American Journal of Alzheimer's Disease & Other Dementias®
Volume 23 Number 4
August/September 2008 382-394

10.1177/1533317508317527
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The Effects of a Multimodal Intervention on Outcomes of Persons With Early-Stage Dementia

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Theories supporting the existence of a use-dependent neuroplasticity in the older brain were used to guide this pilot study. A repeated-measures randomized design was used to test the effectiveness of a multimodal (Taiji exercises, cognitive-behavioral therapies, support group) intervention on cognitive functioning, physical functioning, and behavioral outcomes in persons with dementia. The treatment group (n = 24 persons with dementia) participated in a 40-week intervention, with outcomes assessed at 20 and 40 weeks to assess optimal treatment length. Control group subjects (n = 19 persons with dementia) received attention-control educational programs. At 20 weeks, differences between groups were found for mental ability and self-esteem, with gains in balance being evident. Also, stability in depression and physical health were evident at 20 and 40 weeks for treatment group subjects. Continued improvement in outcomes was not observed at 40 weeks. However, findings support further testing of the intervention along with potential for achieving positive outcomes in early-stage dementia.

Keywords: multimodal intervention; Taiji exercises; randomized design; cognition; balance

Persons with dementia (PWD) experience progressive loss of cognitive, physical, and functional ability beyond that accounted for by normal aging processes.[1] Nonpharmacological interventions initiated early in the disease have the potential to improve outcomes, including cognition and functional ability. Functional status could be improved with exercise, but exercise interventions are rarely recommended for PWD, despite a large body of evidence showing the efficacy of exercise.[2] Studies supporting the effects of exercise on cognitive function have been conducted primarily in institutional settings and with persons at later disease stages.[2-5] Cognitive therapies have also been tested extensively in PWD with consistent improvements in cognitive outcomes that are comparable to drug trials.[6,7] Support programs, such as support groups, have been used with PWD for over a decade, although systematic studies of the benefits of support programs are lacking. Few studies, however, have tested multimodal interventions that combine exercise, cognitive therapies, and support programs for persons in the early to early-middle stages of dementia.[8] The purpose of this pilot study was to test the feasibility and the effects of a multimodal intervention (Taiji exercise, cognitive therapies, and support group) on cognitive functioning, physical functioning, and behavioral outcomes of PWD. The research questions guiding this pilot study included

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This study was funded by Midwest Roybal Center for Aging, Center for Research on Health and Aging at University of Illinois at Chicago, Center for Reducing Risks in Vulnerable Populations, and Internal Research Support Grant, University of Illinois at Chicago College of Nursing.

The authors have reported no conflicts of interest.

This article was presented at Annual Scientific Meeting of the Gerontological Society of America, Dallas, Texas, on November 18, 2006

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1. What are the effects of a multimodal intervention (Taiji exercise, cognitive-behavioral therapies [CBT], and support group) on cognitive functioning, physical functioning, and behavioral outcomes of PWD compared with PWD not receiving the intervention? It was hypothesized that the treatment group would show improved cognitive functioning (mental status), physical functioning (balance, lower leg strength, illness), and behavioral outcomes (self-esteem, depression) compared with the usual care, attention-control group.
2. What are the benefits of a 40-week intervention compared with a 20-week intervention? It was hypothesized that an additional 20 weeks of the intervention (40 weeks total) would achieve gains beyond those achieved with the 20-week intervention.

Theoretical Support

Theories of neurological functioning and regeneration guided this pilot study. Research primarily using animal models suggests that the brain, despite injury, is capable of reorganization, termed brain plasticity. The results of animal studies have been reported since the mid-1980s providing evidence of the brain's capacity to respond structurally to external stimuli.[1,9] Early studies in mice provide evidence of the environmental effects on neuronal density and synapses per neuron. Research indicates that the exercise form may determine the degree of neuronal development, and some exercise forms may improve learning. Using 2 exercise conditions (acrobatic and forced exercise) versus a control, acrobatic animals (rats) were found to form greater numbers of Purkinje cell synapses than comparison groups as a result of the motor learning required in learning a complex task.[10] In adult primates (macaques), new neurons have been found to develop in 3 areas of the brain essential to cognitive functioning: prefrontal, inferior temporal, and posterior parietal cortex.[11] However, findings have not been consistent across studies. Increased numbers of neurons have been found postinjury in animal studies (rats). However, differences in cell proliferation between the groups (complex environment, exercise, or control) have not been consistently found.[12,13] Collectively, studies using animal models suggest the existence of a use-dependent neuroplasticity in the older brain, although findings are lacking in consistency.

In humans, the production of new neurons has been shown to continue even into later years. On the basis of animal studies and clinical trials in humans, plasticity theory suggests that both rehabilitative and pharmacological interventions may facilitate neuronal reorganization and recovery of function.[14-16] Within the rehabilitative framework, studies using humans as subjects have begun to test the effectiveness of enriched environments on preservation of neuronal function, including the slowing of cell death inherent in progressive dementia, such as Alzheimer disease (AD).[16] Robertson and Murre[17] conducted a review of studies regarding brain plasticity in humans and concluded that the adult brain can undergo dramatic changes in neural structures, including dendritic and axonal sprouting. Studies testing the effects of stimulating and rehabilitative activities on neuronal development support the potential effectiveness of multimodal interventions with PWD.

Background

Effects of Exercise on Cognitive, Physical, and Behavioral Outcomes of PWD

The positive effects of exercise on a cognitive functioning of older adults have been well supported. Specific to PWD, results from a meta-analysis of exercise interventions include moderate, positive effects on cognitive performance (effect size [ES] = .57).[2] Specific cognitive effects of exercise for PWD include increase in mental status,[5,18] improved word fluency,[19] and increased free-recall and recognition performance.[20] The types of exercise forms tested include mobility and endurance exercises, isotonic and isometric exercises, endurance-seated exercises, light aerobic exercises, and range of motion and resistance exercises.[2]

A growing body of research supports the positive benefits of exercise on physical outcomes in PWD. Significant effects of exercise in PWD for strength (ES = .75), physical fitness (ES = .69), and functional performance (ES = .59) have been found across 30 clinical trials using a variety of exercise forms.[2] Gains in flexibility (ES = .91) and cardiovascular effects (ES = .62) have also been identified. However, some contradictory findings are evident. In community-dwelling PWD, positive effects on functional outcomes were not showed using both resistance[21] and endurance (walking, exercise bicycle) exercises.[4]

Behavioral outcomes in PWD are often defined in terms of difficult or problematic behaviors. Although reducing problematic behaviors is a recognized priority due to the accompanying care demands and costs, the primary behavioral symptoms in the early-stage dementia are mood changes (increased depression) and lack of interest or apathy.[22] As persons in the early stages of dementia were the target population for the pilot study, appropriate behavioral outcomes included depression and self-esteem. Studies examining the effects of exercise in PWD showed improvements in depression[23-25] and lower rates of depression in exercisers compared with nonexercisers, although sample sizes have tended to be small, <30/group.[26] The type of tested exercise form varied, with home-based aerobic/endurance activities, strength training, balance and flexibility training being most common.

Taiji exercises. Taiji (a more modern spelling of the traditional TaiChi exercise form) is a particularly salient exercise form for PWD as it supports the development of a memory for movement and a relaxation response.[27] Adherence to Taiji is also higher for older adults, 80% for Taiji exercisers compared with <30% for other exercise forms.[28] Also, the American Geriatrics Society[29] has recommended Taiji as the most beneficial form of exercise for fall prevention, although other researchers have noted the need to further investigate the mechanism underlying fall reduction and identify consistent Taiji forms associated with fall reduction.[30] Studies of Taiji (or Tai Chi) in older adults reveal increases in hip and knee flexion, muscle strength, and balance, as well as decreased fear of falling.[31-33] Importantly, in animal studies, the exercise form that produced greater benefits for neurogenesis and synaptic plasticity was acrobatic exercise, requiring motor learning, compared with forced exercises, such as running or exercise on a treadmill.[34] These findings suggest that exercise forms that require motor learning, such as Taiji, will have more positive effects on cognitive functioning than other exercise forms.

Effects of CBT on Cognitive, Physical, and Behavioral Outcomes of PWD

Cognitive training interventions have been shown to improve a variety of cognitive functions, including memory storage and retrieval.[35] In fact, the effects on cognitive functioning for participating PWD are similar to the effects of medications.[7] Cognitive-behavioral therapies combined with use of acetylcholinesterase inhibitors improved cognitive functioning, orientation, and discourse ability compared with medication therapy alone.[36,37] In a review of cognitive therapies, a medium ES was found for multiple outcomes, including learning (Cohen's d = 2.16 for verbal and visual learning).[38] More equivocal outcomes have been reported by Chapman et al.[39] Cognitive therapies resulted in stable cognitive functioning, indicating no significant decline, with no gains in mental status being found. Although some discrepancies in findings are noted, CBT have generally produced benefits on cognitive functioning in PWD.

The effects of CBT on physical functioning in PWD are expected to be limited, given the CBT focus on cognitive and behavioral functioning. Positive effects of CBT on physical functioning have focused primarily on gains in activities of daily living, rather than gains in overall physical ability. Cognitive-behavioral therapies training programs and pharmacotherapies (primarily cholinesterase inhibitors) for PWD have shown improved functional outcomes (activities of daily living) in the combined therapy groups compared with medication alone.[39]

Kasl-Godley and Gatz[40] found evidence for positive benefits of CBT on behavioral outcomes in PWD, including reduction of distress and increased coping. Using experimental designs, CBT have resulted in significant improvements in depression in treatment groups compared with controls (ES range: d = 0.4 to d = 1.0) and decreased anxiety in PWD.[41,42] Importantly, continued improvement in depression in treatment group participants was found at a 6-month follow-up evaluation.[41]

Effects of Support Group Participation on Cognitive, Physical, and Behavioral Outcomes of PWD

Studies testing support group interventions have been limited in both number and outcomes tested. Generally, studies have used 1-group, pre/posttest designs and have included small sample sizes (13-22 subjects).[43,44] Although studies have failed to show a quantitative effect on depression, qualitative findings support positive effects for mood, coping skills, and a positive outlook.[45,46] Tested support group interventions have varied from 16 to 20 weeks, with support for a longer intervention being untested, with the exception of a support program being continuously offered in the Netherlands.[47]

Effects of Multimodal Interventions

Combined exercise and cognitive interventions have been tested in PWD. Positive effects have been found for cognitive and affective outcomes, including depression.[6,48] Persons with dementia receiving combined therapies evidenced less decline in mental status and improvement in depression compared with controls. Positive effects were also found for behavioral disturbances and relationships with others, including maintenance of leisure activities. These limited studies testing combined therapies support the effectiveness of combined interventions on broad outcomes in PWD, including cognition and behavior.

Summary

Previous research supports the effectiveness of exercise and CBT on cognitive, physical, and behavioral outcomes in PWD. Positive outcomes include increased muscle strength and balance, improved health, lower rates of depression, improved mood and coping skills, maintenance of cognitive abilities, and increased activity and social behavior. The long-term benefits of participation in exercise and cognitive stimulation interventions have also been showed. Systematic studies of the effectiveness of support group participation are lacking, although some evidence exists for positive benefits of support groups on affective (lower depression) and behavioral outcomes. Importantly, studies examining brain plasticity have used either an enriched environment or an exercise intervention with positive findings. Altogether, the positive effects of individual (exercise, CBT, support group) therapies and the findings from limited studies testing multimodal interventions support the multimodal intervention tested in this pilot study.

Methods

Study Design

A repeated measures, experimental design was used to test the multimodal intervention with subjects (PWD) being randomly assigned to either a treatment or a control (delayed treatment) group. The intervention consisted of Taiji exercises, CBT, and support group participation. Baseline assessments were conducted at entry into the study, with postintervention assessments at 20 and 40 weeks. Subjects in the control (delayed treatment) group were offered the intervention following the 20-week assessment.

Subjects and Setting

Subjects were recruited for the study using several methods. Referrals to the study were made from physicians caring for PWD following the inclusion criteria provided to local practitioners. Self-referrals were also made, following publication of information regarding the study in the local news media. Interested PWD or family members contacted the study staff and received an initial screening over the phone. If the initial screening was positive, the PWD and family member (if available) completed the consent procedure, assignment to study group and baseline assessment. Criteria for participation of the PWD included: (1) a confirmed diagnosis of irreversible dementia (Alzheimer's, Lewy body, vascular, frontal lobe, or mixed dementia) and (2) a score <2.0 on the Clinical Dementia Rating Scale[49] indicating an early to early-middle disease stage. Persons with dementia were offered assistance with transportation if a family member was not able to assist. All assessments and the intervention were conducted at a neutral location: a centrally located church, which housed several large spaces for the conduct of the Taiji exercises and private meeting rooms for the CBT and support group sessions.

Subjects on an average were 77 years of age and well educated, with a mean of 15.8 years of education, as shown in Table 1. As the study was conducted in a large university setting, the high education level is representative of older adults in the population from which the sample was drawn. The sample's gender was biased toward males, 53% of the total sample, whereas most populations of PWD are primarily female, around 60%. However, no significant differences were found between the treatment and the control groups on any demographic variable. Subjects were equivalent on baseline cognitive, physical, and behavioral measures, further assuring equivalence of groups prior to the intervention (Table 2). No differences between groups in overall baseline morbidity were found as evidenced by both the number of medical diagnoses (Table 1) and ratings on the Cumulative Illness Rating Scale (CIRS; Table 2). Importantly, the study sample represented a range of physical abilities, with 4 subjects requiring the use of a cane or other assistive device for ambulation.

Attendance at all exercise, CBT, and support sessions was excellent. For the Taiji classes, 75% of

Table 1. Demographic Characteristics of Study Sample

Variable	Treatment	Control	Difference
Subject variables	n = 24	n = 19	*t* test
Age, mean (SD)	77.9 (7.9)	76.0 (8.1)	1.1 (*P* = .32)
Education, y	16.2 (3.7)	15.4 (3.9)	1.0 (*P* = .31)
Number of medical diagnoses (excluding dementia)	2.5 (1.9)	2.5 (1.8)	0.02 (*P* = .96)
Sex			Chi-square test
Male	13	10	0.64 (*P* = .42)
Female	11	9	
Clinical Dementia Rating Scale			*t* test
Baseline	1.15 (.49)	1.22 (.57)	−.43 (*P* = .67)

Abbreviations: SD, standard deviation.

subjects attended all 3 sessions weekly, with 90% attending at least 2 of the 3 weekly sessions. Similar attendance rates were evident for the CBT and support group sessions. The primary reasons for nonattendance were traveling to visit family members and illness of either the PWD or the caregiver. Attrition from baseline to 20 weeks in the treatment group (n = 24 to n = 19; 20%) was due to change of residence (1 subject), illness (1 subject), and not needing the intervention (3 subjects). Attrition was greater in the control (delayed treatment) group, 24% (n = 19 to n = 14), despite the offering of attention-control educational programs. Primary reasons for attrition in control group subjects were increased disability (3 subjects), change in residence (1 subject), and involvement in other forms of therapy or exercise programs (1 subject).

Study Variables

The independent variable was the multimodal intervention including Taiji exercises, CBT, and support group participation. Dependent variables included (1) cognitive functioning: Mini-Mental State Examination (MMSE)[50]; (2) physical functioning: single leg stance (SLS), Berg Balance Scale (BBS), and CIRS[51-53]; and (3) behavioral outcomes: Geriatric Depression Scale (GDS) and Rosenberg's Self-Esteem Scale (SES).[54,55] With interval scales, such as Rosenberg's SES, a large-print scoring guideline was reviewed with the PWD to quantify subject responses. The printed guideline was available throughout the interview to assist in providing meaningful responses. Persons with dementia were able to grasp the concept of the scaled responses and described their responses appropriately. Study variables with operational indicators are listed in Table 3.

Independent Variable: Multimodal Intervention

Taiji exercises. The Taiji intervention consisted of 1-hour classes offered 3 times weekly for 40 weeks. Taiji exercises consisted of strength and balance training adapted for the PWD. The Taiji curriculum was a distillate of various components of traditional Taiji training, including form choreography, dynamic Qigong, and standing and sitting meditation The Taiji curriculum was created by YY, specifically for research on older adults.[56] Mind and body connection, mobility, flexibility, and agility are emphasized in the 7 forms. These forms emphasize movements that shift weight while using both the upper and the lower extremities, facilitating flexibility and arm range-of-motion. Some forms may be done in a sitting position, accommodating to subjects with varying ranges of ability and endurance. Inherent in Taiji is the practice of Qigong. "Qi" is a Chinese medicine concept meaning vital energy. "Gong" means exercise or practice. So, Qigong basically means the way of nurturing human vital energy. Qigong relaxation exercises encompassed approximately 30 minutes of the 60-minute class. Instructors had received extensive training in Taiji, with a minimum of 5 years of practice. Although a wide range of exercise interventions have been tested with PWD, alternative exercise forms, such as Taiji, are gaining in acceptance and undergoing more widespread testing and application in clinical settings.[31-33]

Cognitive-behavioral therapies. The CBT included both small groups and individual counseling (based on individual needs) and were conducted bi-weekly for the 40 weeks. The 90-minute sessions were structured and used standard CBT treatments for mood and depression following guidelines by Teri and Gallagher-Thompson.[57] Cognitive strategies were used to challenge dysfunctional cognitions and replace them with positive ones, develop positive coping skills to manage the effects of the disease, and enhance the sense of personal control. Behavioral strategies included the incorporation of participation in pleasant activities into the routine schedule, modifying the activities as needed to allow for success. Homework

Table 2. Differences in Subject Outcomes by Group at Baseline and 20 Weeks (Posttreatment)

Variable	Treatment	Control	Difference, *t* tests
Cognitive functioning			
MMSE			
Baseline	24.8 (3.5)	22.9 (5.2)	1.5 (*P* = .17)
20 wk	25.2 (3.1)	22.4 (7.6)	2.0 (*P* = .05)[a]
Absolute difference	+0.4	−0.5	
40 wk	25.2 (2.4)		
Physical functioning			
SLS			
Left leg, eyes closed			
Baseline	3.4 (6.8)	1.7 (1.1)	0.60 (*P* = .55)
20 wk	6.3 (14.2)	3.6 (4.8)	0.50 (*P* = .62)
Absolute difference	+2.9	+1.9	
40 wk	6.1 (11.2)		
Right leg, eyes open			
Baseline	5.9 (5.6)	6.0 (5.5)	−0.11 (*P* = .91)
20 wk	10.4 (15.5)	3.7 (2.1)	1.7 (*P* = .09)
Absolute difference	+4.5	−2.3	
40 wk	9.8 (19.1)		
BBS			
Baseline	49.1 (5.0)	50.8 (4.2)	−0.86 (*P* = .39)
20 wk	50.8 (4.3)	50.5 (3.5)	0.17 (*P* = .87)
Absolute difference	+1.7	−0.3	
40 wk	48.7 (5.6)		
CIRS			
Baseline	6.8 (3.9)	7.3 (3.8)	−0.41 (*P* = 68)
20 wk	7.2 (4.5)	9.0 (3.7)	−1.6 (*P* = .25)
Absolute difference	+0.4	+1.7	
40 wk	6.8 (4.1)		
Behavioral outcomes			
Geriatric Depression Scale			
Baseline	2.9 (3.4)	3.4 (2.9)	−0.52 (*P* = .61)
20 wk	3.3 (2.9)	4.3 (3.4)	−0.90 (*P* = .37)
Absolute difference:	+0.4	+0.9	
40 wk	3.1 (2.6)		
Rosenberg's SES			
Baseline	39.5 (7.3)	39.8 (8.9)	0.20 (*P* = .89)
20 wk	40.2 (5.1)	35.5 (5.6)	2.68 (*P* = .01)[a]
Absolute difference	+0.7	−4.3	
40 wk	39.1 (5.5)		

Abbreviations: MMSE, Mini-Mental State Examination; SLS, single leg stance; BBS, Berg Balance Scale; CIRS, Cumulative Illness Rating Scale; GDS, Geriatric Depression Scale; SES, Self-Esteem Scale.
[a]Significant between group differences.

activities were assigned to reinforce the use of positive coping strategies. Cognitive exercises focused specifically on memory enhancement, verbal fluency, visual or spatial learning and accuracy, and verbal comprehension. Master's-prepared social workers certified in individual and family therapy conducted the CBT intervention.

Support group. The support group met bi-weekly, alternating with the CBT group. The support group focused primarily on coping with the effects of dementia and creating a sense of a shared experience. Interpersonal connections and development of relationships with others sharing similar experiences were also emphasized. The 90-minute sessions used the group structure for support groups outlined by Yale.[58] Subjects were encouraged to share their experiences with managing dementia at each session, with an emphasis on positive problem-solving for specific issues or concerns. The content of all CBT

Table 3. Study Variables With Operational Indicators

Variable	Operational Measure
Independent variable	
Multimodal intervention	Taiji exercises: 1 h, 3 × wk
	CBT: 90 min bi-weekly
	Support group: 90 min bi-weekly
Dependent variables	
Cognitive functioning	MMSE
Physical functioning	SLS
	BBS
	CIRS
Behavioral outcomes	GDS
	Rosenberg's SES

Abbreviations: CBT, cognitive-behavioral therapies; MMSE, Mini-Mental State Examination; SLS, single leg stance; BBS, Berg Balance Scale; CIRS, Cumulative Illness Rating Scale; GDS, Geriatric Depression Scale; SES, Self-Esteem Scale.

and support group sessions were considered to be confidential and not to be shared outside the group.

Dependent Variables:

Cognitive functioning. The MMSE was developed and tested by Folstein et al[50] as a short, easy-to-administer measure of mental status and screening tool for dementia. The MMSE consists of giving subjects 11 questions or commands, such as what is the year? or write a sentence. The instrument yields a total score of 30, with scores below 24 suggesting dementia. The MMSEs reliability is consistently reported as high, with test-retest coefficients ranging from .83 to .98. Criterion-related validity is evident in correlations of .66 to .78 with standard cognition measures.[59] The MMSE yields an objective measure of mental ability, with the participant's written or verbal response to each question being used to rate each question as either correct or incorrect.

Physical functioning. Three measures reflecting physical functioning, primarily lower leg balance and strength, were included: the SLS, BBS, and a measure of physical illness: CIRS. The SLS measures both lower leg strength and balance. This test takes approximately 6 minutes to complete and consists of asking subjects to stand on a single leg alternately for 60 seconds with both the eyes open and eyes closed. Timing for the stance is recorded by 2 observers simultaneously using calibrated stopwatches. Timing begins with a signal, Start, by a rater, at which time the participant assumes the SLS. This stance is repeated for 3 trials. To assure reliable and objective ratings, rater reliability measures were randomly conducted with 91% to 100% agreement with 2 raters observing and scoring the same assessment (n = 5). Although biomechanical measures are being used increasingly in exercise research, the SLS continues to be used extensively as an objective assessment of balance and exercise outcomes in older adults, with reliability scores ranging from 0.85 to 0.95.[53]

The BBS is a 14-item functional balance assessment that involves simple tasks typically performed over the course of a normal day, such as rising from a chair, standing with one foot in front of the other, and picking up an object from the floor. The assessment takes about 20 minutes to complete. An overall scale score ranges from 0 to 64, with higher scores indicating better balance. This scale has been used extensively in exercise studies with older adults as an objective indicator of balance. In this study, BBS items were rated by 2 observers timing the performance (with calibrated stopwatches) or simultaneously rating the participant's performance (ie, the reach test). Intraclass correlation coefficients measuring the interrater and the intrarater reliability for the test have been adequate, .97[60] to .99, respectively.[51] Correlation coefficients for individual items range from .71 to .99, supporting construct validity. In this pilot study, rater agreement for BBS items ranged from 90% to 100%, supporting the objective, reliable rating of the BBS. The BBS continues to be used as an objective measure of balance in older adults, with reliability measures being equal to or better than similar balance measures.[60-63] The BBS has also been shown to be sensitive to change overtime, an important consideration in a study testing the immediate and the long-term effects of an exercise intervention.[64-66]

The CIRS is a 13-item scale measuring degree of impairment in major body systems on a scale of 0, no impairment to 4, extremely severe impairment. Pathology is represented by adding the 13 items, producing a total scale score. Interrater reliability estimates for 110 ratings of 20 patients were reported as high, ranging from .83 to .91. Survival in 472 persons was predicted using CIRS scores, supporting the instrument's validity.[52] In this pilot study, 2 experienced nurses completed the CIRS, with agreement being 95% to 100% for individual items and the total scale score. This high level of rater agreement supports the objective measurement of CIRS items in this population of PWD.

Behavioral Outcomes

The 15-item GDS was used to measure affective outcomes. When comparing the shortened 5-item GDS version with the longer 15-item version, Lyness et al[54] found the longer GDS (15-items) yielded the highest level of sensitivity at 100% and specificity of 84%, very close to the Center for Epidemiologic Studies Depression Scale. When used with nursing home residents, the GDS has been found to be a useful screening tool in persons with mild to moderate cognitive impairment. Using yes-no responses, PWD were easily able to self-rate the GDS items in an interview format with a trained data collector, providing an objective indicator of depression in the study sample.

Rosenberg's SES consists of 10 items describing self-perceptions of worth on a 5-point scale from strongly agree to strongly disagree.[55] The SES was administered in an interview format, with PWD providing self-ratings of each item. Internal consistency reliability for Rosenberg's SES was adequate in this pilot study, with an $\alpha = 0.89$ to 0.92 across the 3 assessment points. The SES has been used across a variety of disciplines and age groups, including persons with impaired mental ability and has been found to be a reliable and valid indicator of the person's self-evaluation.

Procedures

Following the initial phone contact with study staff, potential subjects were screened (MMSE and Clinical Dementia Rating Scale) to assure early to early-middle stages of dementia. Subjects were randomized to group and completed the baseline assessment, including physical testing. After completion of the baseline testing, treatment group subjects were given a schedule of the times and dates for the intervention, and transportation was arranged as needed. Subjects in the control (delayed-treatment) group were given information about educational programs (attention-control component), contact information for study staff should questions arise, and proposed times for repeat testing in 20 weeks.

Project assistants completing the physical testing received extensive training (two, 2-hour sessions and observation) in the rating of the physical measures prior to the actual assessment. No fewer than 2 raters were available for each testing. The second rater assured the safety of the subject during the physical measures, such as the SLS, and provided additional ratings for items within the BBS. Rater consistency during testing was evaluated through random observations by a third rater simultaneously observing and rating the physical measures with the project assistants. Following a review of the measures, the researcher or assistant completed the cognitive functioning and behavioral measures with the subject.

The Taiji exercise intervention was led by no fewer than 3 instructors, with an assistant to record attendance. Similarly, no fewer than 2 members of the research team led the CBT and the support group interventions. A master's prepared social worker led the CBT intervention, whereas the researcher, a gerontological nurse practitioner, led the support group. Follow-up phone calls were made to subjects if they missed more than 1 treatment session. As reported earlier, attendance at all intervention sessions was excellent, with subjects expressing high motivation and positive responses to their participation and potential benefits.

Results

Data were entered and cleaned using the SPSS 13.0 (SPSS Inc, Chicago, Illinois) statistical package. Due to the large standard deviations for the SLS data, transformations were performed on the raw data for this measure prior to analysis. The psychometric testing included in the pilot study supported the reliability of the study measures. Rater reliability estimates for the SLS ranged from 91% to 100% agreement on the timed ratings with 2 raters observing and scoring the same stance ($n = 5$). For the BBS, rater agreement for selected items ranged from 90% to 100%. Internal consistency reliability for Rosenberg's SES was adequate, $\alpha = 0.89$ to 0.92 across the 3 assessment points. Two experienced nurses completed the CIRS, with agreement being 95% to 100% for individual items and the total scale score. Due to the small sample size and resulting low power, group differences (independent) and change overtime (dependent) were examined primarily using *t* tests to assess for significant effects of the intervention.

Research Question 1

What are the effects of a multimodal intervention on cognitive functioning, physical functioning, and behavioral outcomes of PWD? Some improvement in MMSE scores was evident for treatment group subjects (+0.4), whereas for control group subjects the scores declined over the first 20 weeks of the intervention (−0.5). Scores for the MMSE varied significantly between the groups at 20 weeks (independent samples *t* tests, Table 2), whereas baseline scores did not differ. For physical functioning, treatment group subjects showed gains in scores on balance measures following the first 20 weeks of the intervention (Table 2) for the SLS, although between and within group differences were not significant. For the eyes open SLS measure, treatment group subjects increased by 4.5 seconds, whereas the control group subjects decreased by −2.3 seconds. Findings from the BBS scores indicated the same trends. Scores increased by 1.7 points for the treatment group, whereas scores declined slightly (−0.3) for the control group, although differences were not significant. Scores showed a stabilization effect for illness (CIRS), with treatment group subjects increasing by 0.4 points and the control group increasing by 1.7 points on illness ratings.

Some group differences were found for the behavioral outcomes. Between group differences were evident for self-esteem (SES) at 20 weeks (independent samples *t* tests) although no baseline differences were found. Treatment group subjects increased slightly in self-esteem, whereas control group subjects declined in self-esteem. A nonsignificant stabilization effect was found for depression, with the treatment group subjects increasing by 0.4 and the control group increasing by 0.9 on the GDS.

Research Question 2

What is the optimal length of the intervention, 20 versus 40 weeks? For all outcomes, no significant gains were found from 20 to 40 weeks for any outcome variable. The MMSE scores remained stable, but did not increase. Ratings on the SLS also remained stable, whereas slight decreases were found for the BBS. Scores for the CIRS returned to baseline, indicating a positive, but nonsignificant effect on illness ratings. Behavioral outcomes did not improve significantly although a slight decrease in depression and stabilization in self-esteem was evident from 20 to 40 weeks. Overall, significant improvement in outcomes was not evident from the 20- to 40-week assessments, representing effects from the additional 20 weeks of treatment. However, a continued stabilization effect was noted. As the control group entered the treatment after the 20-week assessment, scores for control group outcomes at 40 weeks (representing no treatment) were not available.

Discussion

Overall findings are encouraging regarding the feasibility of conducting a multimodal study with persons in the early stages of dementia, including persons with significant functional impairment. Findings also provide preliminary support to the potential benefits of the intervention. The treatment group showed improved cognitive functioning following the 20-week intervention, with significant differences in MMSE scores between groups being evident following the intervention although no significant differences were found at baseline. Gains in MMSE scores at 40 weeks were not evident, however, for the treatment group. The lack of continuing increases in MMSE scores with the sustained treatment may be due, in part, to the MMSE's limits in measuring change in mental ability overtime. It is suggested that other dimensions of cognitive functioning, such as spatial and verbal memory, attention, and psychomotor speed, be measured in future studies to more fully capture any positive benefits from the intervention for overall cognitive functioning.

Physical functioning, reflected by gains in the SLS, improved for the treatment group following the 20-week intervention, although these scores did not reach statistical significance. Clinically, significant changes may be reflected in the SLS scores, however, given that the times almost doubled following the intervention. The SLS scores increased 85% from baseline for the treatment group, with this outcome exceeding gains found in other studies (43%).[32] This increase in ability to perform a SLS may reflect overall improved balance. This effect was observed in 2 subjects who began the intervention using assistance (cane or walker) for ambulation. Both men were able to walk without assistance following the 20-week intervention and maintained that ability throughout the study. Although a small gain was found in 1 aspect of the SLS for the control group, a lower score was evident in the other measure (right leg, eyes open).

Although further gains in balance and leg strength were not observed with the additional 20 weeks of the intervention, physical functioning remained stable. These findings suggest that the additional 20 weeks of Taiji exercise may be beneficial for maintaining any gains in functioning achieved following the first 20 weeks, but may not result in continued improvement in lower extremity strength or balance.

Behavioral outcomes displayed trends toward improvement for treatment group subjects, although only self-esteem scores varied significantly between the groups following the 20-week intervention. The trends found in the stabilization of depression, although not significant, were encouraging given the small sample size. Anecdotal responses from subjects during the exit interview indicated that participation in the intervention was perceived as a positive experience. Some sample comments included: “This has been the only thing I've found that feels like I'm doing something to help myself”, “It's great to have positive things to do-I now feel as if I'm doing something about my memory loss”, “I really enjoy the exercises—I feel better on the days that I exercise”, and “These people feel like my family—I'm more comfortable here than I am about anywhere else right now.” These anecdotal comments were consistently positive and reflected the personal benefits to subjects, supporting the stabilization in depression and modest gains self-esteem. Importantly, treatment group subjects improved in self-esteem, whereas control group subjects declined. Given the progressive nature of dementia, this improvement in treatment group subjects is a noteworthy response to the intervention.

Consistent with the extant literature regarding multimodal interventions, including exercise and cognitive therapies, results from this pilot study support the potential benefits of an exercise intervention focusing on balance and strength training in older adults. The benefits of an alternative exercise form, such as Taiji, for PWD include high adherence rates, potential for fall prevention, and benefits for cognitive functioning due to required motor and sequence learning.[28,34] Interestingly, this exercise form has also been used as a videoconferencing, internet-based intervention delivered in the home setting with increases in balance and strength found in older adults (mean age, 81 $\pm$ 8 years).[32] Cognitive and emotional benefits of exercise for PWD have been well supported in other studies, including decreased depression and apathy in exercisers compared with nonexercisers.[5,18-20,23,24] Findings from this pilot study are also consistent with the growing body of research describing the effects of CBT on cognitive and behavioral outcomes, including depression.[7,36-38,40] Overall, results from this preliminary study are consistent with findings from previous studies, including the measures used to assess the effects of the multimodal intervention.

Recommendations for Future Studies

Throughout the 40-week intervention, it became evident that overlap existed between the support group intervention and CBT. Additionally, significant interpersonal interactions were occurring in both the CBT and the Taiji exercise sessions. To test the most parsimonious intervention, it is suggested that future research include only the Taiji exercise and the CBT components of the multimodal intervention. As many forms of Taiji exist, it is further suggested that the multivariable components of traditional Taiji training be studied separately to evaluate individual and combined effects of various aspects of traditional Taiji training. Also, as significant social support occurred within all components of the intervention, future studies should include support mechanisms for control group subjects to eliminate this threat to internal validity. Due to repeated administrations of the MMSE, some learning effects may be evident in MMSE scores. Future studies should include cognitive measures with multiple forms to prevent any learning effects from influencing reliable measurement of cognitive functioning. Additionally, biomechanical measures of physical functioning should be included as outcome measures, along with the observation measures used in this pilot study. Due to the funding limits of this pilot study, the intervention's posttreatment, long-term effects were not evaluated—a recommendation for future studies. Long-term outcomes, such as total costs of care, incidence of falls, and maintenance in the home, would be meaningful outcomes to fully evaluate the intervention's effects.

Conclusions

Findings support the feasibility of conducting an intensive intervention with persons in the early to early-middle stages of dementia. Improvements in physical outcomes (SLS) in treatment group subjects provide some evidence that subjects were able to reproduce and use the Taiji exercises, suggesting that learning occurred. Although the control group declined in self-esteem, treatment group subjects increased, again possibly reflecting utilization of the interventions. A stabilization effect was also found for both illness and depression ratings in the intervention group. In the presence of a progressive neurological disease, such as dementia, declines in performance are an expected result. Stabilization, then, may actually represent positive effects. Increases in functioning, such as those found for mental status and balance, are particularly promising in view of the progressive nature of dementia. Testing combined therapies optimizes the power of the intervention while operationalizing an enriched environment essential to the cognitive model on which this study was based. Using the intervention with persons in the early to early-middle AD stages optimizes the likelihood of effective learning and a training effect on outcomes. With further testing, this multimodal intervention may prove to be an effective adjunct therapy along with pharmacotherapies for persons in the early stages of dementia.

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