A SCALABLE MODEL FOR PROMOTING FUNCTIONING AND WELL-BEING AMONG OLDER ADULTS WITH MILD COGNITIVE IMPAIRMENT VIA MEANINGFUL SOCIAL INTERACTIONS: PROJECT SPEAK!

NCT04717479

Document date: June 25, 2021

Study Title: A Scalable Model for Promoting Functioning and Well-Being among Older Adults with Mild Cognitive Impairment via Meaningful Social Interactions: Project SPEAK!

Principal Investigator: John Piette, Ph.D.

I. Background, Rationale, and Objectives

Specific Aims

More than 15 million Americans are expected to suffer from Mild Cognitive Impairment (MCI) in 2060, twice as many as the already-alarming number in 2017. People with MCI are at heightened risk of progressing to Alzheimer's Disease (AD), and many suffer from social isolation and limitations in functioning. As a consequence, large numbers of MCI sufferers experience depressive symptoms and a lower quality of life – both of which increase the risk of progression to AD. Volunteering and other meaningful social interactions may improve patients' mood and preserve cognitive functioning. Unfortunately, in most communities there are not enough meaningful and accessible volunteer opportunities tailored to the needs of MCI sufferers or those who report symptoms of Subjective Cognitive Decline (SCD). The goal of this study is to refine and test a strategy for engaging older adults with symptoms of SCD/MCI as volunteers to help English language learners (ELLs) who live in the US improve their speaking skills via structured conversations using videoconferencing. Our expectation is that contact with ELLs around this concrete goal (i.e., English practice) using simple, accessible technology will enhance a sense of purpose, connectedness, and psychological wellbeing among older adults with symptoms of SCD/MCI. **The program we will refine and pilot test is called SPEAK! - Seniors Promoting English Acquisition and Knowledge.**

SPEAK! has already been alpha-tested with small numbers of older adults without symptoms of SCD/MCI, and that experience has been overwhelmingly positive – both in terms of the number of older adults who have volunteered to participate in regular webcam conversations with ELLs as well as in their high levels of satisfaction after those interactions. SPEAK! also builds on an exciting small-scale implementation of a similar program in a Chicago residential facility. The study has enthusiastic support from community centers representing older adults, the University of Michigan Alzheimer's Disease Center, and organizations representing large numbers of ELLs. We expect that SPEAK! may be an effective and scalable tool for cognitive stimulation among people with symptoms of SCD/MCI and older adults more generally in part because of the large unmet need for English language practice among ELLs in the US. According to census data, the foreign-born population in the US increased from 14 million in 1980 to 40 million in 2010. In 2012, 85% of these residents reported speaking a language other than English in their home, and roughly 11.7 million reported that they speak English either "not well" or "not at all."

The proposed study is designed to tailor SPEAK! to the unique needs of people with symptoms of SCD/MCI and gather preliminary data on its feasibility and impact in that population. Despite our extremely encouraging experience to date recruiting older adults for SPEAK! (many of whom have contacted us with little or no prior outreach), an important goal of the R21 will be to determine whether we are able to recruit and retain older adults with symptoms of SCD/MCI as well as their ELL conversation partners at a rate sufficient to ensure accrual goals for the subsequent R01-funded randomized trial. We also will tailor current SPEAK! orientation and session-support materials to address the unique consent and informational needs of people with symptoms of SCD/MCI, and we will gather preliminary data on satisfaction with the SPEAK! experience and its impact on participants' mental health and functioning. The study will provide vital data for the submission of a competitive application for a larger randomized trial evaluating the intervention's impact on SCD/MCI patients' mental health (e.g., depression, loneliness, and sense of purpose) and cognitive functioning. Consistent with the NIA Stage Model for Behavioral Intervention Development, the current study will include elements of Stage 0 (intervention generation, refinement, modification, and pilot testing) and Stages 1-2 (efficacy testing with various levels of control). Specifically, the study will include a mixed-methods user-centered design

process (Aim 1, NIA Stage 0) followed by a randomized waitlist-controlled trial with an 8-week follow-up (Aims 2 and 3, NIA Stages 1-2). The study's specific aims are:

Aim 1: Conduct a user-centered design process to refine the SPEAK! training protocols for older adults with symptoms of SCD/MCI and ELLs, and the materials that will support productive, engaging English conversation practice.

Aim 2: Conduct a randomized, wait-list controlled trial of 8 weeks of SPEAK! participation, using a variety of recruitment sources, in order to evaluate our capacity to recruit, implement the intervention, and retain older adults with symptoms of SCD/MCI in sufficient numbers for a subsequent randomized-controlled trial evaluating the intervention's impact on participants' psychological well-being, mood, and cognitive functioning.

Aim 3: Using mixed methods, evaluate the communication process between older adults with symptoms of SCD/MCI and ELLs including factors that contribute to satisfaction of both parties, engagement in planned contacts, possible contributors to stress or dissatisfaction, and perceptions among older adults of being appreciated and effective. We also will estimate variances for key outcome variables and conduct exploratory analyses of intervention-control differences in participants' perceptions of their wellbeing, mood, and cognitive functioning.

Significance

Mild Cognitive Impairment (MCI) as a public health problem. Between 10% and 15% of Americans over age 65 (5 to 7.5 million people) have MCI. People with MCI are at heightened risk of progressing to Alzheimer's disease (AD), and economic estimates suggest that delaying progression by six months could save billions of dollars in healthcare costs while preserving the independence and quality-of-life for millions of people. Risk factors for MCI include increasingly prevalent cardiovascular diseases such as hypertension and diabetes; given those growing epidemics and the expected doubling of the over-65 population by 2060, as many as 15 million Americans are projected to have MCI that year. To date, no pharmacologic therapies have been identified that prevent conversion from healthy cognition to MCI or progression from MCI to AD. As a consequence, identifying scalable public health interventions is a national priority. Lack of social engagement and purpose, sometimes labeled as the "epidemic of loneliness", are increasingly common risk factors for mood disorders among older adults and likely exacerbate the risk of depressive symptoms among people with MCI. More generally, poor psychological wellbeing and social withdrawal have been causally implicated in cognitive decline and are commonly-recognized features of the disorder. Rates of loneliness have doubled since the 1980s, and as more older adults live alone, strategies are badly needed to increase meaningful social engagement in order to prevent mood problems and preserve cognitive functioning.

Theoretical foundations for the SPEAK! intervention. Volunteering has been shown in numerous studies to improve wellbeing and other health outcomes for older adults. Helping others is powerfully therapeutic, increasing the life expectancy of the helper whether the help they provide is instrument or emotional. Volunteering can protect against cognitive decline, through both neurological and psychological mechanisms. Volunteering reduces depressive symptoms, improves physical functioning, increases positive health behaviors, and reduces hospitalization rates. Addressing life purpose through volunteerism is especially important for older adults, because purpose is one of the dimensions of wellbeing that decreases the most with age (see Figure 1). People with a greater sense of purpose have better health behaviors; as well as lower risk of stroke, poor diabetes control, sleep disturbance, and early death. By addressing a lack of purpose, increasing exposure to engaging and challenging social interactions, and increasing a sense of "mattering", SPEAK! is designed to increase SCD/MCI patients' mental health, quality of life, and cognitive functioning. Because SPEAK! sessions are possible by webcam, the intervention has potentially much broader reach than in-person volunteering opportunities. A nationally-representative study demonstrates that videoconferencing is the only communication technology shown to prevent depression. Two pilot studies have shown that web-enabled conversational interactions have high levels of engagement, and may improve depressive symptoms and cognitive functioning among older adults with MCI.

SPEAK! incorporates fundamental principles of Cognitive Stimulation Therapy (CST) and Cognitive Training that have been demonstrated to improve outcomes for people across the spectrum of cognitive decline. CST can improve not only functioning on cognitive tasks, but also participants' sense of well-being, quality of life, and ability to interact socially.

The mechanisms of CST likely include the preservation (or possibly improvements) in neuroplasticity and hippocampal neurogenesis. Moreover, while participants in this study will not be speaking a language other than English, they will be challenged to hear vocabulary, pronunciation, and grammar in unstandardized ways and to come up with creative solutions such as alternative phraseologies when misunderstandings occur. Such linguistic tasks may be stimulating in ways that preserve cognitive functioning, with some research suggesting that linguistic training may prevent cognitive decline. Studies of bilingual individuals suggest that they perform better than their monolingual counterparts on tasks requiring executive control. Other studies suggest that bilingualism is causally implicated in promoting cognitive reserve and may significantly delay the onset of dementia.

Innovation

Despite the health benefits of volunteering and social engagement, most older adults with symptoms of SCD/MCI lack the opportunity to be engaged. Many people face transportation problems, physical disabilities, or other barriers to participating in traditional volunteer activities that require fixed hours and group activities in inconvenient locations. SPEAK! represents a scalable, flexible, and accessible program allowing older adults with symptoms of SCD/MCI to increase their social interaction in a stimulating way either from their home or an outside organization. Pairs will use a novel curriculum structured around principles of CST to promote "mattering" among older adults and designed to facilitate valuable English conversation practice for the learners, resulting in a meaningful volunteer experience. While we have not tested SPEAK! with older adults who have symptoms of SCD/MCI, initial outreach to older adults without symptoms of SCD/MCI who are lonely or experiencing depressive symptoms has been overwhelming in terms of the number who have come forward expressing interest, as well as their positive feedback from initial sessions with ELLs. The proposed study will provide vital data for the submission of a competitive application to NIH or NINR for a clinical trial testing SPEAK!'s impact on the cognitive functioning, mental health, health service use, and other important outcomes for older adults with symptoms of SCD/MCI.

We expect that SPEAK! will be effective and scalable in part because of the large unmet need for English language practice among ELLs in the US. According to census data, the foreign-born population in the US increased from 14 million in 1980 to 40 million in 2010. In 2012, 85% of these residents reported speaking a language other than English in their home, and roughly 11.7 million spoke English either "not well" or "not at all." ELLs who cannot communicate effectively have extremely limited opportunities in the American economy and typically work in low-paying jobs that require little or no speaking, such as housekeeping, landscaping, or dishwashing. English teaching programs universally recognize that classroom-based services provide little chance to converse. The proposed intervention will provide a unique, 1-on-1 opportunity for ELLs to converse with a native English-speaker (in this case a person who has symptoms of SCD/MCI), improving their fluency and expanding their employment opportunities. Feedback from dozens of SPEAK! ELLs to date suggests that the opportunity to be of assistance to an older adult who may be struggling is highly motivating to ELLs who want to help.

Our team is uniquely qualified to conduct this important and innovative study. Several team members (including the PI) have learned a second language as an adult and therefore understand the challenges faced by ELLs and those trying to help them. We have already forged strong connections that will make the study successful, including with: the Michigan Alzheimer's Disease Center (a source of both expertise and potential participants), the University of Michigan English Language Institute (which serves more than 800 English-learners on campus), community-based senior centers, and Hilton Hotels International which employs thousands of ELLs, 23 of whom have participated in initial SPEAK! sessions with older adults.

Approach

Prior experience. After developing this idea, the PI learned about a similar program in a residential facility in Chicago that began in 2014 through a personal connection between a resident and a for-profit English language institute in San Paulo, Brazil (reviewers can search in YouTube for "CNA – Speaking Exchange"). In that program, 2-4 seniors connect online with English learners 1-2 times a week for 12 minutes. The program has no training, screening, or conversation materials. Residents rarely re-connect with the same learner. Feedback suggests that a more structured program, such as we propose, could be valuable for a more diverse group of older adults with symptoms of SCD/MCI. No problems

have been documented since that program has been operational. We will expand on the program's initial anecdotal-success by focusing on older adults with symptoms of SCD/MCI and including a diverse group of ELLs in the US who are highly motivated to practice their speaking skills. Based on feedback from initial SPEAK! participants, we expect that sessions in the proposed study will be roughly an hour in length, allowing for more in-depth interaction. We will develop materials specifically to promote cognitive stimulation and feelings of "mattering," self-efficacy, and accomplishment among older adults with symptoms of SCD/MCI.

In 2018, Dr. Piette held a focus group with older veterans to get their feedback about the acceptability of SPEAK!. The group included both men and women, African Americans, and several veterans with mental health challenges (e.g., generalized anxiety disorder, post-traumatic stress disorder, and depression). The group universally reported that SPEAK! would be beneficial for seniors struggling with a loss of purpose. Veterans with mental disorders felt that the structured interaction via webcam would be an ideal way to increase social engagement without triggering anxiety. Beginning in January 2019, we began meetings with ELLs and older adults (i.e., without identified symptoms of SCD/MCI) to gauge their interest in participating and find out how to make the program a success. Response has been overwhelmingly positive. A notice describing SPEAK! was placed in the University of Michigan's research portal in December 2018, and within the first week 58 older adults contacted our team asking to learn more – more than two thirds of whom reported symptoms of depression or loneliness. In January 2019, a Michigan Community Senior Center found out about SPEAK! from word-of-mouth and reached out to our team. Dr. Piette met with 16 older community members from that center in February 2019 and enthusiasm was strong. We also have engaged both older adult volunteers and Chinese graduate students at UM, all of whom were excited about the chance to participate. Online conversations between older adults (without symptoms of SCD/MCI) and ELLs began in February 2019. To date 25 older adults and ELLs have done more than 50 hour-long sessions online, with orientation and technical support by our staff. Feedback after these initial sessions from both older adults and ELLs has been universally positive, with many participants asking to be paired with multiple partners or to speak more often than once per week. No older adults have had technical problems that we were unable to resolve, and those with hearing problems report that they have no difficulty hearing and understanding their partner.

II. Research Design and Methods

Overview of the study design. Prior to the waitlist-controlled trial, we will conduct a qualitative, user-centered design process with up to 10 pairs of older adults with symptoms of SCD/MCI and ELLs to iteratively refine the training protocols and the materials that will support productive, engaging conversations. We then will conduct a mixed-methods pilot randomized trial with a waitlist control group in which 44 pairs of older adults with symptoms of SCD/MCI and ELLs will be recruited from a variety of sources. Pairs will participate in webcam conversations supported by research staff for 8 weeks, using materials designed to promote positive and effective conversation sessions. Data will be collected from older adults with symptoms of SCD/MCI and ELLs via observations of videoconference sessions, qualitative semi-structured interviews, and quantitative surveys at baseline and the 8-week follow-up. The primary goal of the randomized pilot study will be to evaluate our capacity to recruit pairs, implement the intervention, and retain participants with symptoms of SCD/MCI in sufficient numbers for a subsequent trial evaluating the intervention's impact on participants' psychological well-being, mood, and cognitive functioning. We also will use mixed methods to evaluate the communication process between older adults with symptoms of SCD/MCI and ELLs including factors that contribute to satisfaction of both parties, engagement in sessions, contributors to dissatisfaction or dropout, and perceptions among older adults with symptoms of SCD/MCI of being appreciated and effective. Finally, using data from the waitlist-controlled trial, we will estimate variances for key outcome variables for planning the subsequent clinical trial, and we will conduct exploratory analyses of intervention-control differences in participants' perceptions of their wellbeing, mood, and cognitive functioning.

Sequence of the investigation. Months 1-6 will be devoted to developing protocols and materials for screening/surveys, recruitment, training, and supervision of sessions. In Months 7-11 we will conduct a user-centered design process (Aim 1) and refine protocols and materials in preparation for the trial. Months 12-17 will be devoted to enrolling 44 pairs of older adults with symptoms of SCD/MCI and their ELL partners for the pilot trial. Older adults' cognitive functioning,

sense of well-being, and other key variables will be measured using validated scales at baseline and the 8-week follow-up. Data collection will be completed in month 20, waitlist control participants will complete the intervention in month 23, and months 23-24 will be devoted to statistical analysis, presentations, and the submission of an application for a larger, definitive randomized trial focusing on measures of cognitive functioning, well-being, depressive symptoms, and physical health outcomes.

Eligibility and screening of older adults with symptoms of SCD/MCI. To be eligible, older adults with symptoms of SCD/MCI must: be 55+ years of age, fluent speakers of English of any race/ethnicity, and be able to participate in a videoconference via a smartphone, tablet, laptop, or desktop computer in their home or referring organization using a widely-accessible, no cost videoconferencing platform. Participants will be ineligible if they have a history of stroke or traumatic brain injury, bipolar disorder, schizophrenia, or current alcohol or drug abuse/dependence, that would affect their ability to participate in the study. Our primary source of recruits will be the Michigan Alzheimer's Disease Core Center (MADCC) registries which include detailed information about individuals who have indicated a willingness to be contacted regarding studies and have undergone detailed neuropsychologic evaluations. Dr. Hampstead (Co-I) is the Clinical Core Leader for the MADCC and Dr. Roberts (Co-I) is the MADCC Director for Outreach and Recruitment. More than 100 MADCC registry participants have been identified with MCI and this number is expected to increase. Additional participants will be identified via outreach and referrals from specialty clinics including the UM Cognitive Disorders Clinic, two area community senior centers, as well as Michigan Chapters of the national Alzheimer's Association (see letters of support).

Potential recruits will be screened by a trained research assistant and will be eligible for further evaluation if they have a MoCA score of 12 or higher. Potential participants with symptoms of SCD/MCI will have their decisional capacity assessed prior to completing the recruitment and informed consent process using a decision-making capacity tool developed based on the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). See the section on Protection of Human Subjects for more details. We will perform the following neuropsychological tests immediately after acquiring informed consent in order to (a) ensure there has been no clinical conversion or reversion in the time between diagnosis and study enrollment and (b) to characterize participants at the time of enrollment. Measures include: (1) The RBANS given its extensive supporting literature across dementia subtypes and in clinical trials and findings that performance is inversely related to amyloid load and positively related to medial temporal neurodegeneration. (2) The Cognitive Change Index (CCI), a commonly used measure of self-reported perception of cognitive decline. This battery of cognitive assessments takes roughly one hour to complete and can be conducted by the research assistant with training and supervision by Dr. Hampstead (Co-I, neuropsychologist). Performances on these measures will be interpreted by Dr. Hampstead. Participants who report symptoms of SCD or MCI using validated measures identified by the SCD Initiative Working Group will be eligible. The diagnosis of MCI will follow the Albert et al. criteria, i.e., (1) subjective report of cognitive decline, (2) objective evidence of memory decline relative to the participant's premorbid functioning, with index scores typically -1.5 SD below the mean, and (3) intact everyday functioning as measured by a Functional Assessment Questionnaire score of < 9. Patients found on review by Dr. Hampstead to have normal cognition will be excluded; patients found to have more significant cognitive dysfunction beyond the range of MCI also will be excluded and will be encouraged to contact their primary care physician and/or referred to the appropriate clinics within Michigan Medicine or the participant's preferred healthcare system.

Alternative plans for recruiting older adults with symptoms of SCD/MCI. A primary goal of this R21 is to demonstrate our ability to recruit and maintain pairs of older adults with symptoms of SCD/MCI and ELLs, since recruitment is the single greatest challenge for studies such as this that includes "dyadic" participation and people with symptoms of SCD/MCI. In the event that accrual is slower than anticipated, we have identified several alternative sources of recruits. Drs. Piette and Hampstead are both investigators within the VA healthcare system and well-versed in identifying VA patients based on electronic medical record data and outreach to clinics. VA's national network of Geriatric Research Education and Clinical Centers (GRECCs) includes a center in Ann Arbor and would be a fruitful secondary source of participants with symptoms of SCD or diagnoses of MCI or who are identified as high risk by their providers. Additional participants could be identified via referrals from the University of Michigan (UM) Geriatrics Center and through the UM Health Research database, which includes more than 34,000 individuals expressing an interest in participating in

research. Other sources of older adults who could be screened for symptoms of SCD/MCI include Michigan's network of Area Agencies on Aging, Michigan chapters of the national Alzheimer's Disease Association (see letters of support), and community outreach to residential facilities and community-dwelling older adults.

Eligibility and enrollment of English-language learners. To be eligible, ELLs must be 18+ years of age and be able to participate in a videoconference via a smartphone, tablet, laptop, or desktop computer in their home or referring organization using a widely-accessible, no cost videoconferencing platform. ELLs will have the study explained to them before they verbally consent to participate. After consultation with the UM Human Subjects Committee, we expect that written informed consent will not be required. ELLs will be expected to have a basic ability to understand and speak English. We will use a common evaluation rubric in which speakers are evaluated during a 10-minute conversation and scored on dimensions of fluency, pronunciation, grammar, vocabulary, and ability to speak on specific topics. Two raters will be trained in using the rubric. During that training, audio samples from ELLs at various levels of fluency will be evaluated by each rater. Ratings of each verbal sample across raters will be compared using standard metrics. Our goal will be to achieve an inter-rater reliability of 0.80. Reliability below that level will be corrected through additional training and collective discussions about what verbal characteristics are driving variances in scores.

We have access to multiple recruitment sources for enrolling ELLs who are diverse with respect to their primary language and level of education. Half of ELLs will be enrolled via the University of Michigan English Language Institute, which serves roughly 600 ELLs on campus and has connections to roughly 500 additional ELLs working as research staff or postdocs in the medical school (see letter of support). The Institute will serve both as a source of referrals (mostly from Asian countries) as well as a resource for expertise in making the conversations as useful and engaging as possible for the learners. To identify additional Spanish-speaking ELLs, we will place advertisements in newspapers, radio programs, churches, and community-organizations in Michigan serving the Spanish-speaking community. Additional Spanish-speakers will be identified and recruited through the University of Arizona Center for Health Disparities Research, and the employees of US-based Hilton Hotels which have been a strong supporter of this program during the initial development and testing (see letters of support).

Orientation. Both older adults with symptoms of SCD/MCI and ELLs will participate separately in a one-hour orientation presented by a study representative in-person or via videoconference. Additional 1-1 training and trouble-shooting will be provided as needed. Program orientation for older adults with symptoms of SCD/MCI will emphasize strategies to ensure that they can hear and understand the ELL effectively, are comfortable communicating using the webcam and software, and strategies for handling situations in which they are having difficulties understanding each other. For ELLs, we will emphasize strategies they can use to be more effectively understood, and how to manage instances where the older adult might get nervous or frustrated. We will review strategies for giving positive feedback, provide concrete strategies that learners can use to communicate their appreciation so that the older adult feels effective and engaged, and suggest alternatives ways of phrasing in the event of a miscommunication.

Online sessions. We will use a standard videoconferencing platform (e.g., "BlueJeans") or the SPEAK! platform for the study. While specially-customized videoconferencing software may be useful, we believe that at this stage of the research it would be wiser to invest resources in first understanding the types of customization that would be beneficial. Both older adults with symptoms of SCD/MCI and ELLs will be sent reminders prior to each session via a telephone call, email, or text message according to their preference. Videoconferences will be facilitated by study staff who will introduce each session, assist with technical issues, and ensure that both parties have their materials and are comfortable. Older adults and learners will be provided with a suggested session outline. More detailed information will be provided in a variety of formats including a comprehensive manual, flashcards, and lists of common phrases to ensure that conversations do not stall. Our expectation based on initial experience with older adults who do not have symptoms of SCD/MCI is that pairs will meet online for a one-hour session once a week for a total of 8 weeks. Meta-analyses of factors determining the impact of volunteering or psychological interventions indicate that effects are not sensitive to the number or duration of sessions. However, we will specifically inquire about the length and frequency of sessions during follow-up surveys and qualitative interviews with participants for Aim 1. Based on that feedback and

more detailed input from experts in gerontologic mental health, the frequency and duration of sessions may be modified.

While we fully expect that conversations will be a positive and productive experience for the older adult with symptoms of SCD/MCI and ELL, training materials will include a discussion of topics that both parties should avoid. These will include financial problems, medical problems, or potentially contentious issues such as political or religious differences. We will make special emphasis regarding types of comments that would be considered inappropriate, even as "jokes." We will inquire about questions and comments that would be considered too sensitive during the Aim 1 development interviews. Pairs will be instructed regarding the types of information that they should never share, such as financial data, and we will emphasize the importance of being available at scheduled times and communicating in advance if availability changes.

III. Statistical Design and Data Analysis

Aim 1 qualitative data collection and analysis. **For Aim 1**, analyses will be qualitative and conducted through a process of testing recruitment and intervention protocols with iterative revision. We will conduct a user-centered iterative design process with 10 pairs of older adults with symptoms of SCD/MCI and ELLs. In-depth interviews will be conducted separately after each pair completes one session and again after pairs complete six sessions. Topics in interviews with older adults with symptoms of SCD/MCI will include the extent to which they found the sessions enjoyable, felt appreciated, were invested in their partner's learning goals, and other factors that may contribute to the program's impact on their engagement and sense of purpose. Interviews will be recorded and detailed notes will be taken. Study staff will also listen-in to sessions in order to assess factors such as the extent to which participants roughly followed the recommended agenda, used materials such as suggested role-play scenarios, and the proportion of time in which each party was listening versus speaking. Key utterances such as statements by the ELL giving appreciation and framing requests in a positive manner will be noted. We will compile the data from interviews and session observations and identify overarching themes, creating coding templates, connecting themes to existing literature, and seeking out additional data to confirm or refute initial insights. Using this process, we will iteratively refine the training materials, resources for use during sessions, and quantitative measures of program impacts. We also will identify implementation factors that would support longer-term sustainability. While our primary focus will be on the older adult with symptoms of SCD/MCI, we will pay close attention to the factors associated with ELLs' satisfaction and success in improving their verbal English proficiency, since one path to sustaining this program will be via support from organizations employing workers who need to interact with English-speaking clients (e.g., major hotel chains, tourism locations, and housekeeping services). Based on feedback, recruitment protocols, orientation materials, and session materials will be iteratively revised.

Aim 2-3 waitlist controlled trial. While our primary scientific goal is not to evaluate intervention-control differences in outcomes, we will include a waitlist control group in order to get an unbiased estimate of recruitment rates for that subsequent randomized clinical trial. We will generate a randomization sequence and randomization envelopes to assign 44 older adults to the intervention or waitlist control group (1:1 ratio). Randomization will be conducted after older adults with symptoms of SCD/MCI complete their baseline survey. Older adults with symptoms of SCD/MCI assigned to the intervention will be matched with an ELL for 8 weeks of hourly SPEAK! sessions with orientation and materials refined as part of Aim 1. Older adults with symptoms of SCD/MCI assigned to the waitlist control will be matched with an ELL after completing their 8-week follow-up survey, at which time the pair will complete the 8-week intervention.

Quantitative measures for Aims 2-3. Older adult with symptoms of SCD/MCI surveys. Sociodemographic characteristics of older adults with symptoms of SCD/MCI will be measured using standard items to evaluate the generalizability of the study findings and possible moderators of intervention effects. General health status will be measured at baseline using standardized items to identify common chronic diseases. At baseline and follow-up, older adults with symptoms of SCD/MCI will complete the Psychological Well-Being Scale (PWB), a validated measure shown to be sensitive to intervention effects and with subscales measuring respondents' sense of autonomy, environmental mastery, personal growth, positive relations with others, life purpose, and self-acceptance. The PWB will be supplemented with measures

of quality-of-life specifically designed for people with symptoms of SCD/MCI. Loneliness will be measured using the 20-item UCLA Revised Loneliness Scale which has an alpha reliability of .94. "Mattering" will be measured using the multi-dimensional scale developed by France and Finney. Cognitive functioning will be assessed as described in the Enrollment section, above. Depressive symptoms will be measured at baseline and follow-up using the short-form or full 30-item Geriatric Depression Scale. Inpatient and outpatient health service use over the prior three months will be measured using standard questions. Program satisfaction among older adults with symptoms of SCD/MCI will be measured using items based on dimensions highlighted as important during qualitative interviews conducted as part of Aim 1, e.g., the extent to which older adults felt appreciated, were able to use the videoconferencing software without difficulty, felt supported by study staff, and felt that the program enhanced their sense of social connection and purpose.

English language learner surveys. ELLs will be asked to complete a baseline survey about their sociodemographic characteristics, experience and barriers to practicing English, and reasons for wanting to improve their English fluency. At follow-up, ELLs will complete an evaluation of their experience based on widely used course evaluations and including topics such as: the extent to which they felt they improved in various areas of English learning (vocabulary, grammar, fluency, confidence), possible barriers to communicating with their partner, whether they would recommend the experience to someone else, and the extent to which the experience helped the learner in areas such as: "using English in their daily life," "communicating with friends, co-workers, and the community," and "working well with different types of people."

Primary outcome and sample size for the pilot trial. The pilot trial (Aims 2-3) has been designed to be consistent with the goals of pilot studies articulated by Thabane et al., i.e.: to assess key processes (rates of recruitment, retention, and engagement); determine resources needed for a definitive trial (e.g., staff time required for recruitment and intervention delivery), and possible issues related to patient safety, dose-response, and variation of treatment effects. We expect that the outcomes for a larger, statistically-powered trial will be the Psychological Well-Being Scale (PWB) with secondary outcomes being measures of cognitive functioning and mood. The current trial is not intended to estimate those effect sizes, but rather to optimize the intervention and ensure that we have the capacity to reach the subsequent trial's recruitment goals given expected timeline and resources. For that larger trial, we estimate we would need resources to recruit, retain, and implement the intervention with approximately 262 pairs recruited over 36 months. A target sample of this size would be sufficient to detect a small/medium impact on Psychological Wellbeing scores (PWB; Cohen's d=0.45) with 0.90 power, a 0.05 probability level, and assuming a 20% dropout rate. To assure that we have the capacity to enroll at that same rate, we will recruit 44 pairs in the waitlist trial for Aims 2-3 over 6 months. According to the Poisson distribution, if our observed recruitment over 6 months falls below 35 pairs, that would indicate that we would be unlikely to be able to recruit our target sample of 262 in the subsequent trial over 36 months (P<.10). We will conduct monthly reviews of our observed versus expected recruitment rate, and should recruitment fall more than 10% below expectation in the first two months, we will seek out additional sources of older adults with symptoms of SCD/MCI as described above.

Additional analysis for Aims 2-3. Older adults with symptoms of SCD/MCI will be asked to consent to a brief screening survey, and initial analyses will focus on the sociodemographic, health, and mental health characteristics of potential participants who do versus do not enroll, and reasons for non-participation. Recruitment rates will be tracked overall as well as by gender, age, race/ethnicity, and educational attainment. Among enrollees, we will calculate descriptive statistics of the proportion of older adults with symptoms of SCD/MCI who choose to discontinue participation, as well as baseline predictors of dropout and session completion, with a particular emphasis on baseline measures of cognitive functioning, and psychological indicators such as PWB and depressive symptoms. While these will be quantitative analyses, results will not include statistical inference (i.e., "p-values"). **For Aim 3.** We will examine correlations between measures of (a) intervention satisfaction and the number of missed sessions, and (b) baseline measures of characteristics of older adults with symptoms of SCD/MCI including measures of cognitive functioning and PWB. Examination of intervention/control differences in PWB will be purely exploratory and used to generate hypotheses and strategies for modifying the intervention to make it more impactful. Change scores for continuous outcomes (e.g., PWB) will be computed, and differences across randomization groups will be compared using the Wilcoxon rank sum test.

In a purely exploratory mode, we will examine differences in outcomes between intervention and control groups, controlling for any baseline differences in group characteristics. Older adults who drop out of the program or who complete less than the expected number of sessions but complete outcome surveys will be included in outcome analyses. We also will conduct 'completer' analyses including only intervention-group older adults who complete 8 out of the 12 planned sessions (or the equivalent out of 8 planned sessions). Whenever possible, we will create graphical displays comparing pre-post changes in outcomes across groups to make the findings as interpretable as possible for various audiences.

IV. Potential Risks, Minimizing Risks, and Potential Benefits

Protection of Human Subjects

Human Subjects Involvement and Characteristics

1. Risk to Subjects

Overview. Prior to beginning recruitment, the study protocol will be approved by the University of Michigan Human Subjects Review Committee. The trial protocol will be registered in a national clinical trials database (clinicaltrials.gov). Older adults with symptoms of SCD/MCI will be considered research subjects for a minimal risk educational intervention. Older adults with symptoms of SCD/MCI will have their decisional capacity assessed during the recruitment process using an established protocol and will only be recruited if they are able to understand and voluntarily provide informed consent for a minimal risk study. ELLs will be 18+ years of age. Both parties will have the study explained to them in detail including topics that they should and should not discuss during videoconference sessions. Both parties will be told that they can disconnect from any conversation that makes them uncomfortable and can report concerns to the study coordinator.

Risks to older adults with symptoms of SCD/MCI. There are no physical risks to older adults with symptoms of SCD/MCI. Potential participants will be screened and excluded if they have life-threatening health problems that would affect their ability to participate in the study, as indicated by (for example) active treatment for cancer other than skin cancer, advanced heart failure or COPD, serious mental illnesses such as schizophrenia, or advanced dementia. This study does not involve the provision of medical care, pharmacotherapy, or invasive procedures. The study does not require the collection of physiologic samples. Older adults with symptoms of SCD/MCI will be asked to provide their name, mailing address, a telephone number, and an email address.

It is possible that some older adults may find that participating in qualitative interviews or surveys is stressful. Participants will be told they can discontinue an interview at any time or refuse to answer any questions they find uncomfortable. Based on our experience with older adults who do not have symptoms of SCD/MCI, we do not expect that videoconferences with ELLs will cause significant risk or discomfort for the older adult with symptoms of SCD/MCI. However, this will be monitored during select sessions and addressed during baseline orientation for both the older adult with symptoms of SCD/MCI and the ELL.

There is a small risk of a breach of confidentiality in which the ELL would share information about the older adult with a third party, and vice versa. We believe this risk is extremely small. Older adults and ELLs will be instructed regarding information they should not discuss, and will be carefully instructed about the importance of maintaining the topics of conversation confidential, even if they seem benign.

Risks to learners. These risks are negligible. Language learners will be reminded that they can easily disconnect from any session if they find it bothersome, and that they can contact the study team if they want to report inappropriate behavior by the older adult. Survey questions will focus only on basic sociodemographic information (e.g., age, educational attainment, reason for practicing English) and learners' satisfaction with the intervention.

2. Adequacy of Protection from Risks

Recruitment of older adults with symptoms of SCD/MCI and informed consent. Potential recruits will be screened by a trained research assistant and will be eligible for further evaluation if they have a MoCA score of 12 or higher. Potential participants with symptoms of SCD/MCI will have their decisional capacity assessed prior to completing the recruitment and informed consent process using a decision-making capacity tool developed based on the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). The decision-making capacity tool based on the UBACC takes roughly 5 minutes to complete verbally and can be administered by a bachelors' trained research assistant. The scale includes items assessing key factors of the consent process such as participants' understanding of the study, that participation is voluntary, possible risks and benefits, and participants' ability to withdraw without affecting their care. These items and the range of responses indicating decisional capacity are designed to be tailored to the specific protocol. That process of tailoring the decision-making capacity tool based on the UBACC will occur prior to initiating recruitment with active input from Co-I's who have extensive expertise in neuropsychology and MCI. A secondary goal of the R21 will be to test the decision-making capacity tool based on the UBACC prior to the subsequent R01-funded trial in order to ensure that participants who indicate decisional-capacity at baseline are not found later to have problems due to a miss-understanding of the protocol and their role. The UBACC has been validated against longer, gold-standard instruments such as the MacCarther Competence Assessment Tool for Clinical Research (MacCAT-CR) in diverse samples including patients with schizophrenia, dementia, and MCI.

Among patients with cognitive deficits, the UBACC was found to have acceptable reliability and construct validity. In that study, only 18 out of 130 participants were found to require more detailed assessment of capacity to consent to a "moderate risk" research protocol. The proportion requiring more detailed evaluation is likely to be less for this proposed low-risk protocol. In addition to evaluating decisional capacity, the decision-making capacity tool based on the UBACC assessment will be used to identify aspects of the protocol and expectations for participation that the potential participant found unclear. This type of discussion with "teach-back" opportunities (e.g., "please tell me what your understanding is about what happens if you want to drop out of the study?") has been found to significantly improve the informed consent process for people with cognitive deficits. Older adults with symptoms of SCD/MCI will be given a written copy of the consent document. Participants will have the opportunity to ask questions, and we will emphasize that they can choose not to participate or drop out at any time without consequences. Eligible interested older adults with symptoms of SCD/MCI will be asked to provide informed consent to participate and their verbal consent will be documented in their study record. They will receive $25 for completing the baseline survey and $25 for completing the follow-up survey. This amount is not expected to be coercive.

We will perform the following neuropsychological tests immediately after acquiring informed consent in order to (a) ensure there has been no clinical conversion or reversion in the time between diagnosis and study enrollment and (b) to characterize participants at the time of enrollment. Measures include: (1) The RBANS given its extensive supporting literature across dementia subtypes and in clinical trials and findings that performance is inversely related to amyloid load and positively related to medial temporal neurodegeneration. (2) The Cognitive Change Index (CCI), a commonly used measure of self-reported perception of cognitive decline. This battery of cognitive assessments takes roughly one hour to complete and can be conducted by the research assistant with training and supervision by Dr. Hampstead (Co-I, neuropsychologist). Participants found on review by Dr. Hampstead to have normal cognition will be excluded; participants found to have more significant cognitive dysfunction beyond the range of MCI also will be excluded and will be encouraged to contact their primary care physician and/or referred to the appropriate clinics within Michigan Medicine or the participant's preferred healthcare system. At follow-up we will repeat these measures.

Recruitment of English-language learners. The only identifying information ELLs will provide will be basic demographics (e.g., age, gender, educational attainment, work history), reasons for wanting to practice English, name, an email address, and a telephone number in order to receive reminders about upcoming sessions. ELLs will complete a satisfaction survey about their experience with the sessions but will not be asked about their physical or mental health, or any other behaviors that could be considered protected health information. The study will be explained to ELLs, and they will be emailed a written copy of the consent document. We will emphasize that they can choose not to participate or dropout at any time without consequences. ELLs' verbal consent to participate will be documented in their study

record and will be implied by their participation in videoconferencing sessions and completion of surveys. ELLs will not be compensated for survey completion.

Surveys and videoconferences. Older adults with symptoms of SCD/MCI will be informed at the time of enrollment and immediately prior to each interview/survey that they can drop out of the study at any time and that they can refuse to answer any questions they do not want to answer. There is a small risk that the older adult with symptoms of SCD/MCI will receive comments or questions from the ELL that they find intrusive or bothersome. ELLs will be carefully screened and provided with detailed information regarding issues such as how to speak in a way that maximizes their likelihood of being understood, how to positively provide feedback and suggestions, topics to avoid because they may increase the older adult's stress, and how to express appreciation for the older adult's assistance. All older adults with symptoms of SCD/MCI will be provided with a study telephone number they can call to discuss any problems or concerns with staff for problem solving and if needed discontinue participation. They will be reminded during their orientation and during interviews/surveys that they can easily disconnect from any session that they find bothersome and that they can contact the study team to report any stressful interactions. Older adults with symptoms of SCD/MCI will be instructed not to share identifying information including their home address, telephone number, financial data, or other information that could be used to identify them. Any breach of confidentiality or other concern expressed to study staff will be immediately reported to the study Principal Investigator, with follow-up as needed to address the issue.

3. Potential Benefits of Research to Subjects and Others

Older adults with symptoms of SCD/MCI will have the opportunity to use videoconferencing software that may be new to them – a skill they can use for communicating with family and other social network members at a distance. Our hypothesis is that sessions with ELLs will increase older adults' sense of social engagement and purpose (which may improve their mood); and that the conversations may improve aspects of their cognitive functioning. ELLs will have the opportunity to build skills and confidence related to English fluency, and this may be useful as they seek jobs and training opportunities. ELLs who complete 6 out of 8 sessions will receive a certificate acknowledging their participation in the program. Such certificates are highly valued among language learners and can be useful to support job applications for positions that require communication with English-speakers (e.g., work in hotels or restaurants).

4. Importance of Knowledge to be Gained

This research study has an excellent risk/benefit ratio. While risks to participants are minimal, the potential benefit is great. If the results of the proposed trial are positive, the study will identify a scalable and cost-effective strategy for increasing social engagement among older adults with symptoms of SCD/MCI and consequently improving their mental health and lowering their risk for cognitive decline.

Data and Safety Monitoring

The research team is very experienced in maintaining the security of research data. Participants will be assigned a unique study identification number that will serve as their primary identifier for all analytic files. We will create a secure electronic tracking file that maps the participant's identifying information to the study ID number. A hard copy of the cross-walk file will be maintained in a locked file cabinet separately from other study-related documents, and an electronic version of the cross-walk will be maintained in a secure directory accessible only to the PI and authorized staff members. Identifiers of potential recruits and study participants will be maintained throughout the data collection phase to allow for follow-up contacts and to ensure that study refusers/drop-outs are not inadvertently re-contacted. Following the completion of data collection and once datasets have been cleaned and built, the linkage code will be securely overwritten using a standard protocol for removal/destruction of sensitive material.

All study staff will complete the web-based University of Michigan's Responsible Conduct of Research Training Program, known as PEERRS (Program for Education and Evaluation in Responsible Research and Scholarship). Proof of their certification and completion of the training program will be kept on file. Staff will sign a pledge of confidentiality, and we will ensure that all staff understand that a breach of confidentiality is grounds for dismissal. Electronic survey data and analytic files will be maintained on servers that are behind secure firewalls and protected in accordance with University

of Michigan data security requirements. Data access will only be allowed for authorized investigators who have up-to-date HIPPA and Human Subjects research training and are on our IRB approval. Study personnel who leave the research team will have their access to study files revoked.

Qualitative interviews will be conducted by well-trained research assistants via telephone, videoconferencing or in-person. Quantitative surveys will be conducted via telephone, videoconference, or in person by well-trained research assistants who will enter responses in real-time using the survey software Qualtrics or RedCap. These types of software promote high quality data collection, and each fully customizable survey is designed so that only valid responses are entered. Survey data will be checked electronically for out-of-range values and logical consistency across variables. For open-ended questions, we will produce coding manuals with detailed instructions for issues such as how to adjudicate coding decisions when survey response options are unclear. A coding-decisions log will be maintained to ensure that coding is consistent across experimental conditions and over time. Paper surveys will be available if needed.

Staff training will include information regarding evaluating warning signs of significant distress that could occur as a result of the screening or research-related surveys and means of addressing such issues and minimizing distress. Such strategies will include maintaining an empathic response, acknowledging the distress through reflection, avoiding blame, processing in a non-confrontational manner, and eliciting or encouraging use of relaxation and cognitive calming strategies.

Regular study team meetings will be used to ensure that all data quality and IRB policies and procedures are being followed. This will include ensuring that: (1) all participants understand, agree to, and complete the informed consent process before participating; (2) strict adherence is maintained to communication regarding the participants' right to withdraw or refuse to answer questions as well as the limits on confidentiality in the event that the participant or someone else is at acute risk; (3) staff maintain confidentiality both by protecting hard-copy and electronic data collection forms and also by avoiding all unauthorized conversations about individual participants; (4) any identifying information is kept separately from study related information about participants' socio-demographics, clinical characteristics, disease self-care, service use, and outcomes; (5) all identifying information is kept in locked file cabinets and sensitive computer files are maintained on a secured server; (6) coding for ambiguous responses is handled in a way that is consistent and clear across data collectors and over time; and (7) participants are informed in writing how to contact the study PI, the study coordinator, and the relevant IRB office with any questions or concerns.

Quality control and reliability of the screening, baseline, and follow-up survey data will be monitored by Dr. Piette throughout the trial via regular meetings and observation of the research staff conducting the assessments. The study coordinator may additionally contact participants following completion of study assessments to ensure that study staff members have completed all study tasks and followed procedures. Any deviation from the protocol that may have an effect on the safety or rights of the participants or the integrity of the study will be reported promptly to the appropriate agencies and boards and will result in staff re-training. Staff will review logs weekly to verify all participants are accounted for as screened, refused, missed, etc. Discrepancies in tracking data will be compared and will be corrected in consultation with Dr. Piette. We will regularly review frequency data from surveys and examine those data for unexpected results or patterns of missingness. All data will be backed-up on UM's secure network, and folders/files will only be accessible to the PI and authorized staff members. The study coordinator will ensure that all participants are accounted for in tracking databases and will update the flow chart to ensure accurate numbers recorded as screened, baseline survey completed, refused, etc. We will review interview and survey data monthly for unexpected result patterns.

Data Safety and Monitoring Plan (DSMP). A DSMP has been developed for this study.

Dissemination Plan

Prior to beginning recruitment, the study protocol will be approved by the University of Michigan Human Subjects Review Committee. The trial protocol will be registered in a national clinical trials database (clinicaltrials.gov). Older adults will be considered research subjects for a minimal risk educational intervention. At the time of enrollment, the

study will be explained to them in detail, including information about posting study findings to clinicaltrials.gov. The University of Michigan has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

The dissemination goals and strategies related to study results will be addressed early in this project, first to understand the needs of audiences who will use the evidence to make decisions related to adoption, endorsement, and financial support; and also, to address research questions that are relevant to multiple stakeholders and audiences. Dissemination efforts will include identification of partners who are trusted and able to reach specific audiences and provide information about those audiences that will help tailor information in ways that will be useful. As results are analyzed, there will be a process in place for jointly interpreting the results with relevant constituents. Included in this process will be the tailoring of information and strategies for communicating results to multiple stakeholders in ways that are useful, culturally appropriate, take account of the literacy and numeracy of audiences, and when the evidence can be used to inform changes in policy and practice. Stakeholders engaged in the dissemination process will include members of partner organizations, organizations representing communities of older adults, professional gerontology, neuropsychological and social work organizations, employers and educators of adult workers who speak English as a second language, labor unions representing workers in the hospitality industry, and other identified stakeholder groups.

The dissemination plan will be guided by the Replicating Effective Programs (REP) framework (Kilbourne, 2007). The REP framework includes guidelines within four stages for program implementation and dissemination: pre-conditions (e.g., identifying need, the target population, and a suitable intervention); implementation (e.g., package dissemination, training, and technical assistance), maintenance, and evolution (e.g., fidelity assessment). Given the state-of-the-science, we will focus mainly on gathering and disseminating information related to the implementation and potential program maintenance as a sustainable, inter-compatible program within public health and community service environments.

The Principal Investigator is part of a large, national and international network with extensive experience in disseminating results from studies such as this one. In addition to serving as the Director for the University of Michigan (UM) Center for Managing Chronic Disease, Dr. Piette is on the Leadership Board for the UM Institute for Healthcare Policy and Innovation (IHPI). IHPI represents one of the nation's largest communities of health services researchers, clinicians, and policy analysts dedicated to studying how health and public health services work and how they can be improved. IHPI includes members from more than 30 research groups, focusing on issues including chronic disease management, health information technology, global health, intervention design, and health communication. Dr. Piette also has available the extensive community engagement, marketing, and dissemination teams through the Michigan Institute for Clinical and Health Research (MICHR) which fosters community partnerships and bi-directional engagement in rigorous science throughout Michigan and nationally. Our team of investigators has an extensive record of publishing results of studies in high-quality peer-reviewed scientific journals, and in presenting at professional meetings. Dr. Piette has published more than 250 studies, and he is a frequent speaker nationally and internationally, giving presentations to both academic and community groups in both English and Spanish.

Barriers to disseminating and implementing the results of this research may operate at multiple levels (individual, organizational) and include reactions to the evidence due to previously held beliefs or practices; lack of advocates, incentives, or opportunities for change; lack of resources; or lack of alignment to existing individual priorities or organizational missions and goals. In many cases communication of study results does not take into consideration the time it takes at the organizational level to read, evaluate, analyze, disseminate, and implement research evidence. To address these concerns, we will use the Consolidated Framework for Advancing Implementation Science (Damschroder 2009), which describes five major domains and associated constructs that can be used to address barriers and build the implementation knowledge base across multiple studies and settings.

Results of this study will provide multiple opportunities for continued support. As a program of research, the study will provide vital data for submission of a proposal to the National Institutes of Health/National Institute on Aging and the National Institute for Nursing Research for a larger, multi-site trial. The purpose of that study will be to evaluate more

definitively the longer-term benefits of the intervention in terms of the health and functioning of older adults with cognitive deficits. Dr. Piette is a Department of Veterans Affairs Research Career Scientist, and we will use the current study as pilot data for a similar grant proposal to VA's Health Services Research and Development program. That project may focus on older veterans in general as well as priority subgroups of VA patients such as those with mild to moderate symptoms of Post-Traumatic Stress Disorder (PTSD).

As an economically sustainable service, the program we will develop in this study could have several avenues for continued financial support. If effective in improving older adults' psychological wellbeing, cognitive functioning, depressive symptoms, and other health outcomes, we believe organizations such as the Area Agency on Aging, senior living centers, home health agencies, the AARP, and other organizations may find this to be a financially viable way to improve the health status of their clients. If we find that English learners report that they are able to make significant improvements in their fluency, there may be multiple opportunities for financial support, including: the large number of English-language institutes and other educational institutions such as community colleges, government agencies interested in improving capacity for tourism in their country, and businesses in the hospitality industry such as hotels or restaurants. We have already engaged organizations that may be interested in supporting this intervention over the longer-term, including the Ministry of Tourism from the Mexican government, the Hilton Hotels Director of Human Resources for Latin America and the Caribbean, and the Vice President for Global Language Learning for Marriott hotels. These companies hire tens of thousands of workers worldwide whose native language is something other than English, and they have expressed a strong interest in developing this idea as a potential resource for their employees while simultaneously helping older adults.