



Preventing disability in older adults with mild cognitive impairment: A Strategy Training intervention study

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ABSTRACT

Non-pharmacological interventions designed to change cognitive function in older adults with Mild Cognitive Impairment have shown mixed results. Few studied interventions directly address preclinical disability. Slowing changes in disability are critical preserve independence and health related quality of life in older adults with Mild Cognitive Impairment. In this study, we discuss the design of the trial, challenges encountered, and solutions generated to guide future trials designed to prevent the onset of disability among at-risk older adults. We compared Strategy Training to enhanced-usual care in 30 older adults with Mild Cognitive Impairment. We recruited 79.7% (n = 188) of the potential participants through direct-to-consumer recruitment. We refined a three-step screening process, including a phone screen, initial in-person screening, and full in-person screening. This screening processes resulted in a high percentage of older adults completing the neuropsychological battery and adjudication of Mild Cognitive Impairment. Conducting a disability prevention among individuals without overt disability is a novel approach. Nevertheless, one of the greatest limitations to our project is the fact that follow-up is restricted to 1 year. Findings from this study can inform the design and conduct of future clinical trials that seek to slow progression of disability in older adults with Mild Cognitive Impairment.

1. Introduction

In this report, we describe the process for conducting an intervention study designed to prevent disability in older adults with Mild Cognitive Impairment (MCI) and depressive symptoms. MCI is the state between normal cognitive aging and dementia. Older adults with MCI have a high risk of developing dementia, as well as disability associated with dementia. Unfortunately, 50% of individuals with MCI experience elevated depressive symptoms, which confer accelerated cognitive decline [1] and increased risk of both disability and a diagnosis of dementia [2].

The extant literature on the progression to disability for individuals at-risk for dementia is inconclusive because disability was historically only considered once an individual was diagnosed with dementia. However, it is increasingly clear that individuals with MCI demonstrate preclinical disability [3]. Preclinical disability is defined as subtle differences in the effort required and adaptations noted in daily activities

[4]. Individuals with MCI most often demonstrate preclinical disability in cognitively challenging activities (i.e., financial management and medication management) [3].

To date, non-pharmacological interventions designed to change cognitive function in older adults with MCI have shown mixed results [5]. Some cognitive training interventions, physical exercise, and psychotherapeutic interventions demonstrate greater improvements than care as usual in selected cognitive domains with small effect sizes [5]. Few directly address preclinical disability. Since preclinical disability emerges early in the disease trajectory, and is potentially more amenable to slowing, interventions that address preclinical disability are timely and critical with respect to the broader goal of preserving independence and health related quality of life.

We designed a pilot intervention study that aimed to delay the onset of overt disability by teaching individuals with MCI and depressive symptoms strategies to work through and around preclinical disability. Our intervention employed a process known as “Strategy Training”,

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which is based on the principles of behavioral activation, viz., avoidance behaviors are developed to limit exposure to negative stimuli or difficult activities [6,7]; however, such avoidant coping may lead to the worsening of disability and mood. By engaging in an intervention based on behavioral activation, the downward spiral of avoidant coping is disrupted by facilitating and reinforcing a positive problem orientation and active coping strategies, to maintain effective engagement in meaningful activities for as long as possible. In this report, we discuss the design of the trial, challenges encountered, and solutions generated to guide future trials designed to prevent the onset of disability among at-risk older adults.

2. Methods

2.1. Study design and specific aims

We conducted a randomized controlled trial to examine:

- Whether differences existed in preclinical disability, as measured by the Performance Assessment of Self-Care Skills [8,9], at 12 months between Strategy Training and Enhanced-Usual Care groups.
- relationships between clinical variables and preclinical disability. We sought to examine the relationships of (1) physical activity levels, (2) sleep, and (3) medical co-morbidity with disability.

Participants were randomized to Strategy Training and Enhanced-Usual Care using a 1:1 allocation with permuted blocks of varying size. We used a computer-generated random numbers table for randomization. Participants were stratified by whether a support person was involved because intervention uptake may be positively influenced by involvement of others in a participant's life.

2.2. Participants

Participants were adjudicated to have MCI (criteria provided below), a minimum of 60 years of age, living in the community, scored ≥ 1 on the Patient Health Questionnaire 2-item version (PHQ-2) assessing low mood and anhedonia [10], and had self-reported difficulty in at least 1 daily activity (see Table 1). Exclusion criteria included having complex medical history, such as a central nervous system disorder (other than MCI), presenting with current major depression, reporting alcohol or illicit substance use disorder in past 5 years, or having a lifetime history of bipolar disorder or schizophrenia. These criteria ensure that included participants had MCI and depressive symptoms but not conditions that may influence the diagnostic process or study outcomes for another reason. If potential participants presented with an exclusion criterion, they were referred for treatment outside of the study.

Table 1
Inclusion and exclusion criteria and rationale for these decisions.

Inclusion Criteria	Rationale
Age ≥ 60 years	Incidence and prevalence of MCI increases after age 60 Interventions designed to prevent disability in older adults are different than those for younger adults
Adjudicated to have MCI	Adjudication of MCI ensured commonality of cognitive changes experienced by participants
PHQ-2 > 0 (low mood or anhedonia endorsed)	Endorsement of cardinal symptoms of depression places individuals in the subthreshold range for depression, making them at greater risk for decline
Self-reported difficulty in an activity of daily living	Self-reported difficulty resulted in the inclusion of participants who may be more likely to identify areas for improvement
Community-dwelling	Interventions designed to support individuals living in the community are different than interventions for individuals not living in the community
Exclusion Criteria	Rationale
Current episode of major depression	Comorbidity may influence the outcome. Treatment should be sought outside of this study
Central nervous system disorder (other than MCI)	Other central nervous system disorder may interfere with the ability to fully participate in the intervention
Alcohol or illicit substance use in the past 5 years	Comorbidity may influence the outcome. Treatment should be sought outside of this study
Lifetime history of bipolar or schizophrenia	Comorbidity may influence the outcome. Treatment should be sought outside of this study

MCI diagnoses were conferred using a comprehensive assessment program suggested by National Institute on Aging-Alzheimer's Association criteria [11]. We used a three-step process comprised of a phone screen, initial in-person screening, and full in-person screening. The phone screen assessed for endorsement of depressive symptoms [10] and self-report of difficulty in a daily activity. The initial in-person screen was comprised of the Modified Mini-mental State Examination (3MS) [12], Trail Making Test A and B (Trails) [13], and the Quick Mild Cognitive Impairment Screen (Qmci) [14]. Individuals who scored < 84 on the 3MS were excluded from the study due to potential dementia. Those who scored in the dementia range on Trails and Qmci (> 2 SD below normed means) were also excluded from the study. Those who scored ≥ 1 SD below normed means on either or both Trails or Qmci proceeded to the full in-person screen.

The full in-person screen consisted of the Wide Range Achievement Test-IV Reading Subtest [15], Repeatable Battery for the Assessment of Neuropsychological Status [16], Delis-Kaplan Executive Function System Trail Making and Color-Word Tests [17], Measurement of Everyday Cognition [18], Older Americans Resources and Services [19], Clinical Dementia Rating Scale [20], Unified Parkinson's Disease Rating Scale [21], and Cumulative Illness Rating Scale- Geriatric [22]. Data gleaned during the assessments were reviewed by a neuropsychologist (MAB), neurologist (OL), and occupational therapist (JR), to diagnose MCI.

2.3. Recruitment

Participants were recruited from the Alzheimer's Disease Research Center (ADRC) at the University of Pittsburgh, as well as community-based outreach as appropriate. We engaged with partners across the University, including the Clinical and Translational Science Institute (CTSI).

2.4. Schedule of assessments

An independent assessment team, who was blinded from the condition to which participants were randomized, completed the assessments of study outcomes under the supervision of a neuropsychologist (MAB). Assessors were trained in neuropsychological and all other assessments before conducting assessments for the study.

The primary outcome was preclinical disability as measured with the Performance Assessment of Self-Care Skills (PASS) through standardized, criterion-referenced observations of cognitively challenging instrumental daily activities [3,8,9]. The activities assessed were shopping, bill paying, checkbook balancing, bill mailing, telephone use, medication management, critical information retrieval, and small device repair. We summed the number of cues the independent assessor

Table 2
Study assessments.

Domain	Measure
Disability	Performance Assessment of Self-Care Skills [8]
Cognitive Status	Delis-Kaplan Executive Function System [17] Repeatable Battery for the Assessment of Neuropsychological Status [16] Modified Mini-Mental Status Examination [12]
Medical Co-Morbidity	Cumulative Illness Rating Scale- Geriatric [22] and current medication list
Depression symptom Severity	Patient Health Questionnaire- 9 [38]
Anxiety symptom severity	Generalized Anxiety Disorder- 7 [39]
Occurrence of Insomnia	Pittsburgh Sleep Quality Index- 1 [40]
Physical Activity	Physical Activity Scale for Elderly [41]
Social Support	Interpersonal Support Evaluation-12 [42]
Self-Appraisal of ability to take care of self	Appraisal of Self-Care Agency Scale [43]
Coping	Ways of Coping [44]
Worry	Penn State Worry Questionnaire [45]

provided the participant during the completion of the activities. The types of cues could have been verbal, gestural, or physical. The overall score has yielded good internal consistency rating, based on a Cronbach's alpha, of 0.71. The PASS has been found to have good reliability and validity. In particular, the tool has excellent measurement stability and is sensitive to change over time [8]. The PASS was administered pre-intervention, 6 weeks, 3, 6, 9- and 12-months follow-up.

We used additional assessments to measure the following domains: medical co-morbidity, depressive symptom severity, anxiety symptoms severity, perception of sleep quality, degree of daily physical activity, perceived level of social support, self-appraisal coping, and presence of worry (Table 2).

2.5. Intervention

2.5.1. Strategy Training

Strategy Training is based on the theoretical and empirical evidence associated with behavioral activation. It is a behavioral approach to help older adults who are beginning to experience preclinical disability to develop solutions and skills to preserve their abilities in daily activities (i.e., independence). Strategy Training optimizes engagement in meaningful daily activities through four integrated components: (i) generating self-selected goals that address activities [23], (ii) monitoring daily activities to provide information on baseline level of activities and to demonstrate the value of participating in activities, (iii) scheduling activities to increase contact with other individuals and participation in pleasurable activities, and (iv) problem-solving solutions to remove or circumvent barriers experienced when engaging in activities [5,24–27]. The hallmark of Strategy Training is its focus on daily activities. Therapists facilitate participants' engagement in daily activities through prompts, questions, and problem-solving. Participants develop goals and develop their own strategies to improve their ability to perform daily activities. Behavioral activation suggests that behavior changes derived through this method are sustainable because participants focus on what they want to do and how they want to do it [28]. Strategy Training is promising in its potential for slowing decline to disability for older adults with MCI and depressive symptoms [5,23,24,29] because older adults with mild cognitive impairments become willing and able to maintain the ability to develop strategies for engaging in daily activities [30,31].

2.5.2. Enhanced-usual care

Participants assigned to Enhanced-Usual Care received the same assessments as those assigned to Strategy Training, but they did not receive the Strategy Training intervention or another intervention. All participants received feedback on their thinking and memory status, and, as appropriate, participants were referred to outside services. For

example, if a participant presented with more than mild depressive or anxiety symptoms, they were referred to services; the same practice was followed in the intervention arm. Participants' experience was considered enhanced because they received close monitoring of their thinking, memory, and mood.

2.6. Interventionist training

Registered and licensed occupational therapists with expertise in the care of older adults served as interventionists for Strategy Training. Experts in Strategy Training (JR, ERS, KWG) trained the interventionists in the protocol using multiple modalities. First, an in-person session described the background and the intervention protocol. Therapists were then provided with video-recorded case examples to review. A subsequent in-person session provided a platform for questions and answers. An expert in Strategy Training (KWG) reviewed video and provided feedback to intervention therapists on protocol adherence and competence. Consistent protocol adherence and competence was generally reached after completion of 2 intervention participants. After training, all sessions are videotaped to assess treatment fidelity. A trained external rater assessed treatment fidelity in a random sample of 20% of the Strategy Training intervention sessions. Our assessment of treatment fidelity was multifaceted, and it included adherence and competence for the Strategy Training procedures and implementation of Strategy Training's active components. Adherence was rated as yes or no. Competence was rated as inadequate, adequate or exceptional.

2.7. Planned analysis

We plan to use descriptive statistics to assess the efficacy of Strategy Training on the primary and secondary outcomes. We will examine differences in preclinical disability, as measured by the PASS, at 12 months between Strategy Training and Enhanced-Usual Care groups. We will use an independent *t*-test to explore differences between Strategy Training and Enhanced-Usual Care at 12-months. The results of the *t*-test will provide parameter estimates, standard errors, and 95% confidence intervals, which will be examined to assess the magnitude of the between-group difference. Statistical significance will be determined based on an alpha level of ≤ 0.05 . If *t*-test assumptions are not met, we will use the non-parametric equivalent. We will explore factors that may influence intervention response by examining associations between (1) physical activity, (2) sleep, and (3) medical co-morbidity with disability using correlational techniques. We will use Pearson correlations with continuous factors, and we will use Spearman correlations with ordinal factors.

2.8. Sample size justification

A formal sample size calculation was not performed due to the pilot feasibility nature of the study. We estimated that approximately 80% of participants will complete the intervention program with the 1-year follow-up (24/30 participants). Findings from this study will provide preliminary information relevant to conduct power analyses for future studies.

3. Results

Table 3 includes a list of the challenges encountered and the effective solutions. Our research team, including the staff and principal investigator, met on a weekly basis to discuss recruitment, assessments, intervention, and follow-up to develop effective solutions. Themes for (1) recruitment, (2) assessment procedures, and (3) intervention are below.

Table 3
Challenges and solutions.

Challenges	Solutions
Recruitment	
• Slow recruitment • Participants ineligible due to no depressive symptoms • Recruitment of spousal pairs	• We expanded recruitment strategies to include the development of relationships with community-based services. • We presented information on normal and abnormal cognitive aging to community-based groups. • We requested permission from participants to contact them again to reassess their depressive symptoms a minimum of 3 months later • When both members within a spousal pair were interested in participating, we asked the pair to prioritize one individual within the pair instead of allowing both members to complete screening assessments to ensure the ability to randomize appropriately.
Assessment	
• Difficulty scheduling assessments • Ruling out participants due to complicated medical history after they completed cognitive testing • Participants expressing stress about cognition during baseline testing • Participants declining in-person assessment visits	• At the end of each assessment, we immediately scheduled the next follow-up assessment. • We moved assessments of mood and medical history to earlier in the screening process to rule-out ineligible participants as early as possible to limit unnecessary participant burden. • We waited to provide participants feedback on neuropsychological testing until after all baseline measures were completed to limit potential bias in psychosocial measures. • Participants who decline or were unable to complete in-person assessments completed assessments over the phone. We expanded our process from only in person to accommodate participants.
Intervention	
• Participant difficulty generating goals for intervention • Therapist noted complexity of describing intervention language to participants • Large goals were unable to be achieved in 1 session	• We altered our goal-setting process to use the modified Activity Card Sort. This process included visuals of common daily activities to stimulate participant thinking about desired activities to consider for goals. • We discontinued use of forms that were created for our previous goal setting process to limit participant burden with paperwork. • We reduced the reading level and eliminated unnecessary words for describing the intervention and language used in intervention materials to enhance ease of use and participant understanding of materials. • We added prompts to develop specific plans that break down large goals (e.g, asking about frequency and intensity). • We allowed continuation of goals across sessions because goals were often too large to be completed within one session.

3.1. Recruitment

Identifying and recruiting individuals with mild cognitive impairments and depressive symptoms required a multipronged approach. In addition to using developed infrastructure at the ADRC and the University of Pittsburgh (such as the CTSI), we invested resources to develop several community-based partnerships to reach older adults who may be interested in participating in research. We built relationships with independent living facilities, public libraries, senior high-rises, senior centers, community centers, and via participation in community services and events (e.g., health fairs). We employed a variety of methods for recruitment with the help of these relationships, including visual advertisements in print- and on-air media, radio advertisements, internet advertising, and community mailings. Based on these partnerships, we gave presentations on the influence of aging-related changes in thinking and memory on daily activities. Afterward, interested participants provided contact information for further screening.

Fig. 1 shows our CONSORT diagram up until the point of randomization where we assessed 236 individuals for eligibility and randomized 30 individuals. Among those we assessed, we recruited 79.7% ($n = 188$) of the potential participants through direct-to-consumer recruitment (e.g., community-based partnership talks, radio-advertising, social media, Craigslist). The rest were recruited through university-related research registries (18.2%, $n = 43$), and primary care practices (2.1%, $n = 5$).

Table 4 provides the descriptive statistics for demographic characteristics for all 30 participants at baseline. In brief, participants were, on average, older than 75 years, majority female, majority white, with high school education or above, reported mild depressive symptoms, mild anxiety, fairly good sleep, and average levels of physical activity.

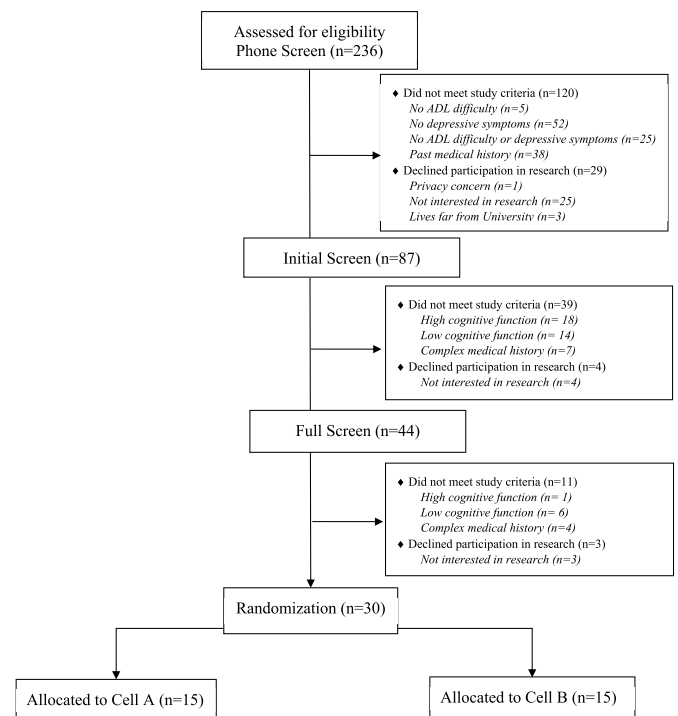


Fig. 1. CONSORT diagram.

3.2. Assessment procedures

We employed a multistep screening process such that only individuals most likely to have MCI completed the neuropsychological

Table 4
Baseline Characteristics (N = 30) mean (sd).

Variable	Descriptive Statistics		
			Range
Age, mean (SD)	77.97	(8.68)	62–96
Female, n (%)	20	(66.7)	
White, n (%)	26	(86.7)	
Education, n (%)			
High School Educated	13	(43.4)	
Vocational or Associates	4	(13.3)	
Bachelors	6	(20.0)	
Master and above	7	(23.3)	
Performance Assessment of Self-Care Skills (range: 0–486), mean (SD)*	17.97	(9.69)	2–37
DKEFS (range: 0–19; mean:10; SD:3), mean (SD)			
Trail Making Test: Set Shifting Scaled Score	9.07	(3.79)	3–14
Trail Making Test: Speed Scaled Score	10.50	(2.24)	5–14
Trail Making Test: Set Shifting vs. Motor	8.57	(3.45)	2–15
Color Word: Inhibition-Switching Scaled Score	10.86	(3.34)	1–16
RBANS (range: 40–160; mean:100; SD:15), mean (SD)			
Immediate Memory Index	96.77	(12.35)	76–120
Language Memory Index	99.10	(12.57)	71–127
Delayed Memory Index	95.03	(14.44)	52–126
Attention Index	101.60	(18.36)	68–142
Visuospatial Index	93.87	(14.91)	58–121
Total Score Index	95.70	(11.04)	82–133
Modified Mini-Mental State Examination (range: 1–100), mean (SD)	93.6	(3.91)	84–99
Patient Health Questionnaire-9 (range: 0–27), mean (SD)*	5.6	(4.75)	0–20
Generalized Anxiety Disorder-7 (range: 0–21), mean (SD)*	3.9	(4.16)	0–18
Pittsburgh Sleep Quality Index-1 (range: 0–3), mean (SD)*	0.97	(0.93)	0–3
Physical Activity Scale for the Elderly Questionnaire (range: 0–400), mean (SD)	109.25	(72.70)	20.8–278.1
Interpersonal Support Evaluation List- 12 (range: 12–48), mean (SD)*	38.5	(6.49)	27–47
Appraisal of Self-Care Agency Scale (range: 24–120), mean (SD)	83.33	(4.80)	73–91
Ways of Coping (range: 0–198), mean (SD)	82.63	(25.20)	31–123
Penn State Worry Questionnaire (range: 16–80), mean (SD)*	43.67	(11.62)	22–67

Notes: DKEFS: Delis-Kaplin Executive Function System; RBANS: Repeatable Battery for the Assessment of Neuropsychological Status; *lower is better.

examinations. Among the individuals contacted for phone-screen, 63.1% (n = 149) were deemed ineligible. The primary reasons for exclusion were lack of depressive symptoms (34.9%, n = 52) and complexity of past medical history (25.5%, n = 38). Forty-three (49.4%) potential participants did not meet study criteria after the initial screen. Individuals were excluded due to high cognitive function 41.9% (n = 18), low cognitive function 32.6% (n = 14), and a complex medical history 16.3% (n = 7). Additionally, 4 individuals withdrew due to lack of interest in research participation. Fourteen (31.8%) potential participants did not meet study criteria after the full clinical and neuropsychological examinations. Individuals were excluded due to high cognitive function 7.1% (n = 1), low cognitive function 42.9% (n = 6), and a complex medical history 28.6% (n = 4). Per our recruitment and screening process, 30 out of 45 individuals who completed the neuropsychological examinations were adjudicated to have MCI. Three participants withdrew before randomization. In the end, 30 were adjudicated to have MCI and depressive symptoms and were randomly assigned to Strategy Training or Enhanced-Usual Care.

3.3. Intervention

We developed a standardized goal-setting process that was modified from the Activity Card Sort [32]. Described elsewhere, it is a theoretical hallmark of behavioral activation [28]. It ensures that the intervention

is personally meaningful to the participants. Administration of the goal-setting process took between one to three sessions to complete. Guided by the occupational therapist, participants would identify activities and prioritize a minimum of 5 personally meaningful goals.

After the first two study participants, we recognized that participants quickly demonstrated the acquisition and use of the global strategy in the addressed activity; that is, participants were learning how to apply their self-identified strategies to their activity of interest. We noticed, however, that participants were not using their effective strategies in related daily activities; they were not generalizing their strategies to other activities. Generalization is considered the use of the same strategy with a different activity or in a new context. Thus, we increased our emphasis on the generalization of strategy use during the intervention sessions. This aligns with behavioral activation and encourages active problem solving and use of coping strategies to main engagement in daily activities. We enhanced generalization by implementing questions in each intervention session about effective and ineffective strategies and related activities or contexts where effective strategies could be applied.

Informal feedback from participants indicated satisfaction with the Strategy Training intervention. One participant said, “this was the first [study] so far that made an impact on me ... This [study] is the one that gave something back to me.” Another participant indicated that s/he was able to develop effective strategies to work through and around barriers to daily activities, saying, “When I have a problem, I think about the fact that I have a plan”.

3.4. Intervention fidelity

In our preliminary studies, Strategy Training therapists demonstrated excellent treatment fidelity, demonstrated that our training and supervision achieved good treatment fidelity. Therapists implemented and demonstrated competence in the Strategy Training procedures and active components more than 90% of the time. Table 5 depicts the percentages of adherence and competence to the procedures and active components.

4. Discussion

This pilot intervention development study is based on the theoretical framework of behavioral activation and is designed to delay the onset of disability by teaching individuals with MCI and depressive symptoms strategies to work through and around preclinical disability. Since preclinical disability emerges early in the disease trajectory [3,33], interventions that address preclinical disability and daily life are timely and critical. This intervention approach is unique in its focus on preclinical disability; few current nonpharmacological interventions address or influence preclinical disability [5].

Our experience suggests that with a strong emphasis on recruitment, it is feasible to recruit community-dwelling older adults with MCI and depressive symptoms for a disability-prevention study. Multiple direct consumer recruitment methods were successful in reaching older adults who were interested in participating in research. Ultimately, the majority (80%) of our interested participants were recruited through direct consumer recruitment methods. These methods require delivering presentations to groups of older adults about aging and the progression

Table 5
Percentages of adherence and competence to treatment principles.

Variable	Percent
Adherence to procedures	93
Competence with procedures	95
Adherence to active components	97
Competence with active components	98

of disability. While community-based sampling methods require investment from staff and consistent monitoring to ensure enrollment of interested individuals, we reached our recruitment targets.

Our stepped screening and assessment procedures were helpful in optimizing efficient use of staff resources and in reducing participant burden. Two-thirds of the potential participants who completed the neuropsychological examinations during the full assessment phase, were adjudicated to have MCI. With the prevalence of MCI being an estimated 5.9 (5.5–6.3)% of older adults [34], our protocol was efficient in identifying older adults for the study who were likely to have MCI.

Non-pharmacological interventions, if they are to be beneficial for older adults with cognitive decline, are likely to be complex interventions. The Medical Research Council guidelines for developing and evaluating complex interventions encourages careful conceptualization and operationalization of the intervention using a sound theoretical background to understand how change occurs [35]. With the Medical Research Council guidelines in mind, the combination of the Strategy Training components for older adults with MCI and depressive symptoms were carefully conceptualized and operationalized for further implementation and study. We trained three occupational therapists to implement Strategy Training for older adults with MCI and depressive symptoms. They subjectively reported satisfaction with the training and protocol clarity. They indicated that Strategy Training provides an explicit framework for what they think to be best practice. One therapist commented, “This intervention has made me a better therapist”, and “I learned skills that work with everyone that I treat, whether in research or my practice.” This subjective feedback suggests that we have the infrastructure required to conduct therapist training.

Several additional points from this study are worth highlighting. This project necessarily involves a multidisciplinary team. A research groups with diverse expertise was required to address the complex issues related to cognitive decline and the risk architecture associated with disablement. Our team included an occupational therapist with expertise in disability, a neurologist, a neuropsychologist, a geriatric psychiatrist, and a methodologist with expertise in prevention trials. Prevention of disability in a group of older adults with MCI and depressive symptoms requires this expertise to assess cognition and conduct adjudications, monitor depressive symptoms, and deliver the intervention protocol designed to slow decline to overt disability.

Conducting a disability prevention among individuals without overt disability is a novel approach. Nevertheless, one of the greatest limitations to our project is the fact that follow-up is restricted to 1 year. While this is similar to other prevention intervention protocols [36], an ideal protocol would follow participants longer, because (1) preclinical disability, while present, is subtle [33] and (2) the rate of conversion from MCI to dementia is around 10% per year [37]. An ideal protocol would follow older adult with MCI until the onset of overt disability which may not occur until the onset of dementia. Then, the time of onset of disability could be compared between groups.

Given the great personal and societal effects of disability associated with dementia and limited numbers of effective interventions that influence disease pathology, a promising non-pharmacological intervention designed to slow decline to disability is critical. We will report findings from this trial once available.

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References

- [1] K. Palmer, F. Di Iulio, A.E. Varsi, W. Gianni, G. Sancesario, C. Caltagirone,

- G. Spalletta, Neuropsychiatric predictors of progression from amnesic-mild cognitive impairment to Alzheimer's disease: the role of depression and apathy, *J. Alzheimer's Dis.* 20 (2010) 175–183, <https://doi.org/10.3233/JAD-2010-1352>.
- [2] G.S. Alexopoulos, D.N. Kiosses, S. Klimstra, B. Kalayam, M.L. Bruce, Clinical presentation of the “depression-executive dysfunction syndrome” of late life, *Am. J. Geriatr. Psychiatry* (May 18, 2018) 98–106 10 (n.d.) <http://www.ncbi.nlm.nih.gov/pubmed/11790640> accessed.
- [3] J. Rodakowski, E.R.E.R. Skidmore, C.F.C.F. Reynolds, M.A.M.A. Dew, M.A.M.A. Butters, M.B.M.B. Holm, O.L.O.L. Lopez, J.C.J.C. Rogers, Can performance on daily activities discriminate between older adults with normal cognitive function and those with mild cognitive impairment? *J. Am. Geriatr. Soc.* 62 (2014) 1347–1352, <https://doi.org/10.1111/jgs.12878>.
- [4] D. Blazer, Neurocognitive disorders in DSM-5, *Am. J. Psychiatry* 170 (2013) 585–587, <https://doi.org/10.1176/appi.ajp.2013.13020179>.
- [5] J. Rodakowski, E. Saghaei, M.A. Butters, E.R. Skidmore, Non-pharmacological interventions for adults with mild cognitive impairment and early stage dementia: an updated scoping review, *Mol. Aspect. Med* (2015) 43–44 <https://doi.org/10.1016/j.mam.2015.06.003> 38–53.
- [6] P. Cuijpers, A. van Straten, L. Warmerdam, Behavioral activation treatments of depression: a meta-analysis, *Clin. Psychol. Rev.* 27 (2007) 318–326, <https://doi.org/10.1016/j.cpr.2006.11.001>.
- [7] B.W. Rovner, R.J. Casten, M.T. Hegel, B.E. Leiby, Preventing cognitive decline in older African Americans with mild cognitive impairment: design and methods of a randomized clinical trial, *Contemp. Clin. Trials* 33 (2012) 712–720, <https://doi.org/10.1016/j.cct.2012.02.016>.
- [8] M.B. Holm, J.C. Rogers, The performance assessment of self-care skills (PASS), in: B. Hemphill-Pearson (Ed.), *Assessments Occup. Ther. Ment. Heal.* second ed., SLACK, Thorofare, NJ, 2008, pp. 101–110.
- [9] J. Rogers, M. Holm, *Performance Assessment of Self-Care Skills (PASS, Versions 3.1), (1989) Pittsburgh.*
- [10] K. Kroenke, R.L. Spitzer, J.B.W. Williams, The patient health questionnaire-2, *Med. Care* 41 (2003) 1284–1292, <https://doi.org/10.1097/01.MLR.0000093487.78664.3C>.
- [11] D.L. Beekly, E.M. Ramos, W.W. Lee, W.D. Deitrich, M.E. Jacka, J. Wu, J.L. Hubbard, T.D. Koepsell, J.C. Morris, W.A. Kukull, The National Alzheimer's coordinating center (NACC) database: the uniform data set, *Alzheimers Dis. Assoc. Disord.* 21 (2007) 249–258, <https://doi.org/10.1097/WAD.0b013e318142774e>.
- [12] E.L. Teng, H.C. Chui, The modified mini-mental state (3MS) examination, *J. Clin. Psychiatry* 48 (1987) 314–318 <http://www.ncbi.nlm.nih.gov/pubmed/3611032>, Accessed date: 26 July 2016accessed.
- [13] T. Tombaugh, Trail Making Test A and B: normative data stratified by age and education, *Arch. Clin. Neuropsychol.* 19 (2004) 203–214, [https://doi.org/10.1016/S0887-6177\(03\)00039-8](https://doi.org/10.1016/S0887-6177(03)00039-8).
- [14] R. O'Caomh, Y. Gao, C. McGlade, L. Healy, P. Gallagher, S. Timmons, D.W. Molloy, Comparison of the quick mild cognitive impairment (Qmci) screen and the SMMSE in screening for mild cognitive impairment, *Age Ageing* 41 (2012) 624–629, <https://doi.org/10.1093/ageing/af509>.
- [15] D.A. Kareken, R.C. Gur, A.J. Saykin, Reading on the Wide range achievement test-revised and parental education as predictors of IQ: comparison with the barona formula, *Arch. Clin. Neuropsychol.* 10 (1995) 147–157, [https://doi.org/10.1016/0887-6177\(94\)E0012-E](https://doi.org/10.1016/0887-6177(94)E0012-E).
- [16] C. Randolph, M.C. Tierney, E. Mohr, T.N. Chase, The repeatable battery for the assessment of neuropsychological status (RBANS): preliminary clinical validity, *J. Clin. Exp. Neuropsychol.* 20 (1998) 310–319, <https://doi.org/10.1076/jcen.20.3.310.823>.
- [17] D. Delis, Delis-Kaplan Executive Function System, D-KEFS, 2001, <http://www.worldcat.org/title/delis-kaplan-executive-function-system-d-kefs/oclc/812888503>, Accessed date: 14 August 2013accessed.
- [18] S. Tomaszewski Farias, D. Mungas, D.J. Harvey, A. Simmons, B.R. Reed, C. Decarli, The measurement of everyday cognition: development and validation of a short form of the Everyday Cognition scales, *Alzheimers. Dement.* 7 (2011) 593–601, <https://doi.org/10.1016/j.jalz.2011.02.007>.
- [19] G.G. Fillenbaum, *Multidimensional Functional Assessment of Older Adults: the Duke Older Americans Resources and Services Procedures.*, (n.d.).
- [20] C.P. Hughes, L. Berg, W.L. Danziger, L.A. Coben, R.L. Martin, A new clinical scale for the staging of dementia, *Br. J. Psychiatry* 140 (1982) 566–572 <http://www.ncbi.nlm.nih.gov/pubmed/7104545>, Accessed date: 26 July 2016accessed.
- [21] Movement Disorder Society Task Force on Rating Scales for Parkinson's Disease, The unified Parkinson's disease rating scale (UPDRS): status and recommendations, *Mov. Disord.* 18 (2003) 738–750, <https://doi.org/10.1002/mds.10473>.
- [22] B.S. Linn, M.W. Linn, L. Gurel, Cumulative illness rating scale, *J. Am. Geriatr. Soc.* 16 (1968) 622–626 accessed <http://www.ncbi.nlm.nih.gov/pubmed/5646906>, Accessed date: 26 July 2016.
- [23] J. Rodakowski, A.M. Becker, K.W. Golias, Activity-based goals generated by older adults with mild cognitive impairment, *OTJR Occup. Participation Health* (2018), <https://doi.org/10.1177/1539449217751357> 153944921775135.
- [24] J. Rodakowski, C.F. Reynolds, O.L. Lopez, M.A. Butters, M.A. Dew, E.R. Skidmore, Developing a non-pharmacological intervention for individuals with mild cognitive impairment, *J. Appl. Gerontol.* (2016), <https://doi.org/10.1177/0733464816645808>.
- [25] D. Dawson, J. Richardson, A. Troyer, M. Binns, A. Clark, H. Polatajko, G. Winocur, A. Hunt, Y. Bar, An occupation-based strategy training approach to managing age-related executive changes: a pilot randomized controlled trial, *Clin. Rehabil.* 28 (2014) 118–127, <https://doi.org/10.1177/0269215513492541>.
- [26] E.R. Skidmore, E.M. Whyte, M.A. Butters, L. Terhorst, C.F. Reynolds, Strategy training during inpatient rehabilitation may prevent apathy symptoms after acute

- stroke, *Pharm. Manag. PM R* 7 (2015) 562–570, <https://doi.org/10.1016/j.pmrj.2014.12.010>.
- [27] E.R. Skidmore, M. Butters, E. Whyte, E. Grattan, J. Shen, L. Terhorst, Guided training relative to direct skill training for individuals with cognitive impairments after stroke: a pilot randomized trial, *Arch. Phys. Med. Rehabil.* 98 (2017) 673–680, <https://doi.org/10.1016/j.apmr.2016.10.004>.
- [28] J.W. Kanter, R.C. Manos, W.M. Bowe, D.E. Baruch, A.M. Busch, L.C. Rusch, What is behavioral activation? A review of the empirical literature, *Clin. Psychol. Rev.* 30 (2010) 608–620, <https://doi.org/10.1016/j.cpr.2010.04.001>.
- [29] J. Rodakowski, E.R. Skidmore, Non-pharmacological interventions for early cognitive decline, *Am. J. Geriatr. Psychiatry* 25 (2017), <https://doi.org/10.1016/j.jagp.2016.12.006>.
- [30] R. Fernández-Ballesteros, M.D. Zamarrón, L. Tárraga, R. Moya, J. Iñiguez, Cognitive plasticity in healthy, mild cognitive impairment (MCI) subjects and Alzheimer's disease patients: a research project in Spain, *Eur. Psychol.* 8 (2003) 148–159.
- [31] E.J. Mufson, M.D. Ikonovic, S.D. Styren, S.E. Counts, J. Wu, S. Leurgans, D.A. Bennett, E.J. Cochran, S.T. DeKosky, Preservation of brain nerve growth factor in mild cognitive impairment and Alzheimer disease, *Arch. Neurol.* 60 (2003) 1143–1148, <https://doi.org/10.1001/archneur.60.8.1143>.
- [32] D.F. Baum, C. M. Edwards, *Activity Card Sort Test Manual*, second ed., AOTA Press, Bethesda, MD, 2008.
- [33] K. Jekel, M. Damian, C. Wattmo, L. Hausner, R. Bullock, P.J. Connelly, B. Dubois, M. Eriksdotter, M. Ewers, E. Graessel, M.G. Kramberger, E. Law, P. Mecocci, J.L. Molinuevo, L. Nygård, M.G. Olde-Rikkert, J.-M. Orgogozo, F. Pasquier, K. Peres, E. Salmon, S.A. Sikkes, T. Sobow, R. Spiegel, M. Tsolaki, B. Winblad, L. Frölich, Mild cognitive impairment and deficits in instrumental activities of daily living: a systematic review, *Alzheimer's Res. Ther.* 7 (2015) 17, <https://doi.org/10.1186/s13195-015-0099-0>.
- [34] P.S. Sachdev, D.M. Lipnicki, N.A. Kochan, J.D. Crawford, A. Thalamuthu, G. Andrews, C. Brayne, F.E. Matthews, B.C.M. Stephan, R.B. Lipton, M.J. Katz, K. Ritchie, I. Carrière, M.-L. Ancelin, L.C.W. Lam, C.H.Y. Wong, A.W.T. Fung, A. Guaita, R. Vaccaro, A. Davin, M. Ganguli, H. Dodge, T. Hughes, K.J. Anstey, N. Cherbuin, P. Butterworth, T.P. Ng, Q. Gao, S. Reppermund, H. Brodaty, N. Schupf, J. Manly, Y. Stern, A. Lobo, R. Lopez-Anton, J. Santabàrbara, C.S., M, An I.C. Cohort studies of memory in an international consortium (COSMIC), the prevalence of mild cognitive impairment in diverse geographical and ethnocultural regions: the COSMIC collaboration, *PLoS One* 10 (2015) e0142388, <https://doi.org/10.1371/journal.pone.0142388>.
- [35] P. Craig, P. Dieppe, S. Macintyre, S. Michie, I. Nazareth, M. Petticrew, Developing and evaluating complex interventions: the new Medical Research Council guidance, *BMJ* 337 (2008) a1655 <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2769032&tool=pmcentrez&rendertype=abstract>, Accessed date: 22 October 2013accessed.
- [36] A.G. Gildengers, M.A. Butters, S.M. Albert, S.J. Anderson, M.A. Dew, K. Erickson, L. Garand, J.F. Karp, M.H. Lockovich, J. Morse, C.F. Reynolds, Design and implementation of an intervention development study: retaining cognition while avoiding late-life depression (ReCALL), *Am. J. Geriatr. Psychiatry* 24 (2016) 444–454, <https://doi.org/10.1016/j.jagp.2015.10.010>.
- [37] A.J. Mitchell, M. Shiri-Feshki, Rate of progression of mild cognitive impairment to dementia—meta-analysis of 41 robust inception cohort studies, *Acta Psychiatr. Scand.* 119 (2009) 252–265, <https://doi.org/10.1111/j.1600-0447.2008.01326.x>.
- [38] K. Kroenke, R.L. Spitzer, The PHQ-9: a new depression diagnostic and severity measure, *Psychiatr. Ann.* 32 (2002) 509–515.
- [39] R.L. Spitzer, K. Kroenke, J.B.W. Williams, B. Löwe, A brief measure for assessing generalized anxiety disorder: the GAD-7, *Arch. Intern. Med.* 166 (2006) 1092–1097, <https://doi.org/10.1001/archinte.166.10.1092>.
- [40] D.J. Buysse, C.F. Reynolds, T.H. Monk, S.R. Berman, D.J. Kupfer, The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research, *Psychiatr. Res.* 28 (1989) 193–213, [https://doi.org/10.1016/0165-1781\(89\)90047-4](https://doi.org/10.1016/0165-1781(89)90047-4).
- [41] R.A. Washburn, K.W. Smith, A.M. Jette, C.A. Janney, The physical activity scale for the elderly (PASE): development and evaluation, *J. Clin. Epidemiol.* 46 (1993) 153–162, [https://doi.org/10.1016/0895-4356\(93\)90053-4](https://doi.org/10.1016/0895-4356(93)90053-4).
- [42] J.B. Brookings, B. Bolton, Confirmatory factor analysis of the interpersonal support evaluation list, *Am. J. Community Psychol.* 16 (1988) 137–147, <https://doi.org/10.1007/BF00906076>.
- [43] V.D. Sousa, J.A. Zauszniewski, S. Bergquist-Beringer, C.M. Musil, J.B. Neese, A.F. Jaber, Reliability, validity and factor structure of the appraisal of self-care agency scale-revised (ASAS-R), *J. Eval. Clin. Pract.* 16 (2010) 1031–1040, <https://doi.org/10.1111/j.1365-2753.2009.01242.x>.
- [44] N.M. Wineman, E.J. Durand, B.J. McCulloch, Examination of the factor structure of the Ways of Coping Questionnaire with clinical populations., *Nurs. Res.* 43 (n.d.) 268–73. <http://www.ncbi.nlm.nih.gov/pubmed/7937172> (accessed July 26, 2016).
- [45] B. Yao, R.K. Sripada, H. Klumpp, J.L. Abelson, M. Muzik, Z. Zhao, K. Rosenblum, H. Briggs, M. Kaston, R. Warren, Penn State Worry Questionnaire – 10: a new tool for measurement-based care, *Psychiatr. Res.* 239 (2016) 62–67, <https://doi.org/10.1016/j.psychres.2016.02.069>.