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Original research

Effects of a long-term aerobic exercise intervention on institutionalized patients with dementia

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ABSTRACT

Objectives: Long-term interventions aimed at analyzing the impact of physical exercise on important health markers in institutionalized individuals with dementia are relatively scarce. This longitudinal study intends to identify the effects of a physical exercise program on cognitive decline, memory, depression, functional dependence and neuropsychiatric disturbances in institutionalized individuals with dementia.
Design: Randomized controlled trial.
Methods: Homecare residents with dementia were assigned to an exercise (EG) or to a control group (CG). Participants in the EG cycled for at least 15 min daily during 15 months, while those in the CG performed alternative sedentary recreational activities. The Mini-Mental State Examination (MEC), the Timed "Up & Go" Test, the Neuropsychiatric Inventory, the Katz Index, the Cornell Scale for Depression in Dementia and the Fuld Object Memory Evaluation were administered before and after the intervention.
Results: Sixty-three individuals in the CG and 51 individuals in the EG completed the intervention. A statistically significant decline in cognitive function was observed in individuals included in the CG ($p = 0.015$), while a slight improvement was observed in those included in the EG. Significant improvement was observed in the neuropsychiatric symptoms ($p = 0.020$), memory function ($p = 0.028$) and functional mobility ($p = 0.043$) among those who exercised. Exercise seemed to have a greater effect in those suffering from severe cognitive impairment.
Conclusions: This study provides evidence that aerobic physical exercise has a significant impact on improving cognitive functioning, behavior, and functional mobility in institutionalized individuals with dementia.

1. Introduction

Research on the effects of long-term physical exercise programs on the cognitive status in institutionalized individuals with dementia is still scarce.[1] Most studies hold various methodological limitations such as unspecific or unclear exercise interventions,[2] absence of specific or complementary cognitive measurements,[3,4] small sample size and lack of information regarding the effects of exercise on important outcomes such as depression or quality of life.[5] Information is scarce regarding the impact of physical exercise on other important dementia-related features such as functional independence or neuropsychiatric symptoms. For instance, although the effects of exercise on non-cognitive outcomes in dementia patients including physical function, ease of transfers, hospitalizations, mortality and caregiver burden have been documented, some have only included women,[6] others designed a short intervention and included only individuals with Alzheimer's disease[7] or did not include an interventional arm in their study design.[8]

Herein, we present a longitudinal study performed on institutionalized individuals with dementia in order to identify the effects of a physical exercise program on cognitive decline and impairment, memory, depression, functional independence and neuropsychiatric disturbances.

2. Methods

Participants in this study were recruited through a collaborative agreement between the University of Vigo (Spain) and Geriatros S.A., a Management Organization of residential homecare for the elderly. Individuals who met the following criteria were included:

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(a) over 65 years of age, (b) diagnosis of dementia according to *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria,[9] (c) able to stand and walk for 30 m without shortness of breath, (d) able to walk safely without assistance, and (e) resident of an elderly home-care facility in Galicia (northwest region of Spain). Excluded were (1) individuals with a history of major psychiatric illness, serious neurologic, cardiovascular or musculoskeletal disorders limiting the understanding and/or performance of the necessary intervention tasks and (2) refusal by the individual and/or their primary caregiver/closest of kin.

Prior to the start of the study, the participants and their families (primary caregiver/closest of kin) were informed of the characteristics of the research project. Appropriate informed consent in written format was provided to the participant or either the spouse, the next of kin or the primary caregiver. The study was approved by the Clinical Research Ethics Committee of Galicia (CEIC 2009/345).

Age, sex, level of education and pathologies of each individual were registered. Information of associated medical conditions was obtained from available medical records. A modified Self-Administered Comorbidity Questionnaire was used to determine comorbidity. Cognitive impairment was assessed by Mini-Mental State Examination (MEC).[10] The Timed "Up & Go" Test (TUG)[11] assessed functional mobility. The validated Spanish versions of the Neuropsychiatric Inventory (NPI)[12] and the Katz Index (KI) of Independence in Activities of Daily Living[13] were used to evaluate the frequency and severity of neuropsychiatric disturbances and the participant's ability to perform tasks of independent daily living, respectively. The Spanish validated version of the Cornell Scale for Depression in Dementia (CSDD)[14] was used to assess signs and symptoms of major depression. The Fuld Object Memory Evaluation (FOME)[15] was used to assess immediate memory.

All assessments were performed by the staff of each of the medical home-care facility involved in the study. Neurologists and psychologists administered the cognitive and health tests, while physiotherapists supervised the exercise program and administered the TUG. Testing was performed 2 weeks before, and 2 weeks after, the intervention ended.

Group allocation was performed by an independent researcher blinded to baseline interview data. Computer-generated random numbers were assigned to the participants. SPSS® Statistics 19.0 was used to generate the random numbers from a normal distribution with a mean and a standard deviation of any specified variable. Sample data information of the functional mobility was recorded and coded by physiotherapists who were not blind to randomization. The participants were aware of group identity.

Once baseline data were collected, the participants were assigned to one of the two groups. The exercise group (EG) performed an aerobic physical activity program, while the control group (CG) did not exercise and, instead, carried out other non-physical distractive recreational activities as usual and of their choice (for example, card-playing, reading, craftwork, etc.). In order to improve the comparison of the groups, the sample was distributed in four strata according to age and whether or not they were undergoing antidementia medical therapy (acetylcholinesterase inhibitors and/or memantine).[16] The participants were randomly allocated from each stratum with a 2:1 randomization ratio either to usual recreational activities or aerobic exercise. Epidemiological evidence indicates a lower expected death rate risk among elderly people who are active.[17] Anticipating that participants in the recreational activity group would have a higher probability of health problems and mortality risk related to a longer time spent in sedentary behavior, an uneven allocation was performed. This would facilitate a comparison of the results since a higher number of dropouts in the control group and, thereby, a reduction of the sample size was expected. The aerobic physical activity program consisted of daily cycling sessions during 15 months. The participants attended the gymnasium daily and cycled continuously alone, or in pairs, in a recumbent bicycle geared to a very low resistance. They were instructed to pedal for a minimum of 15 min at a constant self-selected pace. A physiotherapist monitored each session registering the amount of time that each individual exercised each day as well as their adherence to the program. The participants who did not complete a minimum of 70% of the total sessions each month were excluded from the data analysis. This criterion for valid attendance was set up to guarantee a minimum weekly practice.[16] In order to adjust the on-going exercise program to each individual's capacity, their performance was assessed every 3 months. The following were specifically recorded: participants' tolerance to the programmed exercise frequency and its duration, attendance and reason(s) for dropping out in either group.

Table 1
Baseline characteristics of the study population by intervention group (mean ± SD).

	Baseline		
	Control	Experimental	*p*
n	116	73	
Age, years	82.90 ± 7.42	80.63 ± 8.32	0.19
Sex, male/female	22M/94F	41M/32F	–
Level of education			
No formal, %	39.20	25.90	
Primary, %	57.60	61.76	
Secondary, %	3.20	7.80	0.22
University, %	–	4.46	
Comorbidities			
HTA, %	52.10	55.90	
Diabetes mellitus, %	28.90	39.30	
Arthrosis/arthritis, %	24.15	29.20	
Stroke, %	12.50	18.15	0.24
Depression/anxiety, %	17.20	15.30	
Bipolar disorder, %	12.40	9.70	
COPD, %	9.30	8.20	
MEC, pts	14.95 ± 2.44	15.16 ± 2.54	0.65
TUG, s	23.44 ± 6.86	24.02 ± 10.14	0.17
NPI, pts	11.32 ± 5.35	9.70 ± 9.45	0.19
KI, pts	4.27 ± 0.93	4.28 ± 0.98	0.13
CSDD, pts	6.71 ± 6.48	6.31 ± 5.07	0.36
FOME, pts	10.29 ± 11.43	6.15 ± 9.95	0.40

COPD, chronic obstructive pulmonary disease; CSDD, Cornell Scale for Depression in Dementia; FOME, Fuld Object Memory Evaluation; HTA, arterial hypertension; IK, Katz Index; MEC, Mini-Examen Cognoscitivo; NPI, Neuropsychiatric Inventory; TUG, Time "Up & Go" test.

Table 1 displays the main characteristics of the participants included in the study.

All serious medical events and causes of death were related to preexisting comorbidity and none were directly or indirectly attributable to the exercise program. The data were analyzed using SPSS 19.0 for Windows (SPSS Inc., Chicago, IL). Normally distributed continuous variables were represented, calculating their means and standard deviation. For baseline comparison between the exercise group and control group, the following were used: Student's *t*-test for independent data (normal distribution), Mann–Whitney *U*-test (non-normal distribution) and Chi square (χ^2) for discrete (categorical) variables.

The *t*-statistic for related samples was used to analyze the intragroup differences. We used two methods for analysis of the differences between both groups. The first was based on an intention-to-treat methodology and the other was based on a complete-case analysis in which participants with valid data at two time points were included in the analysis.

Repeated-measures procedure was used in an analysis of covariance (ANCOVA) in both the intention to-treat and complete-case analyses. For intention-to-treat data, a mixed model with repeated