sit for 2 hours, get up from a chair after sitting for a while, climb 1 or several flights of stairs, lift or carry over 10 lbs., stooping/crouching/kneeling, pick a dime up, reach or extend arms, and pulling/pushing large objects.

b) **Biomarkers**: A1c and body mass index will be assessed at baseline and at the final (or 6-month) follow-up. A1c measures average blood glucose level in the past 3 months. At the time when participants visit VA Ann Arbor for baseline and final assessment, they will be ask to go to the VA Ann Arbor's Ambulatory Care laboratory to have a random blood sample obtained by the staff to assess for A1c value. Standard scales used in Ambulatory care clinics will be used to measure the height and weight of each participant.

c) **Quality of life** will be assessed by VR-12, which is a well validated 12-item questionnaire that assesses both the physical and mental health quality of life of veterans.

d) **Participant retention** is the extent to which our program is able to retain the intended audience to complete the study. [86] Results from participation retention provide information on the acceptance of the intervention by the veterans. Retention can be calculated as [(participants completing post intervention assessment/participants enrolled) x 100].

e) **Intervention feedback** is an important goal for this pilot trial. It will inform the PI if certain part of the intervention should be revised, added, or removed to improve the intervention for future trials and for dissemination. The information will be obtained in two ways at the end of the study:
   1. Participant satisfaction with the program, including participant perception of usefulness of proposed intervention, will be measured by a series of Likert scale satisfaction items adapted from the measures used by Schron et al.[87] (See Appendix).

dverse event rates: Participants can report an AE event by phone or email or at the monthly follow-up phone calls. The AEs will be tracked electronically in a participant management system. Study-related AEs will be classified as serious if they require hospitalization or result in significant disability. All other study-related AEs will be classified as minor, resulting in minimal or no disability and not requiring hospitalization. If a participant experiences a severe symptomatic hypoglycemia, that participant will be temporarily suspended and will need to obtain medical clearance from his or her medical provider before resuming the intervention. The intervention clock will continue to run during the suspension and end of study will not be delayed.

g) Medication changes: The intervention may lead to increase physical activities, which may lead to lower blood glucose, lower blood pressure, lower cholesterol, all possible outcomes associated with regular physical activities. The subjects' health care providers are likely to make medication changes when glucose, blood pressure, and / or cholesterol levels are lowered with the progression of the study. Therefore, medications associated with lowering glucose, blood pressure, and cholesterol, will be assessed for changes by reviewing the subject's VA electronic medical record (CPRS).

Co-variates, predictors and confounders:

1. **Environment:** Contextual environment may be barriers or facilitators for PA and social participation, and will be assessed *at baseline* using a survey, momentary assessment using the Actiwatch, and data from logbook.

a) Measure of the Quality of the Environment (MQE) version 2.0[37] is one of the most comprehensive measurement instruments that address specific ICF categories of environmental factors.[88] (See Appendix) This level of detail information is important for our intervention as it involves using strategies to overcome the environment barriers within the individual's daily life routines. MQE assesses 2 domains of environment that are most relevant to the proposed study: physical environment (40 items) and social environment (69 items). It also assesses an individual's perception of the environment on his/her ability to accomplish daily activities or tasks and social roles. The perception is rated on a 7-point Likert scale ranging from -3 (major obstacle) to 3 (major facilitator). Therefore, MQE produces 2 levels of data: 1) number of self-perceived environment barriers/facilitators, and 2) the perceived level of influence a barrier/facilitator on the person.

b) Momentary assessment of the environment will be obtained through the Actiwatch prompting the participant to record their perception of the environment on their ability to participate in PA and social activities. This method of obtaining immediate-recalled data (vs., delayed recall) in natural settings, ecological momentary assessment (EMA), is a new research method that the PI will be learning from her mentors, and the momentary information obtained will be exploratory, but important in informing the intervention to target those barriers that have the most impact on the activities. To our knowledge, this method has not been used in lifestyle interventions in our study population. During the baseline 7-day home monitoring period, the study participants will enter their perception of the physical and social environment, into the accelerometer 5 times a day. The questions for the participants will be the following:
   1. "Considering your current surroundings, indicate to what extent do they hinder you or prevent you from being physically active?" Answers range from 0 to10.
   2. "Considering your current surroundings, indicate to what extent do they hinder you or prevent you from performing daily routines?" Answers range from 0 to10.
   3. "Are you currently with someone?" Answers are either 0 or 1 (0=No; 1=yes).

c) Description of activities and the involved context (i.e., what, where, with whom) in 2-hour intervals will be recorded by each study participant in an accompanying logbook during the baseline 7-day home monitoring period. An example: 7-9pm on Saturday - dinner, at restaurant, with family. The logbook will provide more descriptive data on the environment and other activities that a participant engaged in a day.

This information will be used in the study for the sole purpose of generating tailored reports on individual environment-activity relationships over the week for the tailored activity intervention in Aim 2.

2. Potential confounders including age, race, sex, global health status, co-morbidities (Charlson Comorbidity Index[89]), depression, attitudes and beliefs about PA and diabetes care will be assessed using validated questionnaires:

- Geriatric Depression Scale (GDS) [90] Short Form is a 15-item questionnaire to screen for depression. It has been extensively used in community, acute and long-term care settings. GDS has 92% sensitivity and 89% specificity when evaluated against diagnostic criteria. It will take 5-7 minutes to complete.
- Diabetes Care Profile (DCP) [91] is a self-administered questionnaire that assesses the social and psychological factors related to diabetes and its treatment. The instrument contains 234 items and sixteen scales. To reduce participant burden, we selected subsets of questions from DCP to assess diabetes-related attitudes and PA barriers, which are important factors for the study. We estimate it will take 10-15 minutes to complete these subsets of questions.

Strategies for Ensuring Treatment Fidelity Treatment fidelity is defined as "the procedures used to monitor and enhance the reliability and validity of behavioral interventions," and is an essential component of our study. Per recommendations from the National Institutes of Health (NIH) behavior change consortium,[71] we will use several strategies to ensure treatment fidelity in this study. The strategies that we will use include standardized modules for the intervention and delivery of the intervention, interventionist (i.e., occupational therapist) training and monitoring based on previously developed protocol by Dr. Murphy's group. Another area of treatment fidelity that we will address relates to how the treatment is received by the participant. This involves an assessment of individual factors such as comprehension of information, and the ability to use and perform skills associated with both the data collection and behavioral elements of the study. We have a standardized interactive learning module to teach the participant how to input ecological momentary activities in the wrist-worn accelerometer. Because the validity of the ecological momentary activity information is central to our tailoring methods, all participants will undergo this learning module prior to their first session with the OT. At the end of the study, we will conduct interviews with each participant to examine their experiences in the intervention including adherence with steps of the self-regulation process.

Statistical Analysis

Univariate analyses

Before conducting formal analysis for each specific aim, descriptive analyses will be performed based on univariate statistics, using t-tests for continuous variables or chi-square tests for categorical variables. This will involve inspection of univariate statistics such as mean, median, standard deviation, skewness and kurtosis for continuous variables, and frequency tabulations for categorical data. We will also inspect for outliers and inspect bivariate plots of PA and participation data over time for each person to identify outliers in the bivariate relationships. All analyses, including descriptive statistics and model fitting, will be carried out using SAS for Windows, release 9.2 (SAS Institute, Inc., 2002-2008, Cary, NC, USA).

Primary analyses

Aim 1: To examine the relationship between PA, contextual environment (physical and social environment), and social participation, among veterans with diabetes.

Hypothesis 1: Lower levels of weekly and daily PA will be associated with a greater number of physical and social environmental barriers and less social participation.

Since PA is measured by Actiwatch objectively and self-reported by CHAMPS, we will first compare them with correlation analyses and identify the correlation coefficient. We will then use separate linear regression models to evaluate if environmental barriers (MQE) and social participation (PROMIS) predict PA, adjusting for baseline co-variates and potential confounders. Separate models will be used for the two different PA measurements - CHAMPS and Actiwatch.

Table 5.	
Variables	Measures
PA(outcome)	Actiwatch – weekly and daily average counts
	CHAMPS – weekly energy expenditure (kcal/wk)
Environment	MQE – summary score of environment barriers/facilitators
	Momentary assessment – daily perception of environmental barrier (3 questions)
Social participation	PROMISE – summary score of participation ability and satisfaction
	Daily assessment – daily satisfaction with participation (3 questions)

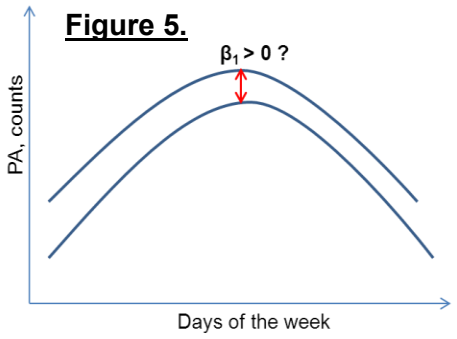
We will then explore if the perception of environment barriers to PA and participation and satisfaction with participation fluctuate daily. Longitudinal analysis models will be built with time as covariate and each of these variables as the outcome. These variables are assessed daily during the home monitoring period by 6 separate questions adapted from validated questionnaires. We expect study participants' answers to some if not all of these questions to vary daily. We will then build separate predictive models using hierarchical linear modeling (HLM) if change in the perception of the environment or satisfaction with participation is associated with PA (Actiwatch daily average counts). The HLMs will allow us to fully utilize the repeated measures of the environment, participation, and PA within each day.

Aim 2: To pilot a randomized-controlled trial to test the efficacy of an individually tailored lifestyle-based PA intervention. An intent-to-treat analysis will be applied to avoid various misleading artifacts that can arise in the trial; all subjects initially enrolled in the trial will be accounted for based on the group they were randomized into. Baseline comparison of the control and intervention groups will be done with ANOVA on PA, participation, and all the co-variates. We will consult our statistician for analysis guidance.

Hypothesis 2a: *At the end of 6 months, individuals in the intervention group will have increased PA compared to the control group.* PA is measured in 3 ways using Actiwatch and CHAMPS (Table 5), so three separate analyses will be done using each measure – Actiwatch daily average counts and weekly counts, and CHAMPS weekly measurement.

The primary analysis is based on comparing the 6-month change in PA between treatment group and control group by t-tests. To adjust for potential confounding, separate models of multivariate regression analyses will be conducted with each measure of PA as the dependent variable, randomization arm as a predictor, baseline PA as a covariate, and potential confounders including age, sex, diabetes status, and number and perception of environment barriers will be included in the model. Assuming that residuals from the model fit are normally distributed, the analysis is equivalent to a classical analysis of covariance. For data that does not fit a normal distribution, inverse, logarithmic or power transformations will be performed or generalized linear models (GLM) with Poisson or gamma error will be considered.

Figure 5.



To further assess if the pattern of PA changed, i.e., whether the change in PA occurred across each day or just a few days in a week, we will graphically compare the daily average counts at 6-month follow-up for the intervention group with the control group (Figure 5). For example: If Y_{ij} = daily average counts at day_j over 7 days after intervention for subject i and j = 1 (d1), 2 (d2)…, 7(d7), then we will try to fit the linear mixed model to test if the slopes of the two PA curves are the same and test for overall difference ($\beta 1 = 0$):
$Y_{ij} = \beta_0 + \beta 1 * \text{intervention} + \beta 2 * \text{days} + \beta 3 * z + \varepsilon ij$

With this small sample of 28-35 participants per treatment group, it is possible that the study may be underpowered to determine significant differences between groups. However, the results will provide essential information about the actual effect size of the treatment which will allow us to better estimate the sample size needed for a larger trial.

Hypothesis 2b: At the end of 6 months, individuals in the intervention group will have improved social participation (ability to participate and satisfaction with participation). Social participation will be measured with the PROMIS questionnaires with a population mean of 50 and standard deviation of 10. The change in *social participation* will be compared between the treatment and control groups by t-tests, similar to the analysis plan described for *Hypothesis 2a*. Multivariate regression analyses will be conducted to evaluate confounding factors, with social participation as the dependent variable, randomization arm as a predictor, baseline social participation as a covariate. Potential confounders including age, sex, co-morbidities, and number and perception of environment barriers will be included in the model. Distribution of the residuals from model fit will be examined, and additional transformations and generalized linear models will be considered.

Additional analyses:
Further exploration of effects at each time points are of interest. Models will utilize outcome measurements at all time-points (baseline, 5 weeks, and 6 months). Different outcome measures and covariates can be evaluated. Repeated measure longitudinal models can be considered:
For example: **Outcome at 5 weeks and 6 months = BA + G + CF + G*TIME + CF*TIME,**
where BA=outcome at baseline; G=intervention group; CF= one or more contributing factors; TIME= time variable; *=interaction between variables. The key aspects of this model for hypotheses 2a and 2b are interactions G*TIME and CF*TIME, and the magnitude and significance of these interaction effects provide insight into mechanisms underlying study group differences. The remaining terms are used to reflect study design and adjust for baseline values. This analysis will yield three tests: 1) a test for outcome changes over time of the study, 2) a test of the intervention vs. control group differences (an intervention effect), and 3) a test for interaction of intervention effect with time. As in the primary hypothesis, we are primarily interested in the overall intervention effect. However, a changing intervention effect over time, as reflected in intervention by time interaction is of great interest since it might suggest that the intervention has a greater impact as time progresses, which would provide support for long-term effect of the intervention. The following methods will be considered: linear mixed effects (LME) models for continuous variables with normally distributed residuals; and generalized linear models (GLM). Both of these methods allow for unbalanced data, time-varying covariates, and structured covariance matrices. Repeated measures models will be developed in the framework of linear mixed effects (LME) models or generalized linear mixed effects models (GLMM).

AIM 3: To assess participant satisfaction with the intervention, we will use a series of Likert scale satisfaction items and a semi-structured interview protocol including open-ended questions to obtain feedbacks. A quantitative analysis and a qualitative analysis will be performed for this aim:
- Results from the Likert scale satisfaction items will be analyzed to identify the association between different characteristics of the study participants and their satisfaction with the intervention. Participant characteristics (e.g., age, sex, race, education background, functional status, co-morbidities, etc.) will be cross-tabulated with the satisfaction outcomes, which can be dichotomized into satisfied or not satisfied. Individual relationships will be assessed using X^2 tests. Multiple logistic analyses will be used to analyze responses according to each factor, controlling for socio-demographic variables.
- Qualitative analysis plan will be directed by mentors and consultants, and the PI will be taking formal courses to learn qualitative analyses. The goal of this analysis is to identify if there are uniform themes in the feedbacks provided by the study participants to inform improvement of future intervention.

Secondary analyses
For change in functional status, biomarkers, and quality of life at 6-month follow-up, separate linear regression analyses will be performed, adjusting for important covariates (age, sex, co-morbidities, etc.). Effect of the intervention on the outcomes will be analyzed using a simple follow-up analysis: $y_{i1}=B_0+B_1X_i+\varepsilon_i$, where y_{i1} is the follow up measurement at 6-month follow up, B_1 is the change in mean outcomes at follow up between the 2 treatment groups, and X_i is the membership of being in the intervention group.

Data Management*:* Data will be entered using case report forms created in Microsoft Access with encrypted password-protected file and stored on a pass-word protected desktop computer in a locked office. Each record

will include1) variables to uniquely identify the subject, 2) the source of the data, 3) site, 4) date, and 5) data collector. We will train the RA to enter data into the database. To protect against potential breach of identifiable information of the research subjects, a master list containing their identifiable information and the study identifier will reside on the VA computer server, accessible only by the PI and RA.

Missing Data: With repeated measurement on each subject on the key outcome variables, some missing data is expected, despite our efforts at follow-up. To get an understanding of the mechanism of missingness we will collect the reasons for missing data such as “death”, “patient refusal due to poor health”, or “patient refusal unrelated to health”. We will compare the distribution of lost patients by reason among the study groups to evaluate any differences in the reasons for losses. We will compare the rate of losses to follow-up among the two groups using the chi-square test of association. In the event that the rate of losses differs among the groups, interpretation of the results will be made in view of this finding. We will also assess whether any baseline characteristics of subjects are associated with losses to follow-up using chi-square tests for categorical baseline data and analysis of variance for continuous baseline data. If baseline variables are found to be associated with the loss to follow-up, then the analysis models to meet the aims will be modified to include the differing baseline variables as covariates. By including baseline variables associated with missing data as covariates we will be able to provide unbiased estimates of intervention effects when the data are either missing completely at random or missing at random.

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