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A Randomized Controlled Trial of an Activity Specific Exercise Program for Individuals With Alzheimer Disease in Long-term Care Settings

Kathryn E. Roach, PhD, PT¹, Ruth M. Tappen, RN, EdD², Neva Kirk-Sanchez, PT, PhD¹, Christine L. Williams, RN, DNSc², and David Loewenstein, PhD, ABPP/CN³

¹ Department of Physical Therapy, Miller School of Medicine, University of Miami, Coral Gables, Florida

² Christine E. Lynn College of Nursing, Florida Atlantic University, Boca Raton, Florida

³ Department of Psychiatry, Miller School of Medicine, University of Miami, Miami, Florida

Abstract

Objective—To determine whether an activity specific exercise program could improve ability to perform basic mobility activities in long-term care residents with Alzheimer disease (AD).

Design—Randomized, controlled, single-blinded clinical trial.

Setting—Residents of 7 long-term care facilities.

Participants—Eighty-two long-term care residents with mild to severe AD.

Intervention—An activity specific exercise program was compared to a walking program and to an attention control.

Measurements—Ability to perform bed mobility and transfers were assessed using the subscales of the Acute Care Index of Function; functional mobility was measured using the 6-Minute Walk test.

Results—Subjects receiving the activity specific exercise program improved in ability to perform transfers, whereas subjects in the other 2 groups declined.

Keywords

Alzheimer disease; exercise; mobility; randomized controlled trial

Address correspondence to: Kathryn E. Roach, PhD, PT, Department of Physical Therapy, Miller School of Medicine, University of Miami, 5915 Ponce de Leon Blvd., Plumer Bldg. 5th Floor, Coral Gables, FL 33146 (keroach@miami.edu).

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R. Tappen, K. Roach, and D. Loewenstein originated the study and obtained the funding. K. Roach designed the exercise intervention and trained the exercise intervenors. K. Roach analyzed the data and K. Roach, N Kirk-Sanchez, R. Tappen, C. Williams, and D. Loewenstein were involved in interpreting the data. N. Kirk-Sanchez was involved in data collection. C. Williams was involved in recruiting subjects. K. Roach drafted the paper. N Kirk-Sanchez, R. Tappen, C. Williams and D. Loewenstein critically revised the paper. All authors contributed to the intellectual content of the manuscript and approved the final version.

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INTRODUCTION

Estimates based on US Census data suggest that there will be 13.2 million Americans with Alzheimer disease (AD) by 2050.¹ A large proportion of individuals with dementia eventually require assistance to perform daily activities such as dressing, toileting, and walking.^{2,3} Caring for an individual with dementia can take a heavy toll; the greater the amount of physical assistance required by the individual, for example, the greater the risk of depression in the caregiver.⁴ Nursing home placement often results when the need for physical assistance exceeds the capacity of the caregivers to provide it.⁵ Although dementia severity is a critical predictor of nursing home placement, the amount of assistance required to perform basic activities of daily living appears to be independently associated with risk of institutionalization and may actually be more important than behavioral or psychiatric symptoms.^{3,5,6} Furthermore, the intensity of care required by individuals in an institutional setting is determined by both severity of cognitive impairment and the amount of assistance they require to perform basic activities of daily living such as toileting and transfers from bed to chair.^{7,8}

In older adult individuals, including those residing in nursing homes, impaired strength, range of motion and balance have been associated with difficulty performing basic activities of daily living.^{9,10} There is mounting evidence that in community-dwelling older individuals, impairments in strength¹¹ flexibility,¹² balance,^{13,14} and gait speed can be reduced through targeted exercise programs.^{15–17} The benefits of exercise also extend to residents of nursing homes. Fiatarone and Evans¹⁸ found that high-intensity resistance training resulted in greater gait velocity, stair climbing power, spontaneous activity level and cross-sectional thigh area in nursing home residents. The positive response to exercise is important because improved strength, balance, and ROM have been linked to improved ability to perform activities of daily living.^{15,16,19–21} However, matching the specificity, intensity, and duration of the exercise program to the characteristics of the subjects appears to be a critical determinant of success. Programs that are not activity specific but are instead designed for general lower extremity strengthening may not improve ability to perform specific activities such as transfers.^{22,23} Intensity and duration of treatment also appear to be important factors. Chiodo et al²⁴ found that 55% more patients improved when subjected to high intensity (3 or more sessions per week for at least 8 weeks) than moderate intensity exercise. It is particularly challenging to design effective exercise programs for individuals with cognitive impairment.^{24–26}

The purpose of this study was to determine whether an activity specific exercise program is more effective than an assisted walking program or social conversation in improving ability to perform basic mobility activities of daily living in long-term care residents with AD.

METHODS

Study Design

This study was a randomized, controlled, single-blind study comparing an activity specific exercise program to a supervised walking program and an attention control (social conversation) group. Raters were blind to treatment group assignment. All interventions were delivered 5 days per week for 16 weeks. Intensity and duration were determined based on our previous experience with exercise interventions in this population.²⁷ The effect of these interventions on mood have been reported previously.²⁸

Study Participants

Eligibility criteria included (1) residence in a long-term care facility; (2) clinical evidence based on a thorough chart review, of probable or possible AD based on the National Institute

of Neurological and Communication Disorders and Stroke--Alzheimer Disease and Related Disorders Association [NINCDS-ADRDA] criteria²⁹; (3) dependence in at least one of the following: bed mobility, transfers, gait, or balance; and (4) ability to walk with or without assistance. Potential participants who walked unaided for 30 minutes or more on their own were excluded. The study was approved by the University of Miami and Florida Atlantic University institutional review boards as well as any participating nursing home that had its own review board. Written consent was obtained from next of kin or legal guardian.

Interventions

Activity specific exercise group—Subjects assigned to the exercise group received an exercise program designed to slow the decline in or improve ability to perform basic mobility activities such as balancing in sitting and standing, transferring from sitting to standing and from bedside to a chair. Because subjects with AD have an impaired ability to learn new information or recall previously learned information, the exercise program was designed around familiar functional activities. The exercise program had 4 components: strength, flexibility, balance, and endurance.

The strength and flexibility exercises were designed to strengthen the trunk and lower extremities by performing eccentric and concentric work in moving the body against gravity. The first of these exercises were hip and knee bends followed by toe rises performed with subject and intervener facing each other in dance position. The muscle groups involved in this activity are the same ones required to perform a sit-to-stand or stand-to-sit transfer. The second exercise was performed with both the subject and intervener seated facing each other and required the subject to lean forward while pushing against the intervener and then lean backward while pulling against the intervener. This exercise was designed to increase trunk strength and as well as hip and trunk flexibility to facilitate the subject's ability to shift the center of gravity over the base of support as is required to transfer sit to stand.

The second set of exercises focused on balance and weight shifting. The subject and intervener performed the exercises in standing with the intervener facing the subject as if in dance position. Subjects placed their hands on the interveners' shoulders and the interveners placed their hands on the gait belt fastened around the subject's waist. The subjects and interveners then side stepped to the left and to the right, walked backward and turned in a complete circle. All exercises began with 2 to 3 repetitions and progressed to 7 to 9 repetitions over the 16-week intervention period based on a predetermined schedule. The amount of assistance provided was reduced and the amount of resistance was increased as the subject improved in their ability to perform the exercise. Total contact time with the subjects in the exercise group started at 15 minutes and increased to 30 minutes by the end of the intervention period.

The final aspect of the comprehensive exercise program was a supervised walk. The subject was allowed to use an assistive device and/or moderate physical assistance and to rest as needed. Verbal cues and physical assistance were given to encourage the subject to attend to the walking task. The duration of the walk started at 10 minutes and progressed to a maximum of 20 minutes.

Supervised Walking Group

Subjects assigned to the walking group performed a supervised walking activity. They were allowed to use an assistive device and were provided with physical assistance as required. Participants were allowed to walk their usual pace and were permitted to rest as needed. Walking sessions initially lasted 15 minutes. The pace, distance, and duration of the walking

session were increased incrementally up to a maximum of 30 minutes and were matched to the duration of contact in the activity specific exercise group.

Social Conversation Control Group

Subjects assigned to the conversation group were engaged in casual, one-on-one conversation with an intervener. Conversations occurred in the participant's room or in a nearby quiet room at the nursing home. Participants were encouraged to talk about topics that interested them. Therapeutically oriented interaction including reminiscence, life review, or cognitive exercise was avoided. Sessions began with 15 minutes of conversation and were progressed as tolerated until 30 minutes was reached. Length of sessions was matched to the duration of the other 2 groups.

Graduate nursing and physical therapy students trained and supervised by the investigators provided all 3 interventions. Before each session with a participant, interveners checked with the charge nurse for any health issues that might preclude treatment. They also monitored vital signs before and after each exercise or walking session. Interveners met with an investigator weekly to problem solve and discuss each participant's progress. On-site visits were made by an investigator every 2 to 3 weeks to observe sessions for quality and consistency.

Primary Outcome Measures

The Acute Care Index of Function—The Acute Care Index of Function (ACIF)^{30,31} was designed for use in an acute neurology setting to measure basic activity limitations in the areas of bed mobility, transfers, and ambulation in patients who often have cognitive and language impairments. The ACIF was selected for use because the subjects in this study had similar impairments and activity limitations. The index contains 20 items and 4 subscales: mental status, bed mobility, transfers, and mobility. It is rater-administered based on direct observation of subject performance. Examination of the item, subscale, and total index score reliability produced intraclass coefficients ranging from 0.98 to 0.99.²⁹ The validity of the ACIF has also been demonstrated in relationship to clinical judgment and discharge destination.³⁰ The transfer subscale contains 6 items involving transfers sit to stand to sit, bed to chair to bed, and sitting and standing balance. Subjects are rated as independent if they can perform the activity without assistance, dependent if they require physical assistance to perform the activity and unable if they cannot physically assist in performing the activity. Transfer subscale scores can range from 0 to 1.0 with 0 indicating that the subject is unable to perform all activities, 0.5 indicating that a subject is dependent in all activities and 1.0 indicating that the subject is independent in all activities.³¹ The Mobility scale contains 4 items involving rolling to both sides and moving from supine to sitting to supine. Subjects are rated as independent if they can perform the activity without assistance, dependent if they require physical assistance to perform the activity, and unable if they cannot physically assist in performing the activity. Bed Mobility scores can range from 0 to 1.0 with 0 indicating that the subject is unable to perform all activities and 1.0 indicating that the subject is independent in all activities. The ACIF Mobility subscale includes items dealing with climbing and descending stairs and wheelchair mobility. Because we felt that these items were not relevant to this subject population, we chose to use the 6-Minute Walk instead of this subscale as a measure of functional mobility.

The 6-Minute Walk—This test was used as a measure of functional mobility. It was performed as a free walk and scored as the distance in feet covered in the 6-minute time interval.³² Subjects were allowed to use assistive devices and were provided physical assistance as needed. Subjects were also allowed to rest during the 6-minute period. The total distance a subject walked was measured with a calibrated surveyor's wheel. Interrater

reliability and validity of this method of administering the 6-Minute Walk test in this population were established previously.³² Intraclass correlation coefficient (ICC) calculation for intrarater and interrater reliabilities ranged from 0.80 to 0.99 for this measure. Stability over 1 week yielded ICCs of 0.99 for the morning and 0.97 for the afternoon.³² A study of the 6-Minute Walk test as a measure of mobility related function in older adults found that residents of retirement homes walked an average of 901 ft in 6 minutes and their scores ranged from 300 ft to 1665.³³ Since 300 ft was the lowest score found in this study, we classified subjects as having low mobility if they had a baseline scores on the 6-Minute Walk test of fewer than 300 ft.

Other Variables

Mental status was measured using the Mini-Mental State Examination (MMSE). The MMSE is an 11-item examination measuring cognitive status with a maximum score of 30 points. The MMSE has been validated against clinical diagnosis and the Wechsler Test. The MMSE tests orientation, attention, registration, calculation, recall, and language. High (0.89) test-retest reliabilities have been reported.³⁴

Procedure

Informed consent was obtained from each subject's next of kin or legal guardian and assent was obtained from those subjects who were cognitively capable of providing it. When all baseline testing was completed, participants were randomly assigned to 1 of 3 groups; activity specific exercise, supervised walking, or social conversation. All interventions were provided 5 days per week for 16 weeks. The duration of the treatment sessions was gradually increased during 16-week intervention period. Treatment sessions lasted 15 minutes during weeks 1 through 6, 20 minutes during weeks 7 through 12, and 30 minutes weeks 13 through 16. All posttesting was performed by a rater who was blinded to group assignment.

Adherence Monitoring

Interveners completed a treatment log after each session. They recorded the participant's vital signs and details of each session, the participant's response, and explanations for any missed sessions. Interveners also recorded the number of repetitions of each exercise as well as walking, exercise, or conversation time in minutes, the total of which constitutes the treatment intensity measure.

Analysis of the Data

Data were analyzed with SAS statistical software Version 9.1.3 (SAS Institute, Cary, North Carolina). Descriptive statistics were calculated to characterize the subjects. Student *t* tests and chi-square statistics were used to compare subjects who did and did not complete the study. Analysis of variance and chi-square tests were used to compare baseline characteristics of subjects in the 3 intervention groups. Repeated measures analysis of variance was used to compare the pre-post intervention change in the 3 groups and in a subgroup analysis of subjects with low mobility at baseline. Pearson correlation coefficients and Student *t* tests were calculated to examine the possible influence of baseline characteristics on changes in the outcome measures.

RESULTS

Attrition

Informed consent to participate was obtained from a health surrogate for a total of 135 residents. Of these 135 subjects, 26 withdrew because of illness, increased disability, or

death prior to baseline testing. Another 4 subjects started, but did not complete baseline testing for similar reasons. A total of 105 subjects began the intervention. Twenty-three subjects withdrew before posttesting was completed due to illness, hospitalization, death due to unrelated causes, or transfer out of the facility. Twenty-seven percent of the supervised ambulation group failed to complete follow-up testing compared to 18% of the exercise group and 19% of the conversation group, but the difference was not statistically significant ($P = .55$). Complete physical performance data were available for 82 subjects.

The demographic and clinical characteristics of the subjects who failed to complete the study appeared very similar to those of the subjects who completed follow-up testing. There were no statistically significant difference between subjects who did and those who did not complete the study (Table 1). The 2 groups of subjects were very similar in age, height, weight, and MMSE. They were also nearly equivalent on baseline Six-Minute Walk test score and ACIF transfer and Bed Mobility scores. Men appeared somewhat more likely to drop out than women (33.33% vs 19.54%, $P = .20$), but this difference was not statistically significant. Twenty-seven percent of the supervised ambulation group compared to failed to complete follow-up testing compared to 18% of the exercise group and 19% of the conversation group, but the difference was not statistically significant ($P = .5460$).

Baseline Equivalence

Of the 82 subjects who completed follow-up testing 28 were randomly assigned to the exercise group, 25 to the conversation group, and 29 to the walking group. The demographic and clinical characteristics of the 3 intervention groups were very similar for age, sex, height, weight, mood, and visual or hearing impairments (Table 2). The walking group had a somewhat higher mean MMSE score than the other 2 groups (12.20 vs 8.71 and 9.44) but this was not statistically significant. The groups were also very similar in sex mix. The exercise group had a smaller proportion of subjects in the low-mobility group at baseline (35.71% vs 64.00% and 62.07%) and this difference approached statistical significance ($P = .063$).

Effect of the Intervention

The Transfer scale scores of subjects in the exercise group increased 6.0% compared to a 2.5% decrease in the conversation group and a 5.7% decrease in the walking group (Table 3). When the analysis was restricted to subjects with low mobility at baseline, the Transfer scale scores of the exercise group increased 17.4% whereas the conversation group decreased 5.6% and the walking group decreased 6.1% (Table 4).

The Bed Mobility scores of subjects in all 3 groups remained essentially unchanged. When the analysis was restricted to subjects with low mobility at baseline, the exercise group, and walking groups remained essentially unchanged whereas the scores of the subjects in the conversation group decreased 11% (Table 4), however, these differences were not statistically significant.

The baseline 6-Minute Walk distance for the exercise group was substantially greater than those of the other 2 groups and it remained essentially unchanged following the intervention. The 6-Minute Walk distance for the conversation group increased 9.5% and the walking group increased 11.4% following the intervention. When the analysis was restricted to subjects with low mobility at baseline, the baseline 6-Minute Walk scores were more similar across the groups. Following the intervention, the 6-Minute Walk scores of subjects in the exercise group increased 29.5% and the walking group increased 23.2% whereas the conversation group only increased 7.1%; however, these findings were not statistically significant (Table 4).

Relationship Between Baseline Characteristics and Changes in Outcome Measures

Age, baseline cognitive status, mood, and length of stay were not related to changes in ACIF transfer score or 6-Minute Walk test score (Table 5). There was a weak but statistically significant relationship between baseline ACIF transfer score and change in ACIF transfer score.

DISCUSSION

Interest in the effects of exercise on the function of frail older adults has increased rapidly in the past few years. However, the majority of recent studies have systematically excluded older people with AD.^{15,35–38} Because this study focused on these previously excluded subjects, it provided evidence that an activity specific exercise program can preserve or improve the ability to perform transfer and mobility activities in individuals who have been institutionalized because of AD. Physical performance, including mobility, requires a certain degree of flexibility, strength, balance, and endurance.^{9,10} The loss of these body functions as a result of disease or decreased activity can produce a range of activity limitations in individuals who have AD.²⁶ The exercise program used in this study was designed to improve flexibility, strength, balance, and endurance by incorporating familiar activities that are components of transfer and mobility tasks.

Specificity of training is one important training parameter in designing successful exercise programs. The results of this study support this concept. Although subjects assigned to both the exercise group and the walking group engaged in physical activity, only the exercise group improved in ability to transfer, whereas subjects in the walking group experienced a decline in ability to perform transfers (Table 3). This finding was even more pronounced for the low mobility group (Table 4). General activity in the form of walking was not sufficient to improve or maintain ability to perform transfers in either the high or low-mobility groups. The average baseline ACIF transfer score for the low mobility group was 0.75, indicating that subjects were dependent in 3 of the 6 Transfer scale activities and suggesting that they could only perform these activities when someone was available to assist them. At posttest, the mean Transfer scale scores of both the conversation group and the walking group had declined slightly (Table 4) whereas the exercise group's Transfer scale score had increased to 0.81 indicating that this group was on average dependent in only 2 activities. Both the exercise group and the walking group engaged in a walking activity and in the low mobility group both the exercise and walking groups improved in 6-Minute Walk distance whereas the conversation group's scores remained unchanged (Table 4).

Intensity of training must also be considered. There is evidence that in frail older adults, high-intensity exercise produced greater improvement in function than did low-moderate intensity exercise.³⁹ The exercise program used in this study was relatively more intense for the subjects with low mobility at baseline. This may explain the finding that the positive effect of the targeted exercise program was even more pronounced when the analysis was restricted to the relatively more frail subset of subjects who had low mobility at baseline.

Important components of a successful exercise program for persons with dementia are concrete structure, repetition, and familiarity with equipment, sequence, and training personnel.²⁶ The exercise program tested in this study did not require subjects to use exercise devices or perform complicated, novel exercises. Instead the exercise program simply required the physical assistance of another person to perform familiar activities. This program was performed by the same intervener at each session and was completed in the subject's room. The majority of participants were able to complete the exercise program, despite the fact that the average MMSE of the participants in this program was 10.7, indicating moderately severe cognitive impairment.

Another benefit of this exercise program is that although the individual assisting with the exercises must be trained to perform them effectively, the simplicity of the activity specific exercise sequence would allow nursing assistants in the residential setting or family members in the home setting to implement the program. This suggests that this type of activity specific exercise program could be provided to a wide range of cognitively impaired individuals under the supervision rather than direct care of physical therapists.

Limitations

Although there were no statistically significant differences in baseline characteristics among the groups, the MMS score of the walking group was somewhat higher than that of the other 2 groups. However, baseline MMS score was not related to change in ACIF transfer score or change in 6-Minute Walk test score (Table 5). The walking group also had a somewhat higher baseline Transfer scale score than that of the other 2 groups. Baseline Transfer scale score was very weakly correlated with change in Transfer scale score, suggesting that this difference might explain a small portion of the differences among the groups.

Because of the advanced age of our subjects, our attrition rate was more than 25% resulting in fewer than 30 subjects per condition. The high attrition rate was not unexpected given the advanced age of these subjects. However, there was not a statistically significant difference in rate of attrition between study groups. Moreover, even when groups were divided into high- and low-initial mobility groups, there was still sufficient statistical power to detect statistically significant group \times time interactions.

Conclusion

The activity-specific exercise and walking program described in this study was designed to improve strength, flexibility, and balance and decrease activity limitations related to transfers and basic mobility tasks. The program used familiar tasks easily accomplished by people with severe dementia. The program was designed to be implemented 5 times per week by a nursing assistant or family member under the supervision of a physical therapist. Results of this study suggest that walking programs may not be sufficient to improve mobility limitations in individuals who are dependent in transfers and support the benefit of a targeted, simple exercise program in reducing mobility limitations in institutionalized patients with moderate to severe cognitive impairment.

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Table 1

Comparison of Participants Who Did and Did Not Complete the Study

Characteristic	Completed, Mean (SD) (N = 82)	Did not Complete, Mean (SD) (N = 23)	<i>t</i>	<i>P</i>
Age (years)	88.23 (6.13)	86.65 (6.19)	1.09	.28
LOS (days)	987.84 (877.9)	884.35 (539.61)	0.70	.49
MMSE	10.17 (7.58)	12.13 (7.98)	-1.08	.28
Height (in)	62.11 (3.89)	62.93 (3.07)	-0.91	.36
Weight (lb)	129.62 (25.94)	133.78 (19.69)	-0.71	.48
6 MWT (ft)	339.29 (231.32)	356.48 (251.65)	-0.31	.76
ACIF Transfer	0.83 (0.20)	0.77 (0.24)	1.24	.22
ACIF Bed Mobility	0.85 (0.25)	0.86 (0.26)	-0.13	.90

Abbreviation: 6 MWT, 6-Minute Walk Test.

Table 2

Baseline Equivalency of Participants Completing the Study

Characteristic	Exercise, Mean (SD) (N = 28)	Conversation, Mean (SD), N = 25	Walking, Mean (SD), N = 29	F	p ^a
Age (years)	89.18 (6.54)	88.24 (5.80)	87.31 (6.08)	0.66	.52
LOS (days)	1072.93 (967.61)	929.32 (553.24)	956.14 (1026.17)	0.20	.82
Mini-mental status	8.71 (7.83)	9.44 (7.21)	12.20 (7.47)	1.71	.19
Height (in)	61.93 (4.08)	62.04 (3.31)	62.34 (4.28)	0.09	.92
Weight (lb)	129.32 (19.78)	127.20 (24.46)	132.00 (32.34)	0.23	.80
6 MWT (ft)	387.07 (214.84)	296.64 (229.40)	329.93 (247.35)	1.05	.36
ACIF transfer	0.83 (0.21)	0.79 (0.21)	0.88 (0.17)	1.49	.23
ACIF bed mobility	0.87 (0.22)	0.86 (0.28)	0.83 (0.25)	0.15	.86

^a ANOVA.

Abbreviations: ANOVA, analysis of variance; 6 MWT, 6-Minute Walk Test.

Table 3

Pre Post Intervention Change by Group

Outcome	Exercise, Mean (SD) (N = 28)		Conversation, Mean (SD) (N = 25)		Walking, Mean (SD), (N = 29)		p ^a
	Pre	Post	Pre	Post	Pre	Post	
ACIF transfer	0.83 (.21)	0.88 (.19)	0.79 (.21)	0.77 (.27)	0.88 (.17)	0.83.20	.04
ACIF bed mobility	0.87 (.22)	0.87 (.27)	0.86 (.28)	0.82 (.31)	0.83 (.25)	0.84 (.25)	.77
6 MWT [ft]	387.07 (214.84)	384.86 (217.56)	296.64 (229.40)	324.80 (274.36)	329.93 (247.35)	367.51 (300.15)	.61

^aRepeated-measures ANOVA, time × group interaction.

Abbreviation: ANOVA, analysis of variance.

Table 4
Pre Post Intervention Change by Group in Participants With Low Mobility at Baseline

Outcome	Exercise, Mean (SD) (N = 10)		Conversation, Mean (SD) (N = 16)		Walking, Mean (SD) (N = 18)		p ^a
	Pre	Post	Pre	Post	Pre	Post	
ACIF transfer	0.69 (0.23)	0.81 (0.23)	0.71 (0.20)	0.67 (0.29)	0.82 (0.19)	0.77 (0.21)	.04
ACIF bed mobility	0.76 (0.25)	0.77 (0.36)	0.81 (0.32)	0.72 (0.35)	0.78 (0.27)	0.79 (0.28)	.63
6 MWT [ft]	163.90 (78.97)	212.20 (137.54)	151.31 (64.22)	162.00 (113.85)	183.28 (83.60)	225.83 (169.47)	.64

^aRepeated-measures ANOVA, time × group interaction.

Abbreviation: 6 MWT, 6-Minute Walk Test.

Table 5

Relationship Between Baseline Characteristics and Changes in Outcome Variables

Variable	Pre-Post Change ACIF Transfer (N = 82)		Pre-Post Change 6 MWT (N = 82)	
	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>
Age	0.15	.17	-0.20	.08
MMSE	0.14	.20	-0.12	.29
LOS	-0.09	.44	-0.09	.40
Baseline ACIF transfer	-0.27	.02	-0.01	.93
Baseline 6 MWT	-0.06	.61	-0.11	.34