PROTOCOL

Translating a 'Stand Up and Move More' Intervention by State Aging Units to Older Adults in Underserved Communities

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Supported by the National Institute on Aging

R21AG054916

Version 2 February 21, 2018

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PRÉCIS

Title: Translating a 'Stand Up and Move More' Intervention by State Aging Units to Older Adults in Underserved Communities

Objectives: To examine the effectiveness of a *Stand Up and Move More* intervention to reduce sedentary behavior, increase physical activity, and improve functional performance and quality of life in older adults. A second objective is to examine the feasibility of implementing the *Stand Up and Move More* intervention by State Aging Units to underserved communities in the state.

Design and Outcomes: A randomized controlled trial will be conducted with older adults from four counties in Wisconsin (i.e., Dane, Rock, Iowa, and Vilas counties) randomized to intervention or wait-list control groups. Sedentary behavior, physical activity levels, functional performance, and health-related quality of life will be assessed at baseline (before the intervention begins), at week 4 (after the intervention), and week 12 (follow-up) to examine the effectiveness of the program. Feasibility of implementing the program by our community partners will be assessed via semi-structured interviews.

Intervention and Duration: The intervention consists of an introductory session, four weekly sessions (i.e., once/week for four weeks), and a refresher session at 8 weeks, and will be delivered by community partners in each county. Based on self-regulation theory, the sessions will elicit ideas from older adults regarding how they can reduce their sitting time, help them set practical goals, develop action plans to reach their goals, and refine their plans across sessions to promote behavior change.

Sample Size and Population: Eighty sedentary adults greater than 55 years of age from four counties made up predominantly of rural older adults and older African American adults will be randomly assigned to intervention (n = 40) or wait-list control (n = 40) groups.

STUDY TEAM ROSTER

The study team consists of the following individuals:

Principal Investigator: Kelli F. Koltyn, Professor
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Role: Dr. Koltyn will be responsible for all scientific aspects of the study. She will lead development of study materials (e.g., manual of procedures, questionnaires, data collection forms, intervention materials), collaborate with the community partners, train the research assistants, supervise data collection and analyses, write manuscripts, and disseminate findings of the study.

Co-Investigator: Jane Mahoney, M.D., Professor
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Role: Dr. Mahoney will provide oversight on safety aspects of this study.

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Jill Renken will promote and facilitate implementation of the intervention through collaboration with the community partners. Jill will conduct training of the community partners as well as monitor fidelity of intervention delivery.

Consultants: Dorothy Edwards, Professor
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Role: Dr. Edwards will facilitate communication and collaboration between the study team and African American older adults.

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Role: Dr. Gangnon will perform the statistical analyses for this study and will provide statistical consultation as needed.

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Role: Dr. Ellingson has extensive experience with objective measurement of physical activity/sedentary behavior using the monitors to be used in this study. She will facilitate the data management of accelerometer data.

PARTICIPATING COMMUNITY PARTNERS AND SITES

University of Wisconsin-Madison: This study involves collaboration between the UW-Madison and 4 county sites.The UW-Madison is the lead site and will serve as the IRB of record for this study.

Community Partners include:

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BACKGROUND AND SPECIFIC AIMS

The number of adults ≥65 years in the U.S. is expected to more than double from 40 million in 2010 to 87 million by 2050.[12] With the aging of the population, a growing number of older adults face complex health issues that often lead to functional limitations. Preservation of functional performance in community-dwelling older adults is critical to maintaining independence and quality of life, as well as containing costs in the older adult population.[19] Since the elderly represent the fastest growing segment of our population, maintaining independence throughout later life has emerged as an important public health goal.[2,4,10] Interventions that remediate functional decline are of high priority.[15] Exercise has been effective in combating functional decline but older adults tend to have low levels of exercise, and few report meeting current national guidelines (i.e., 150 minutes of moderate intensity physical activity/week) which may be

challenging, especially for older adults with existing limitations. There is a clear need for interventions that bridge the gap between inactivity and current exercise guidelines providing older adults with an attainable transition to a more active lifestyle.

A growing body of research demonstrates the negative health consequences of sedentary behavior (i.e., too much sitting). Older adults are one of the most sedentary age groups spending 60-70% of their waking hours in sedentary activities.[14] This amount of sedentary time increases the risk of functional decline, chronic diseases, and premature mortality. Emerging research suggests breaks in sedentary time (i.e., standing up) are associated with better health and function in older adults.[18] Thus, interventions that **shift the focus** from increasing exercise to breaking up extended sitting time by standing up and moving more throughout the day may be **feasible for older adults to do** but there is limited research examining the benefit of such interventions. With funding from the Greater Wisconsin Agency on Aging Resources, we recently developed a behavior change intervention based on self-regulation theory and designed to help older adults break up extended sitting by standing up multiple times throughout the day. Preliminary examination of the intervention, in collaboration with our community partner the Rock County Council on Aging, indicated the intervention was feasible for staff to implement, participants expressed high satisfaction with the program, sedentary time decreased by approximately 1 hour/day ($p < 0.05$), there were moderate effect size increases in physical activity, and large effect size improvements in mobility and vitality in a small sample of older adults. In addition, reductions in sedentary time were still evident four weeks after the intervention ended. These results provide preliminary evidence that our community-based behavior change intervention effectively reduced sedentary behavior, and importantly, could be sustained after the intervention ended. The purpose of the proposed research is to expand upon these initial promising results and examine the effectiveness as well as the feasibility of translating a *Stand Up & Move More* intervention by State Aging Units to underserved communities in the state.

***Aim* 1:** To examine the effectiveness of a *Stand Up & Move More* intervention to reduce sedentary behavior, increase physical activity, and improve functional performance and quality of life in older adults. *Working Hypothesis*: It is hypothesized that there will be significant reductions in the primary outcome of sedentary behavior and increases/improvements in the secondary outcomes of physical activity, functional performance and health-related quality of life in the intervention group compared to no significant changes in the wait-list control group.

***Aim* 2:** To examine the feasibility of implementing a *Stand Up & Move More* intervention by State Aging Units to underserved communities in the state. *Working Hypothesis*: It is hypothesized that the intervention to reduce sedentary behavior will be feasible to implement by State Aging Units to older adults in underserved communities.

The intervention we are proposing to test statewide was developed with community collaborators. Sitting less seems simple but intervention is required to get older adults to do it. If breaking up sitting time by standing up and moving more throughout the day proves to be effective then we will have identified a **practical** intervention with the potential to improve the health and function of older adults that could be translated to communities across the country.

RESEARCH DESIGN AND METHODS

Previous Research: With funding from the Greater Wisconsin Agency on Aging Resources, research was conducted to develop an intervention to reduce sedentary behavior and examine the feasibility of implementing the intervention by a State Aging Unit in a community setting. The research was conducted in two communities in Rock County, Wisconsin which is made up of

small urban and rural communities. The older adults in these communities had high levels of sedentary behavior (averaging almost 11 hours of their waking hours per day sitting) and their function scores were below the population average. A 4-week intervention based on self-regulation theory and designed to break up extended sitting time by standing up multiple times during the day significantly ($p < 0.05$) reduced sedentary behavior (60 min/day), was associated with moderate increases in light intensity physical activity (effect size = 0.52; 35 minutes/day), and large effect size improvements in mobility (i.e., gait speed; effect size = 0.74) as well as vitality (effect size = 1.15). Importantly, reductions in sedentary behavior were sustained 4 weeks after the intervention ended. Strategies used most often included standing up during television commercials, and spreading household chores out across the day. Additional strategies included getting up to get a drink of water, and setting a timer to stand up. Twenty participants (out of a total of 25) completed the 4-week program and 90% of the participants expressed high satisfaction with the program (e.g., "What a great program. It made me realize how much I sit during the day and helped me manage my sitting time"). Also, participants indicated that breaking up sitting time was more appealing to them than increasing exercise. Further, the intervention was found to be feasible for staff to implement. The director of the Rock County Council on Aging who led the workshops stated "The intervention worked because it was simple. It is not complex and that is the beauty of it." Thus, our pilot results are quite promising and represent the development, preliminary feasibility, and piloting stages of the *Stand Up & Move More* intervention in a small sample of older adults.

Design: As a next step, a randomized controlled trial will be conducted with a larger sample of older adults from underserved communities. Older adults from 4 counties in Wisconsin (i.e., Dane, Iowa, Rock & Vilas) will be randomized into intervention or wait-list control groups (Note: a block randomization scheme will be used blocking for age). Our pilot data suggests an intervention design of one session per week for 4 weeks with a refresher session at 8 weeks is feasible and likely to sustain behavior change. The primary outcome measure is sedentary behavior while the secondary outcome measures include physical activity, functional performance, and health-related quality of life. Assessments will be completed at baseline, after the intervention (4 weeks) and at follow-up (at 12 weeks as suggested by our community partners as being a reasonable time for the older adults in the control group to wait for the next workshop to begin). Feasibility of implementing the intervention will be assessed via semi-structured interviews of the health program facilitators, while feasibility of completing the *Stand Up & Move* More program by older adults will be assessed by program adherence and participant satisfaction.

Participants: A power analysis was performed to estimate optimal sample size for detecting potential differences between intervention and wait-list control groups in sedentary behavior using a repeated measures design, with an alpha of 0.05, a power of 0.80, and a medium effect (0.57). Results from the G-power analysis indicated a total of 68 participants (34 per group) would be needed for the proposed study but we have increased sample size in anticipation of a potential attrition rate of approximately 20% (a minimum of 80 adults older than 55 yrs will be recruited). Four counties (Rock, Iowa, Vilas & Dane) will each recruit between 20–30 older adults who will be randomized to either the intervention group (n = 10–15) or the control group (n = 10-15). Inclusion criteria includes > 55 yrs, currently inactive or low active (i.e., < 60 min of physical activity/week), residents of Rock, Iowa, Vilas or Dane Counties, and residing in a home or an apartment. Exclusion criteria are low levels of sedentary behavior (i.e., ≤ 6 hours/day); recent hospitalization (past month); uncontrolled medical conditions including uncontrolled hypertension (BP > 170 systolic or 100 diastolic), heart disease (symptoms of angina with minimal exertion in the past month), actively receiving chemotherapy or palliative care for cancer, stage 4 liver disease (e.g., cirrhosis with ascites or encephalopathy or history of

bleeding esophageal varices), end-stage renal disease (on dialysis or creatine > 4), or end-stage pulmonary disease (dyspnea at rest or with minimal exertion); severe arthritis or any orthopedic condition that could be made worse by standing up and moving more; inability to stand up without assistance of another person; and inability to speak or hear spoken English. Participants will be given a gift card up to $50 upon study completion ($20 for participating in the study plus $10 per each of three assessments).

Recruitment of Participants: Staff from Aging Units in the four counties will recruit older adults from their counties for this study. Recruitment strategies include announcements in senior newsletters, at congregate dining sites, churches, and medical clinics. In addition, announcements will be posted on Aging Unit websites, and flyers will be sent to mailing lists of older adults in the various counties. These strategies were used in our pilot research and worked well in recruiting the estimated sample size.

Individuals who are interested in learning more/participating in the study will be instructed to call a designated phone number and leave a message. A trained research assistant will promptly (within 48 hrs) call the prospective participant back and give a general explanation of the study, ask if the individual is still interested in participating in the study, and inquire whether they are willing to complete a brief interview (i.e., phone screen) to determine eligibility. If the individual agrees to the interview, they will be asked questions based on the inclusion/exclusion criteria. Those individuals who are deemed eligible to participate in the study will be informed of the introductory meeting (i.e., date/time and location). Individuals who are not eligible to participate in this study will be thanked for taking time to answer questions but be told that they will not be able to participate due to the strict requirements for this research.

Introductory Meeting: An introductory meeting will be held in each county for older adults interested in participating in the study. Our community partners will arrange the meeting at a location convenient for participants in their county. The PI will attend the meeting and describe the study (i.e., inform prospective participants of the procedures, risks and benefits, and they are free to discontinue participation in the study at any point). Prospective participants will be provided with ample time to read the Informed Consent Form and have the opportunity to ask and obtain an adequate reply to any questions they may have. Individuals interested in participating in the study will then sign an informed consent document and baseline assessments will be completed.

Intervention to Reduce Sedentary Behavior: The intervention is based on self-regulation theory as self-regulation has been shown to be an important influence of physical activity behavior change.[16, 21] Self-regulation has been defined as a goal-guidance process aimed at the attainment and maintenance of personal goals.[11] Successful strategies for behavior change reflect a recognition that people move toward the goals they set by a process of self-regulatory actions.[5] Most of the self-regulation models include components essential to the process of self-regulation such as 1) **goals** about what people are trying to accomplish, 2) **self-monitoring** of personal behavior and how it links up to goals, 3) **feedback and information** about progress toward each goal, 4) **self-evaluation** of progress, and 5) **corrective behavior** leading to more effective movement toward goals.[5] Strategies incorporated into the *Stand Up & Move More* intervention sessions include individual goal setting, development of action plans to meet goals, information dissemination, self-monitoring, group discussions & feedback, and various problem solving activities. During the intervention, participants are taught how to appropriately set and adjust goals, as well as self-monitor their activity (use of a small click counter every time they stand up and completing daily logs at home at the end of each day). In addition, based on feedback from NIH reviewers, social cognitive theory will also be incorporated as a foundation for the intervention because research indicates that both self-regulation strategies and self-efficacy are associated

with physical activity behaviors.[15] Social Cognitive Theory proposes a theoretical link between self-regulation and self-efficacy, and Annesi et al.[1] reported that use of self-regulation strategies was related to increases in in self-efficacy for eating healthy and being more physically active in middle-aged adults. We will examine whether the same is true for older adults with regards to sedentary behavior in the current study.

Older adults will be asked to break up prolonged sitting (1 hour or more) with short breaks, e.g., get up and move for a couple of minutes multiple times throughout the day. Following the format of our successful pilot, participants will be asked, initially, to break up sitting time an extra 3-5 times/day progressing to 10-12 times/day by week 4. During the sessions participants will strategize on ways they can break up their sitting time safely in their home environment. In subsequent sessions, participants will share strategies that worked for them as well as be introduced to a list of other strategies used by Gardiner et al.[7] (e.g., standing up and getting a drink of water). This will provide participants with a wide range of strategies and participants will choose which strategies to adopt across the 4 weeks. Each session builds upon the previous one with new information provided during each session. An overview of the sessions follows (with a summary table located in the supplemental material):

***Session 1*:** Introduction and overview; group discussion on time spent sitting during the day and then participants will be asked to reflect on their current sitting habits and record how many hours/day they typically spend sitting while watching TV, using the computer, socializing, eating, reading, and driving or riding in a car (awareness of current behavior); information will then be provided on sedentary behavior and the health consequences of sitting too much (information dissemination); discussion of how participants could stand up and move more safely in their home environment (recommended behavior: stand up and move an extra 3-5 times/day); modeling (group leader stands and encourages others to stand up and move); discussion of **goal setting** and participants set a specific manageable goal on how to stand an added 3-5 times/day for the next week; development of an action plan to meet the goal (*Note:* participants will be asked to rate on their action plans their confidence in meeting the goal on a scale from 1, not confident at all to 10, completely confident. If a participant rates their confidence ≤ 5, the facilitator will revisit the action plan to help older adults develop a different strategy in order to feel more confident); and discussion of **self-monitoring** (i.e., use of a click monitor and completion of a daily log at the end of each day to be brought back to the next session).

***Session 2*:** group discussion on why they sit and barriers to standing up; examine behavior (from click monitors and daily logs) and goals from last week (**self-evaluation**); group discussion of strategies that worked, as well as barriers to standing more and then trouble shoot/problem solve (**feedback and information**); discussion of a list of strategies used in a study by Gardiner et al (2011);[7] modeling (group leader stands and encourages others to stand and move); set **new goal** to increase standing and moving for next week (recommended behavior: stand up and move an extra 6-9 times/day); development of action plan to meet new goal (**corrective behavior**); and discussion of **self-monitoring**.

***Session 3*:** discussion of behavior and goals from previous week (**self-evaluation**); confidence building (share successes and discuss incremental progress); discussion of cognitive reframing (i.e., how to reframe unhelpful thoughts); group discussion and information given on the benefits of standing and moving more; discussion of any problem areas with problem solving (**feedback**); modeling (group leader stands and encourages others to stand and move); set **new goal** to increase standing and moving for next week (recommended behavior: stand and move more an extra 10-12 times/day); develop action plan to meet new goal (**corrective behavior**); and discussion of **self-monitoring**.

***Session 4*:** participants asked to reflect on their current sitting habits and record how many hours/day they spend sitting while watching TV, using the computer, socializing eating, reading, and driving or riding in a car (current behavior to compare to week 1); discussion of behavior and goals from last week (**self-evaluation**); information presented on relapse prevention and

recovery; discussion of how to stay active in the community; modeling; set new goals (i.e., **long term goal**); develop action plan to meet new goal (**continued behavior**); and discussion of **continued self-monitoring**.

Note: To support maintenance of behavior change, concepts that have been linked to maintenance of health behaviors will be integrated into the sessions, e.g., building relationships, autonomy, self-efficacy. In addition, a **refresher session** will be held at 8 weeks in which the facilitator will encourage participants to re-examine their motives for sitting less; discuss their progress and strategies that have been most effective, and barriers which have prevented them from standing up and moving more throughout the day. In addition, participants will revisit their goals with a focus on the future and long-term maintenance.

The intervention will be delivered via small group workshops. Research indicates the ideal range to facilitate active group discussions is 10-15 participants,[20] thus, we will recruit 10-15 older adults per workshop in order to create an environment with enough people to have diversity in sharing and yet few enough to ensure that all participants can be involved in the discussions (*note:* this small group format worked well in our previous pilot research). Sessions will last between 1-1½ hrs and be held in locations in each county readily accessible to older adults (note: transportation will be provided to those older adults who require transport to the site). To enhance reach into the older adult communities in each county, the sessions will be facilitated by our community partners who regularly offer health promotion programs to older adults (see training of community partners and fidelity monitoring *note below). The leaders will be trained to act more as facilitators than as lecturers. For example, rather than prescribing specific behavior changes, they will assist participants in making choices and achieving success in reaching self-selected goals. Instruction manuals with scripts will be provided to the leaders for each session to maximize fidelity of delivery of sessions per our intervention protocol.

**Note:* Jill Renken, our community research associate, will provide the training and fidelity monitoring of our community partners. She has been involved in statewide coordination of evidence-based health promotion programs for older adults in Wisconsin for over 9 years. Part of her responsibilities have included training, overseeing, and fidelity monitoring for health promotion programs (e.g., the "Chronic Disease Self-Management" program). In addition, Dr. Mahoney (co-investigator) has expertise in developing tools for fidelity monitoring for the health promotion program "Stepping On." These fidelity tools are used nationally to ensure high fidelity with dissemination of falls prevention programs. Treatment fidelity implementation in the proposed study is consistent with NIH Behavior Change Consortium Treatment Fidelity Workgroup recommendations involving study design, training of providers, delivery of treatment, receipt of treatment, and enactment of treatment skills.[3]

Wait-List Control Group: Older adults assigned to the control group will be instructed to go about their daily routines during the first 12 weeks of the study. They will complete, in the same manner as the intervention group, assessments at baseline, 4, and 12 weeks. The control participants will receive the *Stand Up & Move More* intervention after 12 weeks.

Measures: Data collection sessions will be held the week prior to beginning the intervention (at the introductory meeting), at 4 weeks (following the delivery of the intervention), and at 12 weeks (follow-up) at readily accessible sites in each county (see Appendices for a summary table of outcomes assessment). Assessments will be completed by assessors trained by Dr. Koltyn. The assessors will be blinded to group assignment, and every effort will be made to ensure the assessors remain blinded throughout the duration of the study.

S*edentary behavior* will be assessed both subjectively and objectively: **(a)** Participants will be interviewed by the investigators about their time spent sitting during the day in different activities (e.g., watching TV, reading) over the past week using a previously validated questionnaire for older adults;[7] **(b)** Activity Monitors will be worn at each assessment for one week: The *activPAL*

is a small accelerometer with an inclinometer to measure horizontal/vertical position of the device, and thus posture. This device will be affixed directly to the midline of thigh of the participant with a temporary non-allergenic adhesive. We will be using this device for the purpose of measuring time spent in sedentary behavior (hours/day) and to quantify the number of times sedentary behavior is disrupted by standing up. This device has proven to have excellent validity for the detection of posture.[8] Also, the *Actigraph GT1M* is another small accelerometer worn on the hip. This device records the frequency of accelerations during ambulatory activities and can quantify physical activity across the entire exertion spectrum (sedentary time, light intensity, moderate intensity, and vigorous intensity physical activity). We used both monitors in our previous preliminary research and participants found them acceptable to wear; **(c)** Clickers and Daily Logs: participants will be given a small click monitor and instructed to press a button on the monitor every time they stand up. The monitor will record the number of stands the participant completes on a daily basis. Participants will complete a short daily log before they go to bed each day as a way to self-monitor what they did during the day to reduce sedentary behavior (e.g., how many times they stood and what they did while standing). We used daily logs in our previous preliminary research with minimal burden to participants.
The Short Physical Performance Battery (SPPB)[9]: is an objective measure of functional performance that has been shown to be reliable and is sensitive to change. The test consists of a balance test, a 4-meter walk for usual gait speed, and a timed measure of chair stands.
The MOS 36-Item Short Form Health Survey (SF-36)[23]*:* The SF-36 is a widely used measure of quality of life and has been shown to be reliable and valid. The SF-36 consists of subscales such as general health, physical function, vitality, social functioning, mental health, etc.
PROMIS Questionnaires: Pain and cognition (exploratory measures) will be assessed with the Patient-Reported Outcomes Measurement Information System (i.e., PROMIS questionnaires for pain intensity, pain interference, and cognition).
Demographic and Health History Questionnaire: At baseline, participants will be asked to complete a questionnaire regarding health status and demographic information (date of birth, sex, race, ethnicity, education, and marital status), current physical activity, smoking status, and current alcohol intake.
Mediators of Behavior Change: As suggested by NIH reviewers, we have added selected mediators of behavior change. Participants will complete questionnaires assessing self-regulation strategies,[22] self-efficacy,[13] and outcome expectancies.[17]

Adherence to the Intervention and Outcome Assessments: Adherence to the *Stand Up and Move More* intervention workshop will consist of participants attending at least 50% of the sessions. As for outcome assessments, adherence to wearing the accelerometers will be defined as wearing the monitors 4 out of 7 days.

Analyses: The primary sedentary behavior outcome variables include total sedentary time, time spent sitting in long bouts (i.e., ≥ 60 minutes), and sit-to-stand transitions as measured by the activPAL. These outcomes will be examined adjusting for monitor wear time if wear time differs between groups. We will also be able to analyze changes in specific domains of sedentary behavior (e.g., watching TV, reading) from data obtained from the sedentary behavior questionnaire. A 2 (groups) x 3 trials (pre, post-1, and post-2) repeated measures ANOVA will be used to examine differences between groups in changes in sedentary behavior before and following the intervention and control conditions. Similarly, for the secondary variables of physical activity, functional performance, health-related quality of life, and mediators of behavior change, a series of 2 x 3 repeated measures ANOVA's will be performed. Significant main effects and interactions will be assessed with planned contrasts. Effect sizes will be calculated to examine the magnitude of differences between groups as well as the magnitude of change from pre to post-intervention according to methods described by Cohen[6]. In addition,

correlational analyses will be performed to examine the relationship between sedentary behavior and the secondary outcomes. Significance will be set at $p < 0.05$. {Note: since sample size was estimated for our primary outcome variable of sedentary behavior, we recognize the potential limitation of our sample for secondary outcomes. However, if one or more of the secondary outcomes shows a trend in the direction of significance and/or shows a moderate to large effect size, the number of participants can be expanded in subsequent research to address a specific hypothesis}.
Note: Multiple imputation will be used to account for missing data (and attrition) under a missing-at-random assumption using MICE package in R. Longitudinal models for the outcomes at the two post-intervention visits will adjust the pre-intervention value as a covariate and explicitly model changes in the outcomes over time. Intervention workshop will be included in the included model as a random effect to account for correlations in outcomes between subjects in the same workshop.

Feasibility*:* The feasibility of implementing the program by our community partners will be assessed after the refresher session (at 8 wks) via semi-structured interviews. The Aging Unit Directors and Health Program Facilitators will be interviewed and asked about their satisfaction with the intervention, the ease and difficulty of implementing the program, and their likelihood of sustaining the intervention outside of a research study {*Note: Aging Units offer evidence-based health promotion programs to older adults in their counties which are funded by the Older Americans Act (OAA). When a new health promotion program is shown to be evidence-based (i.e., effective, translatable), Aging Units can use OAA funding to support and sustain implementation of the program}.* Interviews will be transcribed and coded, classified, and organized into main themes using thematic analyses. Feasibility of completing the program by older adults will be assessed after the refresher session (at 8 wks) on the basis of program adherence (i.e., attendance) and participant satisfaction (brief questionnaire).

Cost Estimate*:* The cost of delivering the intervention in each county will be calculated based on the following: a) cost of training the health facilitators, b) payment of health facilitators for leading the workshops, c) cost of program materials, d) cost of transporting participants to the workshop sites (to ensure that older adults without transportation will be able to participate), and e) other miscellaneous costs incurred during the workshops (e.g., room rental).

Potential Problems and Alternative Strategies: We have considered the challenge of recruiting 80 older adults into this study. Based on our preliminary research, we believe we will be able to recruit the sample size (i.e., 10-15 older adults per group in each county) needed for this project based on the following: 1) there was high interest from older adults in our preliminary research, 2) we have established good working relationships with our community collaborators who have had substantial input into the design of the current project, 3) there are good working relationships between county Aging Units and the older adults they serve in their counties, and 4) we will provide transport for older adults who require transportation to the site. Each county will provide two workshops (one for the intervention group and one for the wait-list control group) over a two year period. If we are not able to reach our recruitment target in year one (recruit 3⁄4 of sample, n=60) we will offer additional workshops or expand the program to other counties in the state in year two.

Collaboration with Community Partners: The intervention we are proposing to translate statewide was designed with community collaborators to be able to be implemented by State Aging Units in community settings. Our initial community partners who were instrumental in the design of the intervention included the Greater Wisconsin Agency on Aging Resources (GWAAR) and the Rock County Council on Aging. GWAAR provides community-based aging

services to 70 counties and 11 tribes and considers interventions to increase physical activity a high priority area. For this reason, GWAAR funded our preliminary research which consisted of developing the intervention and conducting preliminary testing in two communities in Rock County, WI. The results indicated significant reductions in sedentary behavior, moderate improvements in physical activity, as well as large improvements in mobility and vitality. As a result of these findings, Jill Renken from GWAAR, who as the Community Research Associate with the Community-Academic Aging Research Network (CAARN) works with research faculty and counties in Wisconsin put out a call to identify community partners who would be interested in participating in the proposed research. Thus, our community partners have expressed high interest in this project. In addition, there is high need in these counties. For example, Vilas County currently ranks 56 out of 72 while Rock County ranks 62 out of 72 in county health rankings. The directors of the Aging Units in these counties see the "Stand Up & Move More" intervention as a viable intervention for older adults in their counties with compromised health and physical limitations. While Iowa County ranks higher in the county health rankings (29 of 72), they have identified a lack of access to physical activity programs as a significant health risk factor. In addition, there are significant health disparities in Dane County. For example, African Americans in Dane County have higher rates of cancer, diabetes, disability, and physical inactivity than any other racial/ethnic group (HeathyDane.org). Therefore, we are including the older African American community from Madison, WI in the proposed project. An African American Program Manager will be hired to recruit and facilitate the project in the community. As recommended by African American community leaders, focus groups with older African American adults will first be conducted to ensure the intervention is culturally relevant and sensitive to the needs of the community. A facilitator from the UW Survey Center who is experienced in running focus groups will conduct 2 focus groups of 8-10 older African American adults. Results will be used to market and tailor the intervention to older African American adults. An African American facilitator will be hired and trained to deliver the intervention.

In sum, our community partners are very supportive of the proposed project and see high need for the *Stand Up & Move More* intervention, especially since the older adult population in these counties is projected to increase substantially in the future. For example, one in three individuals in Iowa County will be aged 60 years or older while 40-50% of the population in Vilas County will be over the age of 60 years by the year 2040. We believe we have an exceedingly strong partnership to be able to successfully conduct this important and promising research. The proposed project will provide an important step in developing effective strategies for maintaining independence in older adults through determining the feasibility and impact of a community-based intervention to break up sitting time.

SAFETY

Data Safety & Monitoring Plan

1). Participants Safety:

Potential Risks and Benefits for Participants

Risks: Participants will be asked to think of things they can do safely in their home to break up prolonged sitting time (e.g., stand up during TV commercials). The intervention should pose minimal risk of falling or injury since the participants will only be asked to engage in activities that are a part of their normal routine. There may be a risk of muscle soreness or increases in pain upon standing up and moving more. In addition, when completing the functional assessments (i.e., balance and chair stand tests), there may be risks of falling, muscle soreness, and pain. There also may be a risk to confidentiality, however, ID numbers will be used in place of participants' names on documents related to this study.

Potential Benefits: Older adults are the most sedentary age group spending 60-70% of their waking hours sitting. This amount of sitting time increases the risk of functional decline, chronic diseases, and premature mortality. The potential benefit of the proposed research to participants is acquiring knowledge on the negative health consequences of sedentary behavior (e.g., increased risk of obesity, metabolic syndrome, type 2 diabetes, cardiovascular disease, some malignancies, and premature death), and developing strategies to reduce sedentary behavior. Sitting less seems simple but intervention is required to get older adults to do it. If breaking up sitting time by standing up and moving more throughout the day proves to be effective, as our pilot data suggests, then we will have identified a practical intervention with the potential to improve the health and function of older adults.

Adverse Event and Serious Adverse Event Collection and Reporting: Adverse events are not expected to occur. The health program facilitators will, however, at the beginning of each workshop session, distribute a brief questionnaire asking about any adverse events (e.g., falling while standing up, injury, muscle soreness, and/or increases in pain) that may have occurred during the previous week. Other information to be gathered at the beginning of each session includes whether any of the participants were sick or sought healthcare during the past week. The health program facilitators will review the responses and then follow-up with respondents during the break or at the end of the session. (Note: the health program facilitators will be trained by Dr. Koltyn to assess adverse events as part of a day-long 'Stand Up and Move More' workshop training session for the community partners). Adverse events (AE) occurring during the study will be documented and reported (to the DSMB, IRB, and NIA) by the Principal Investigator (PI). The occurrence of AEs will be assessed on an ongoing basis during the intervention. If patterns of recurrent AEs across participants suggest modifications of the study protocol are required, such changes will be implemented in consultation with NIH staff and the IRB of record. The PI will be responsible for ensuring participant safety on a daily basis. The PI or research assistant will call the health program facilitators on a weekly basis during the workshop to discuss safety concerns and delivery of intervention content. In addition, bi-weekly phone calls will occur with the PI, Dr. Jane Mahoney, and Jill Renken (for quality assurance). A Data and Safety Monitoring Board (DSMB) will oversee safety monitoring and will act in an advisory capacity to the NIA Director to monitor participant safety.

Protection Against Study Risks:

Informed Consent Process: The consent process will inform volunteers about the study, indicate participation is voluntary, and that she/he has the right to stop at any time. Risks and benefits will be enumerated in the consent form and described orally during the consent process. An introductory meeting will be held for individuals who are interested in participating in this study. An explanation of the study will be given and questions will be answered. Participants will read and sign an IRB-approved consent form. Consent will be obtained by qualified personnel affiliated with the study including the PI and/or research assistants. All participants will receive a copy of their signed consent form.

Protection Against Study Risks: Participants will be asked to think of things they can do safely in their home to break up extended sitting time (i.e., 1 hour or more). The first session of the 4-week workshop will contain a discussion of how participants could stand up and move more safely in their homes (with consideration of any existing chronic pain conditions)**.** When they make their action plans they will think about how to do the activity safely (e.g., is the chair safe

to rise out of? Do they need something to hold onto? What will they use?). Participants will also identify things they should not do, and there will be a discussion on care in case of injury (e.g., call 911 as needed, as they would do in any other incident at home, and be seen by their regular clinical care system for diagnosis, treatment and follow-up. Participants will be instructed on what to report and to whom if they have an adverse event while participating in the workshop). Also, during weekly meetings, participants will report on any situation that arose during their efforts to break up their sitting time (e.g., muscle soreness and/or increases in pain), and then problem solve with input from the health program facilitators (e.g., trying alternative strategies, reducing the number of stands until the soreness subsides, etc). The PI or research assistant will call the health program facilitators on a weekly basis to discuss safety issues & delivery of the intervention, and bi-weekly phone calls will occur with the PI, Dr. Jane Mahoney, and Jill Renken (for quality and safety assurance). Dr. Mahoney has an extensive background in falls prevention. She founded and serves as medical director of the multidisciplinary UW-Health Geriatric Falls Clinic. Dr. Mahoney has researched and published extensively on falls prevention and mobility in older adults and is providing falls prevention expertise for this study. {Note: in our previous preliminary research, there were no injuries and pain did not increase even though the majority of the participants reported having arthritis}. When completing the physical function assessments (i.e., balance and chair stand tests), there are minimal risks of falling, muscle soreness, and/or increases in pain. However, to reduce these risks the physical function tests will be conducted near a table or wall in case a participant needs to steady themselves (in case they begin to fall). Also, the assessor will be close enough to the participant to catch them if need be.

Risks to confidentiality will be minimized by using ID numbers in place of names on all documents related to this study. The only document linking study assignment number and the subject's unique identifiers (along with signed informed consents) will be kept in a locked cabinet in Dr. Koltyn's office. Data will be stored in a password protected area with firewall protection and double backed up on flashdrives on the day of data collection. These back-up copies will be kept in a locked cabinet in the laboratory of Dr. Koltyn. Accuracy of data entry by the research assistant will be checked by Dr. Koltyn on a regular basis.

2). Interim Analyses

Interim analysis of the data will be conducted when 50% of the sample in each group is accrued and has had the opportunity to complete the 4-week intervention. We plan to continue data collection unless interim analyses indicate overwhelming significant effects regarding study aims.

3). Data Safety and Monitoring

The UW-Madison will be the IRB of record and our community partners, the four directors and staff of the Aging Network who regularly offer health promotion programs to older adults in their counties, will receive human subjects training through the UW-Madison. The PI will be responsible for ensuring participants' safety on a daily basis. The DSMB will act in an advisory capacity to the NIA Director to monitor participants' safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, and review the quality of data collection, management, and analyses.

Frequency of Data and Safety Monitoring: The data will be reviewed every 6 months throughout the duration of the study. The PI will be informed of serious AE as soon as they occur and will

notify the NIA and DSMB within 24 hours of notification. The DSMB will meet twice annually via conference call to review study progress, data quality, and participant safety.

Content of Data and Safety Monitoring Report: The content of the report will include: 1) study status, 2) demographic characteristics of enrolled participants, 3) enrollment and attrition statistics, 4) quality assurance and regulatory issues, descriptions of any AEs and/or SAEs, and 6) intervention efficacy (if applicable).

Data and Safety Monitoring Board Membership and Affiliation*:* The Data and Safety Monitoring Board (DSMB) is composed of three members and includes experts in or representatives of the fields of relevant clinical expertise, clinical trial methodology, and biostatistics:

1). Barbara Nicklas, Ph.D. (Chair of the DSMB)
Professor of Internal Medicine, Gerontology & Geriatric Medicine
Wake Forest School of Medicine
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Dr. Nicklas is the Deputy Director of the Sticht Center on Aging at Wake Forest School of Medicine. She has a Ph.D. in exercise physiology and conducts research on the effects of exercise on various health outcomes in older adults (e.g., weight loss, weight regain, inflammation).

2). Lorraine Phillips, Ph.D., R.N.
Associate Professor of Nursing
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Dr. Phillips is an Associate Professor in the Sinclair School of Nursing at the University of Missouri. She conducts research on the physical, cognitive, and emotional functioning of older adults residing in long-term care facilities.

3). Felicity Enders, Ph.D.
Professor of Biostatistics
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Phone: 507 284-2511
Dr. Enders is a lead statistician in the Division of Biomedical Statistics and Informatics at the Mayo Clinic College of Medicine.

Conflict of Interest for DSMB's*:* There are no conflicts of interest as members of the DSMB are not affiliated with this study or with the investigators.

Protection of Confidentiality*:* Data will be reported in a blinded manner in the DSMB report, and the data and discussion with the DSMB will be confidential.

DSMB Responsibilities*:* The responsibilities of the DSMB for this study include:

(a) review the research protocol, recruitment plan, and data and safety monitoring plan
(b) recommend subject recruitment be initiated after receipt of a satisfactory protocol
(c) evaluate the progress of the trial, recruitment, accrual and retention, participant risk vs benefit, performance of the trial sites, and other factors which may affect study outcome
(d) consider factors external to the study when relevant information becomes available that may have an impact on the safety of the participants or ethics of the trial
(e) review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator
(f) protect the safety of the study participants
(g) report to NIA on the safety and progress of the trial
(h) make recommendations to the NIA and the Principal Investigator concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study
(i) if appropriate, review interim analyses in accordance with stopping rules
(j) ensure the confidentiality of the study data and the results of monitoring
(k) assist NIA by commenting on any problems with study conduct, enrollment, sample size, and/or data collection

DATA COLLECTION AND QUALITY ASSURANCE

Data Collection: All study data will be collected solely for the research purposes of this study. Outcome assessments consisting of accelerometer, questionnaire and interview data, as well as the Short Physical Performance Battery (i.e., balance, gait speed & chair stands) will be assessed by research assistants from the UW-Madison who are blinded to group assignment (Note: every effort will be made to ensure the assessors remain blinded throughout the duration of the study). The research assistants including the PI (Dr. Koltyn) will travel to the county sites on designated days to collect data at baseline, after the 4-week intervention, and at follow-up (12 weeks). The research assistants will be trained by Dr. Koltyn to complete data assessments prior to data collection. Data collection forms will be standardized and the participant's ID number will be recorded on the forms (rather than their names). Source documents for each participant's data (i.e., participant binder) will be stored in a locked cabinet in Dr. Koltyn's laboratory. Data will also be entered (using ID numbers only) by one of the research assistants into an electronic database using SPSS statistical computing environment. The data will be stored in a password protected area with firewall protection. Only designated personnel on the project will have access to the file and password.

Data Management: The UW-Madison is the lead site for this study. Dr Koltyn will be responsible for data management including activities such as development and maintenance of study materials including a manual of procedures (MOP) and data collection forms; training and supervising research assistants during data collection; overseeing data management via a secure data management system; reviewing data entry for possible errors; and assisting with data analyses. The community partners will not be involved in collecting, storing or analyzing

the data. Their primary responsibilities include recruiting participants, facilitating the *Stand Up and Move More* workshops, and providing information (via a semi-structured interview) about the feasibility of implementing the workshops. The Steering Committee for this study will meet bi-weekly to discuss study progress, data management, and quality control (with additional conference calls as needed).

Quality Assurance: Quality control and monitoring will be performed by Dr. Koltyn and Jill Renken (Community Research Associate). Dr. Koltyn will train and monitor the research assistants, and ensure quality control regarding all aspects of this study. Jill Renken will provide the training and fidelity monitoring of our community partners. As noted previously, Jill has been involved in statewide coordination of evidence-based health promotion programs for older adults in Wisconsin for over 9 years. Part of her responsibilities have included training, overseeing, and fidelity monitoring for other health promotion programs (e.g., the "Chronic Disease Self-Management Program"). Instruction manuals with scripts for each workshop session will be provided to the health facilitators (and used during training) to maximize fidelity of delivery of sessions per our intervention protocol. The health facilitators will record any deviations from protocol which will be discussed via telephone calls with Jill Renken and Dr. Koltyn. The facilitators will also be asked to record any suggested changes to the protocol which will be discussed at a team meeting following delivery of the workshops.

PARTICIPANTS RIGHTS AND CONFIDENTIALITY

IRB Review: This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB responsible for oversight of the study (UW-Madison Social and Behavioral IRB Committee).

Informed Consent Forms: A signed consent form will be obtained from each participant. The consent form will describe the purpose of the study, the procedures to be followed, the risks and benefits, as well as the voluntary nature of participation and individuals have the right to stop at any time. A signed copy will be given to each participant and this fact will be documented in the participant's record.

Participant Confidentiality: Participants will be assigned a study ID number upon enrollment into the study and this number will be used in place of the participant's name on all recording forms. The only list matching the ID number to the participant's name will be kept locked in the office of the PI (Dr. Koltyn). All computer entry will be done using ID numbers only. Information will not be released without written permission of the participant, except as necessary for monitoring by the IRB and NIA.

Study Discontinuation: The study may be discontinued at any time by the IRB, the NIA, or other government agencies as part of their duties to ensure that research participants are protected.

ETHICAL CONSIDERATIONS

The UW-Madison (and thus this study) is guided by the ethical principles regarding all research involving humans as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research {entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report")}.

COMMITTEES

The Steering Committee for this study includes Dr. Koltyn (PI), Dr. Mahoney (Co-I), and Jill Renken (Community Research Associate). The Steering Committee will be responsible for the overall conduct of the study. Bi-weekly meetings will be held to discuss progress of the study (with additional conference calls as needed).

PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this study will be governed by the policies and procedures developed by the steering committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor prior to submission.

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SUPPLEMENTS

Table 1. Workshop Sessions Topic Overview

Group Workshop	Topic/Activities
Session 1	Introduction and overview of the workshop
	Record time spent sitting/day (e.g., watching TV, reading, etc)
	What is sedentary behavior? Information provided on the health consequences of sitting too much
	Safety discussion: discuss how participants could stand up and move more safely in their environment
	Modeling (group leader stands and encourages others to stand and move)
	Goal setting (set a specific manageable goal for the next week, e.g., # of stands and how this will be accomplished)
	Develop an action plan to meet the goal
	Discuss self-monitoring (click counter & daily log each night)
Session 2	Group discussion on why they sit and barriers to standing up
	Examine goals and behaviors from last week
	Discuss strategies for trouble-shooting/problem solving
	Discuss hand-out (strategies used to sit less in a study by Gardiner & colleagues)
	Modeling (group leader stands and encourages others to stand and move)
	Set a new goal (specific # of stands/day and how this will be accomplished)
	Develop an action plan to meet the goal
	Self-monitoring (discuss self-monitoring during the past week & how to monitor effectively this next week)
Session 3	Discuss goals and behaviors from previous week
	Confidence building: share successes/discuss incremental progress
	Discuss cognitive reframing (how to reframe unhelpful thoughts)
	Discuss the benefits of standing up and moving more
	Discuss any problems encountered with problem solving
	Modeling (group leader stands and encourages others to stand and move)
	Set a new goal (specific # of stands/day and how this will be accomplished)
	Develop an action plan to meet the goal
	Self-monitoring (discuss self-monitoring during the past week & how to monitor effectively this next week)
Session 4	Record time spent sitting/day (to compare to week 1)
	Discuss goals and behaviors from previous week
	Discuss relapsing back into old patterns & how to stay motivated
	Review benefits of standing up and moving more
	Discussion of how to stay active in the community
	Modeling (group leader stands and encourages others to stand and move)
	Set a new goal (i.e., long-term goal: what to do after this program ends)
	Develop an action plan to meet the goal
	Self-monitoring (discuss self-monitoring during the past week & monitoring plans for long-term success)
Refresher Session	Re-examine motives for sitting less
	Discuss progress and barriers
	Share strategies to stand up & move more that worked well
	Revisit goal with a focus on how to maintain new behaviors over the long-term
	Modeling (group leader stands and encourages others to stand and move)
	Congratulate the participants and discuss ongoing activities & social events

Table 2. Schedule of Assessments

Assessments	Introductory Meeting	Session 1	Session 2	Session 3	Session 4	Refresher Session 8 wks	Follow-up 12 wks
Informed Consent	X						
Demographic/health questionnaire	X						
SF-36	X				X		X
PROMIS questionnaires	X				X		X
Sedentary Behavior interview	X				X		X
Self-efficacy questionnaire	X				X		X
Self-regulation questionnaire	X				X		X
Outcome expectations questionnaire	X				X		X
Short Physical Performance Battery	X				X		X
Accelerometers	X				X		X
Adverse events			X	X	X	X	X
Fidelity monitoring		X	X	X	X	X	
Satisfaction						X	
Feasibility						X	
Cost estimate							X

Note. Screening of prospective participants and randomization will be completed prior to the introductory meeting.