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Official Title:

A Cognitive Self-Management Intervention for Persons with Multiple Sclerosis: Adapting Web-based Technology

1. Title
   A Cognitive Self-Management Intervention for Persons with Multiple Sclerosis: Adapting Web-based Technology

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3. Purpose
   Multiple sclerosis (MS), an immune-mediated neurologic disease of the central nervous system, is the chief source of non-traumatic disability among young to middle-aged adults. Over half of the 2.3 million persons diagnosed with MS (PwMS) worldwide experience appreciably impaired cognitive function, which substantially diminishes daily activities, including those associated with disease self-management, employment, and quality of life. Cognitive impairment (CI) varies considerably among PwMS; it may be present in the earliest stages of the disease but is most prevalent in progressive forms of MS. Currently, there are no approved medical therapies, including MS disease-modifying treatments, to manage cognitive symptoms in MS. Cognitive rehabilitation therapies have had mixed results and few treatment options exist outside of research settings.

   Insufficient physical activity (PA) contributes to cognitive impairment in healthy as well as cognitively impaired older adults. Based on this evidence, PA has been postulated as an attractive modifiable behavior to target in the management of MS-related CI. Regrettably, evidence to support PA's effect on CI in PwMS is limited with few well-designed randomized controlled trials published. Conceivably, PA may influence CI indirectly by reducing symptoms common in MS that are linked with CI (i.e., fatigue, depression, and sleep disturbance). Meta-analytic evidence supports PA's positive effect on fatigue and depression in MS but little research exists describing PA's linkage with sleep disturbance, a primary contributor to MS-related fatigue. Sleep disturbance is highly prevalent in MS, occurring in 42-60%, but sleep disorders regularly go unrecognized, and thus untreated. While there is substantial literature on the relationship between sleep disturbance and fatigue in MS, less attention has focused on sleep and cognitive function and therefore, sleep may be critical to fully elucidating the PA-CI relationship. The constellation of MS symptoms - sleep disturbance, fatigue, depression and CI - may impede an individual's capacity to engage in self-management strategies (specifically PA) thus fostering a vicious cycle of progressive disablement.

   The primary objective of this study is to develop and pilot test an innovative cognitive self-management intervention for PwMS delivered via web-based video conferencing. Data derived from interviews will be used to guide the adaptation of Stuifbergen's 8-week Memory, Attention, and Problem-Solving Skills in MS (MAPSS-MS) intervention to be delivered via web-based video conferencing. The adapted MAPSS-MS intervention will be feasibility tested in small groups of PwMS. Outcome variables include: (1) neurocognitive function assessed using the NIH Toolbox®, a comprehensive set of psychometrically sound neuro-behavioral measures[18] that quickly assesses cognitive functions using an iPad, (2) objective PA and sleep using Actigraph™ accelerometers, (3) self-reported sleep, depression, and fatigue using the Patient-Reported Outcome Measurement Information System (PROMIS), and (4) MS specific self-management using the Multiple Sclerosis Self-Management Scale (MSSM). Community-residing PwMS, age 21 to 70, will be recruited from Central Texas to participate in Phase 1 interviews (n=5) and Phase 2 pilot testing (n=20) of the adapted version of the 8-week MAPSS-MS cognitive self-management intervention emphasizing PA delivered via web-based video conferencing. In Phase 2 pilot testing (n=20), an intervention group (n=10) will be compared to an "enhanced usual care" control group (n=10).

The specific aims are to:
Aim 1: (a) Conduct interviews with PwMS to gather data to guide the adaptation of a tailored, cognitive self-management intervention delivered via web-based video conferencing, (b) Develop an adapted version of the 8-week MAPSS-MS intervention guided by the analysis of the interview data.

Aim 2: Conduct a feasibility study of the adapted MAPSS-MS cognitive self-management intervention emphasizing PA using objective and self-report data from community-residing PwMS. Process outcomes include success with recruitment, ability to deliver the intervention using web-based video conferencing, and ability to measure study outcomes.

4. Procedures

Study Design

This pilot feasibility study employs a mixed methods design conducted in a community setting. Phase 1 uses a single-group qualitative design involving a convenience sample of 5 adults with MS; Phase 2 uses a randomized controlled trial (RCT) design conducted with a sample of 20 adults with MS (10 intervention/10 control). Phase 2 data will be collected at baseline (before the intervention) and at 8-weeks (post-intervention). Data includes self-report measures, an objective measure of physical activity, and neurocognitive tests. An "enhanced usual care" control group is selected as most appropriate for this pilot feasibility study of a non-pharmacologic, behavioral intervention.

Phase 1: Qualitative Descriptive Interview Protocol

The initial phase of this study will involve individual interviews with a purposive/convenience sample of 5 participants who have MS. After informed consent has been obtained, the PI will conduct and audio-record individual interviews lasting approximately 45 to 60-minutes with each participant meeting inclusion criteria. The interviews will include questions concerning how participants manage their MS, how they feel MS does or does not affect cognitive function, and how they feel cognitive function affects their MS self-management, as well as other MAPSS intervention topics. Additional probe questions may be used as needed to clarify responses. After interviews are completed, the audio recordings will be transcribed, and analyzed. The team will meet to make changes to the intervention based on those findings.

Qualitative Data Analysis

The goal of the interviews is to acquire specific information in order to adapt the MAPSS-MS intervention. During the interviews, data collectors (the PI and a research assistant) will probe for understanding as well as summarize participant statements for accuracy. Data collectors will also keep field notes of significant ideas and interview setting. The interview transcripts will be analyzed using Miles and Huberman's method of content analysis. The PI and one other member of the research team will initially review the transcripts. The results of the initial coding will then be reviewed by the research team and finalized. Transcripts will be analyzed for common themes regarding sessions, content, and barriers to participation. The research team will meet to review those findings and make changes to the class sessions based on the findings. The adapted MAPSS-MS intervention will not be piloted until reviewed and approved by the IRB.

Phase 2: Intervention Pilot Testing Protocol

Participants involved in Phase 1 will be invited to join the Phase 2 of the study. Additional participants will be recruited to reach the desired sample size (n=20) for Phase 2 pilot testing. Phase 2 participants will be randomly assigned to an intervention group (n=10) or an "enhanced usual care" control group (n=10). Baseline questionnaire booklets (demographic data, functional status, MS self-management, and self-report surveys) will be mailed to all Phase 2 participants upon receipt of the

signed consent form and the verification of clinically definite MS form signed by their healthcare provider. At baseline and 8-weeks (post-intervention), a trained research assistant (RA) will arrange to meet with each participant individually to administer the NIH Toolbox Cognitive Battery at a location of their choice (e.g. home). At this meeting, participants will also receive an accelerometer to wear on their non-dominant wrist for 7 days and 7 nights along with printed and verbal instructions on accelerometer wear and care. The data collectors will have received training on instrument administration and accelerometry. Postage-paid, preaddressed envelopes will be given to participants to return all study materials to the PI's research office at The University of Texas at Austin, School of Nursing.

Participants randomly assigned to the intervention group (n=10) will remotely attend eight weekly 90-minute intervention sessions from the location of their choice (e.g., home) via their chosen device (computer, tablet, and/or smart phone) using a web-based video conference platform. The 10 intervention participants will be divided into 2 cohorts of 4 to 6 persons each. Participants in the "enhanced usual care" control group (n=10) will receive an illustrated instructional booklet on Physical Activity for persons with MS developed by the National Center on Health, Physical Activity and Disability (NCHPAD).

The eight weekly educational classes, originally developed for the MAPSS-MS intervention, will be adapted for remote web-based delivery (Appendix A). Specific intervention content will be modified based on feedback from Phase 1 interviews and research team members. Content will provide educational information emphasizing PA and include: (1) information on MS self-management strategies incorporating PA, fatigue, mood, and sleep self-monitoring; (2) assessment of cognitive problems; (3) resources and barriers to self-management; (4) goal setting and self-monitoring; and (5) lifestyle changes to maximize cognitive health. Phase 2 intervention content will follow the PA guidelines specifically designed for persons with MS developed by The Canadian Society for Exercise Physiology (Ginis & Hicks, 2007). These guidelines promote fitness benefits for adults with MS who have mild to moderate disability through "30 minutes of moderate-intensity aerobic activity (e.g. walking, housekeeping, gardening) 2 times per week and strength-training exercises for major muscle groups 2 times per week" (Latimer-Cheung, Martin Ginis, et al., 2013, p. 1829). All sessions will emphasize maximizing cognitive function in MS and address the interrelated effects of PA and other self-management skills on cognitive function.

Post-intervention data (questionnaire booklets, NIH Toolbox Cognitive Battery, and accelerometry) will be gathered, using the methods described for baseline data collection, within 2 weeks of the final intervention class for those in the intervention group. Those in the control group will complete post-intervention data 8-10 weeks after baseline data collection.

a. Location
   The research will be performed at the University of Texas at Austin, School of Nursing and at locations chosen by each participant (e.g., their home).
   Phase 1 interviews will be conducted by the PI at a location selected by the participant (e.g. home).
   Phase 2 data will be collected by mail (U.S. Postal service) and in-person at a location of the participants' choice (e.g. home). Participants will remotely attend eight weekly 90-minute intervention sessions from a location of their choice (e.g., home) via a web-based video conference platform on their chosen device (computer, tablet, and/or smart phone).

b. Resources
External funding from the Center for Transdisciplinary Collaborative Research in Self-Management Science (National Institute of Nursing Research, National Institutes of Health, Grant: P30 NR0115335: PI Kim) at The University of Texas at Austin, School of Nursing is anticipated to start 9/1/2017.

c. Study Timeline
The estimated completion time for this study is 15 months. Data collection will begin in October of 2017 and continue through September of 2018 or study completion. Data analysis will be conducted from June to August of 2018 with report writing occurring from September through November of 2018.

5. Measures
The following measures will be used to collect data on the effectiveness of the intervention at the two data collection points with the exception of demographic information and MS functional status measure, which are baseline-only measures.

Phase 1 Measures
Interview questions have been designed specifically for this project.

Phase 2 Measures
The following measures will be used to collect data on the effectiveness of the intervention. Contextual factors and MS functional status will be collected at baseline only; the remaining measures will be collected at baseline and 8-weeks post intervention.

1) Contextual Factors – A Demographic Information Sheet will be used to collect baseline information on a variety of demographic (age, gender, education, marital status, ethnicity) and disease characteristics that will be used to describe the sample.

2) MS Functional Status – The Self-Administered Expanded Disability Status Scale (EDSS) will be used to measure MS-related functional impairment. Derived from Kurtzke's (1983) physician-administered EDSS, the self-administered EDSS was developed by Bowen, Gibbons, Gianas, and Kraft (2001) for use in epidemiologic and longitudinal studies. The self-administered test was found to have strong intraclass correlation coefficients with the physician-administered EDSS using gait alone ($r = 0.89$) or gait plus functional systems ($r = 0.87$). While the EDSS has been the subject of both reliability and validity concerns, it is undeniably the most widely used method to quantify MS-related functional status by clinicians and researchers alike (Bowen et al., 2001; Schwartz, Vollmer, & Lee, 1999). Scores derived from the EDSS range from 0 (normal neurologic function) to 10 (death due to MS) with a score of 4.5 reflecting the ability to "walk without aid or rest for some 300 meters" (Kurtzke, 1983, p. 1446).

3) MS Self-Management – The Multiple Sclerosis Self-Management Scale-Revised (MSSM-R) is the only measure developed specifically to address self-management in persons with MS (Bishop & Frain, 2011). The 24-item scale has five-subscales: 1. Healthcare Provider Relationship and Communication (6 items); 2. Treatment Adherence/Barriers (7 items); 3. Social/Family Support (3 items); 4. MS Knowledge and Information (4 items); and 5. Health Maintenance Behavior (4-items). Total scores range from 0 to 100, with higher scores indicating a higher degree of MS self-management.

4) Objective Cognitive Function – assessed with the NIH Toolbox Cognitive Battery – iPad App (Time to administer the 8-measure battery: approximately 34 minutes)
    a. Language - A set of mental processes that translate thought into symbols (words, gestures) that can be shared among individuals for purposes of communication. Tests focus on two aspects of language: 1) Vocabulary knowledge, measured by the Picture Vocabulary Test; and 2) Oral reading (decoding) skills, measured by the Oral Reading Recognition Test
        i. NIH Toolbox Picture Vocabulary Test (4 minutes)
        ii. NIH Toolbox Oral Reading Recognition Test (3 minutes)
    b. Executive Function (EF) and Attention - EF: capacity to plan, organize and monitor the execution of behaviors that are strategically directed in a goal-oriented manner. Focuses on: 1) Inhibition of automatic response tendencies that may interfere with achieving a goal, and 2) set shifting, or the capacity for switching among multiple aspects of a strategy or task. Attention: allocation of one's limited capacities to deal with an abundance of environmental stimulation
        i. NIH Toolbox Flanker Inhibitory Control and Attention Test (EF and Attention) [3 minutes]
        ii. NIH Toolbox Dimensional Change Card Sort Test (EF) [4 minutes]
    c. Working Memory - The capacity of an individual to hold information in a short-term buffer and manipulate the information.
        i. NIH Toolbox List Sorting Working Memory Test (7 minutes)
    d. Processing Speed - The amount of time it takes to mentally process a set amount of information, or the amount of information that can be processed within a certain unit of time. It is a measure that reflects mental efficiency
        i. NIH Toolbox Pattern Comparison Processing Speed Test (3 minutes)
        ii. NIH Toolbox Oral Symbol Digit Test (3 minutes)
    e. Episodic Memory - The acquisition, storage and retrieval of new information. It involves conscious recollection of information learned within a context.
        i. NIH Toolbox Picture Sequence Memory Test (7 minutes)

5) Participant-Reported Outcomes - Assessed with the Patient-Reported Measurement Information System (PROMIS®) developed using Item Response Theory by the Patient Reported Outcomes Measurement System (PROMIS) and the Quality of Life in Neurological Disorders (NeuroQoL) measurement system that evaluates and monitors physical, mental, and social effects experienced by adults living with neurological conditions. Both systems were funded by the National Institutes of Health (www.NIHPROMIS.org). All individual PROMIS and Neuro-QoL SF instruments take less than 5 minutes to complete – approximately 35 minutes for this 7-measure battery
    a. Self-Efficacy –
        i. PROMIS Short Form v1.0 – Self-Efficacy for Managing Medications and Treatments (4-items) - Assesses confidence in managing medication schedules of different complexity. Items also assess managing medication and other treatments in challenging situations such as when traveling, when running out of medication, and when adverse effects are encountered.
        ii. PROMIS Short Form v1.0 – Self-Efficacy for Managing Symptoms (4-items) - Assesses level of confidence to manage/control symptoms, to manage symptoms in different settings (home, public place, an unfamiliar place) and

to keep symptoms from interfering with work, sleep, relationships or recreational activities.

iii. PROMIS Short Form v1.0 – Self-Efficacy for Managing Daily Activities (4-items) - Assesses confidence in performing various activities of daily living (ADLs) without assistance. Items also assess exercise, sexual activities and managing activities in challenging situations (traveling, bad weather).

b. Cognitive Function –
   i. Neuro-QoL Short Form v2.0 – Cognitive Function (8-items) - Assesses mental acuity, concentration, verbal and nonverbal memory, verbal fluency, and perceived changes in these cognitive functions. The extent to which cognitive impairments interfere with daily functioning, whether other people observe cognitive impairments, and the impact of cognitive dysfunction on quality of life are also assessed.

c. Depression –
   i. Neuro-QoL Short Form v1.0 – Depression (8-items) - Assesses self-reported negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose). Somatic symptoms (changes in appetite, sleeping patterns) are not included, which eliminates consideration of these items' confounding effects when assessing patients with comorbid physical conditions. Assesses depression over the past seven days.

d. Fatigue –
   i. Neuro-QoL Short Form v1.0 – Fatigue (8-items) - Assesses self-reported symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one's ability to execute daily activities and function normally in family or social roles. Fatigue is divided into the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities. Assesses fatigue over the past seven days.

e. Sleep Disturbance –
   i. Neuro-QoL Short Form v1.0 – Sleep Disturbance (4-items) - Assesses perceptions of sleep quality, sleep depth, and restoration associated with sleep. This includes perceived difficulties and concerns with getting to sleep or staying asleep, as well as perceptions of the adequacy of and satisfaction with sleep. Sleep Disturbance does not focus on symptoms of specific sleep disorders, nor does it provide subjective estimates of sleep quantities (total amount of sleep, time to fall asleep, amount of wakefulness during sleep). Assesses sleep disturbance over the past seven days.

6) Objective sleep and activity – The ActiGraph™ Model wGT3X-BT (ActiGraph™, Pensacola, FL) has been identified as the benchmark measure of ambulation in persons with neurologic diseases. These accelerometers are small (1"x1") electronic devices worn like a wristwatch that record and store activity counts, steps and sleep data. Evidence of the validity and reliability of accelerometry has been established for persons with MS. Nighttime total sleep time is the main actigraphy sleep outcome. We also will measure other sleep disturbance variables, including nighttime wake after sleep onset, sleep efficiency, sleep latency, and awakenings with the actigraph. We will measure sleep for 7 days and 7 nights at baseline and again after the 8-week intervention is over. Wrist activity measures are

considered a significant part of the evaluations in this study to document restful sleep and the sleep and wake activity levels. Participants will be asked to keep a log documenting when they get into bed at night and when they get out of bed in the morning to define night and day intervals.

6. Participants
   a. Target Population
   The sample for this study will consist of adults with physician-diagnosed MS living in the Austin metropolitan area who meet screening criteria. Up to 25 Participants – maximum of 5 in Phase 1 and 20 in Phase 2 - will be recruited from communities in and around metropolitan Austin, Texas. Austin is the state capital and the center of a metropolitan area of approximately 1 million people. According to the 2011 US Census Bureau estimates, the population is approximately 50% White/non-Hispanic, 34% Hispanic, 9% Black, and 6% Asian and 2% other. The Lone Star Chapter of the National MS Society serves more than 1400 Persons with MS in Travis County. The PI's prior work has allowed her to build strong connections with this population and service providers throughout the community.
   b. Inclusion/Exclusion
   To participate, subjects must be diagnosed with MS, age 21 to 70, and capable of understanding and complying with the study protocol. Participants must be able to read and write in English. All participants must have a diagnosis of clinically definite MS documented by their healthcare provider. Participants must have stable disease at the time of entry into the study (relapse free for at least 90 days), and be willing to participate in an 8-week study promoting physical activity, MS self-management and compensatory cognitive strategies, and data collection. Participants must also have subjective concerns about their cognitive functioning and will be given the 20-item Perceived Deficits Questionnaire to assess this. Those scoring at least 10 will be eligible to participate. Participants may be of either gender or any ethnic/racial group. Subjects will be excluded if they are pregnant or plan to be, have cardiovascular or respiratory disease, other medical causes of dementia or other neurological disorders that may impact cognition or emotions, evidence of major psychiatric disorder, or if they have major functional limitations that preclude them from participating in the study.
   c. Benefits
   Phase 1 - Participants will receive no direct benefit from participating in the interview phase of this study; however, their participation in the study may help researchers better understand MS self-management and cognitive function in persons with MS.
   Phase 2 - Participants in the intervention group will benefit by learning about MS self-management and strategies to potentially improve cognitive function. Participants in the "enhanced usual care" control group will receive an illustrated instructional booklet on PA for PwMS developed by the National Center on Health, Physical Activity and Disability (NCHPAD).
   d. Risks
   There is very minimal risk to participants. The anticipated risks for PwMS participating in this study are:
      1) Breach of confidentiality and loss of privacy
      2) Potential distress related to concerns about MS-related cognitive function and performance on cognitive testing
      3) Physical injury (falling or tripping) and temporary increases in MS symptoms due to increased core body temperature (e.g., fatigue, numbness/tingling sensations, foot drop) that may be related to PA or environmental conditions

   These risks are considered minimal and will be addressed in the study protocol. They will also be described in the consent form. Persons who participate in the study may already have concerns

about their perceived cognitive function and this may be a source of distress. It is not expected that these risks will be greater than those experienced in living with the cognitive demands of everyday life. Although participants with self-reported major depressive disorder will be screened and excluded at the beginning of the study, participants with T-scores $\geq$ 60 (1^{+} SD) on the PROMIS Depression instrument will be referred to their healthcare provider for further assessment and treatment.

Data and Safety Monitoring Plan

An Independent Safety Monitor (ISM) is deemed the appropriate level of monitoring for the small size (N=20) and low level of risk in this pilot study. Heather Becker, PhD, Research Scientist at The University of Texas at Austin, School of Nursing has agreed to serve as the study's ISM. Dr. Becker has extensive expertise in the conduct of human subjects research, is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues. The ISM will meet with the PI to discuss the research protocol approved by the University of Texas at Austin Institutional Review Board (IRB) prior to initiating data collection and then annually thereafter, if the study lasts longer than one year. The ISM will be contacted by the PI in the case of any adverse events potentially related to the study; we consider physical injury (falling or tripping) and temporary increases in MS symptoms due to increased core body temperature (e.g., fatigue, numbness/tingling sensations, foot drop) related to physical activity and distress related to concerns about MS-related cognitive impairment to be the most likely adverse events related to the study. A list of Austin-area mental health resources will be made available to all participants at the time of obtaining consent. Participants who report feeling distressed at any time during the study will be discussed with the ISM. Adverse events, as well as unanticipated problems involving risks to participants, will be reported to the ISM and the University of Texas at Austin IRB by the PI in a timely manner. We will ensure that the National Institute of Nursing Research (NINR) Project Officer is informed of any actions taken by the IRB as a result of such adverse events.

Monitoring Entities

The ISM and the University of Texas at Austin IRB will review this research protocol, all procedures, and will provide oversight. Monitoring will be done by the PI, ISM, and the University of Texas at Austin IRB. The PI is responsible for submitting all necessary reports to the University of Texas at Austin IRB and NINR.

Monitoring Procedures

Monitoring is done of all procedures to ensure that they conform to approved protocol including: ISM auditing 10% of cases for compliance with IRB requirements, conformance with informed consent requirements, verification of source documents, and investigator compliance. Procedures to protect the confidentiality of participant data include using unique confidential ID numbers to identify participant data in lieu of participants' names on all study documents. The key linking participants' names to the ID numbers will be kept separate from the data in a password protected electronic file stored on UTBox. UTBox cloud storage has been approved by the Information Security Office for use with Confidential (formerly known as Category I) university data, including HIPAA data. Data will be collected using individual interviews, surveys of standardized measures (MS Self-Management, PROMIS and NIH Toolbox), and actigraphy to minimize research-associated risk.

Frequency of Monitoring

All adverse events will be assessed continuously and immediately as discovered by the PI. Monitoring by the IRB is conducted at annual continuing reviews, whenever modification requests are considered, and upon receiving reports of adverse events from the investigator or others.

Identifying, Reviewing, and Reporting Adverse Events and Unanticipated Problems
The PI will report adverse events to the ISM and the IRB (using the IRB Unanticipated Problem Report) in a timely manner, and to the NIH annually at the continuing review. NIH requires annual reports of adverse events in the Research Performance Progress Report sent to the NINR. All actions of the IRB in response to an unexpected event or adverse event will be reported to NINR along with any changes or amendments to the protocol requested by the IRB in response to these reports. Proposed change or amendments to the protocol must be requested first in writing to the IRB, which will then grant or deny permission to make the requested change or amendment.

e. Recruitment
Participants for Phase 1 will be recruited from individuals who participated in the PI's previous study, Effects of Physical Activity on Cognition in Persons with MS (IRB Study Number: 2014-02-0031), and indicated that they would be willing to be contacted about future studies. These individuals will be invited to participate in the interview about cognitive function, MS self-management and physical activity by letter signed by the PI.
Participants for Phase 2 will be recruited primarily through presentations at local Austin MS support group meetings, flyers distributed by MS support group leaders and colleagues at Austin area neurology/MS clinics, and word of mouth. Recruitment materials will instruct potential participants to call the PI's research office for additional information about the study. Callers will be screened by study staff and those meeting study inclusion criteria will be administered the Perceived Deficits Questionnaire (PDQ). This 20-item questionnaire assesses self-perceived cognitive difficulties and is made up of questions such as "How often do you lose your train of thought when speaking?" Subjects are asked to rate their responses on a 5-point scale ranging from 0 (never) to 4 (almost always). Responders to the recruitment strategies must score at least 10 on the PDQ.

f. Obtaining Informed Consent
Participants willing to be interviewed for Phase 1 and meeting telephone screen inclusion criteria will be mailed the Phase 1 consent form and the healthcare provider verification of MS diagnosis form to sign and return to the PI via US Postal Service using a postage-paid, preaddressed envelope. At the time of the interview, these participants will be invited to participate in Phase 2 of the study and be given the Phase 2 consent form to sign. Participants responding to Phase 2 recruitment and meeting telephone screen inclusion criteria will be mailed the Phase 2 consent form and the healthcare provider verification of MS diagnosis forms to sign and return to the PI via US Postal Service using a postage-paid, preaddressed envelope. The PI or RA will review the study requirements, answer any questions, and have received the signed informed consent document prior to any data being collected.

7. Privacy and Confidentiality
The PI and RAs have been trained in procedures to respect the rights of human subjects. There will be a special focus on issues related to 1) protecting privacy and confidentiality for participants randomized into the intervention group who will meet remotely in small groups (4-6 persons) via a web-based video conference platform on their chosen device - computer, tablet, and/or smart phone; and 2) awareness of fatigue and potential distress (related to concerns regarding cognitive and physical performance). Confidentiality and privacy of potential participants will be preserved, as the individual must contact the principal investigator to express interest in the study and disclose their name and contact information.

Confidentiality of the Data or Samples

a. Phase 1: An electronic recorder (e.g., Sony IC recorder) will be used to make electronic audio files of Phase 1 interviews. Audio files will be deleted from the recording device when transferred to UTBox cloud storage. UTBox has been approved by the Information Security Office for use with Confidential (formerly known as Category I) university data, including HIPAA data. Audio files will be named using the participant's unique ID number and the date recorded; no identifying data will be included or recorded from individual participants. De-identified audio files will be transcribed by a professional transcription service. Audio files stored on UTBox will be destroyed after they have been transcribed and the transcriptions reviewed by the PI and RA.

b. Phase 2: After receipt of the signed consent and verification of MS diagnosis forms, participants will be mailed: 1) the questionnaire packet to complete at home with instructions (e.g., to take breaks as often as needed); 2) a postage-paid, preaddressed envelope to return the completed questionnaire packet to the PI's research office at The University of Texas at Austin, School of Nursing. A trained RA, blinded to the participant's group assignment, will collect the NIH Toolbox measures using an iPad at baseline and 8-weeks (post-intervention) at a location (e.g. home) selected by the participant. Accelerometer data will be downloaded directly from each device onto the PI's password-protected computer.

c. Confidentiality of data records will be maintained by keeping signed consent forms separate from data files in locked cabinets. Records containing personal information (Phone Pre-Screening Form, PDQ, and Verification of Multiple Sclerosis Diagnosis) will be kept separate from consent forms and data files in a locked cabinet. Participants will be assigned a unique ID number that will be written on their data collection booklets and used to identify NIH Toolbox and accelerometer data to maintain confidentiality of data. A separate list of names with assigned data record identification number will be kept in the password protected UT Box accessed from the PI's password protected computer.

d. De-identified data will be kept in paper form in a locked file for five years after publication of any manuscripts using study data. Scanned copies of de-identified tests, questionnaires and accelerometer data will be kept in the password protected UT Box accessed from the PI's password protected computer. De-identified data from this study will be kept in perpetuity.

e. All data will be kept confidential and labeled only with the participant's unique ID number. The data collected may be made available to other researchers in the future for research purposes not detailed in this study. In those cases, the data will contain no identifying information that could associate the participant with the data or with their participation in the study.

f. Participant consent forms and forms containing personal information (Phone Pre-Screening Form and Verification of Multiple Sclerosis Diagnosis) and the list of names with assigned data record identification number will be destroyed five years after completion of the study. No de-identified data from this study will be destroyed.

8. Compensation

Participants will be compensated for their time and effort contributed to this study.

Phase 1 participants will receive a $25 gift card (e.g. retail or grocery store) upon completing the interview.
Phase 2 participants will receive a $50 gift card upon completion of baseline data collection and a second $50 gift card upon completion of post-intervention (8-week) data collection ($50 x 2 = $100 total per participant).