BRIEF REPORT

Exercise or Social Intervention for Nursing Home Residents with Dementia: A Pilot Randomized, Controlled Trial

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OBJECTIVES: To compare the effects of exercise with those of a structured nonphysical intervention on ability to perform activities of daily living (ADLs) and physical and cognitive function of persons with dementia (PWDs) living in nursing homes (NH).

DESIGN: Cluster-randomized pilot-controlled trial.

SETTING: Seven French NHs.

PARTICIPANTS: PWDs living in NHs.

MEASUREMENTS: NHs were randomized to an exercise group (4 NHs, n = 47) or structured social activity group (3 NHs, n = 50) for a 24-week intervention performed twice per week for 60 minutes per session. The main endpoint was ADL performance (Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory for Severe Alzheimer's Disease Scale (ADCS-ADL-sev); range 0–54, higher is better); secondary endpoints were overall cognitive function (Mini-Mental State Examination (MMSE)) and performance-based tests of physical function (Short Physical Performance Battery (SPPB), usual gait speed).

RESULTS: Ninety-one participants with at least one post-baseline ADL assessment were included in efficacy analysis. Groups differed at baseline in terms of sex, neuropsychiatric symptoms, and nutritional status. Multilevel analysis adjusted for baseline differences between groups found no significant difference between effects of exercise and social activity (group-by-time interaction), with adjusted mean differences at 6 months of 1.9 points for ADCS-ADL-sev and 0.55 points for MMSE favoring social activity and 0.6 points for SPPB and 0.05 m/s favoring exercise. Adverse events did not differ between groups, except that the social activity group had more falls than the exercise group.

CONCLUSION: A larger, longer trial is required to determine whether exercise has greater health benefits than nonphysical interventions for institutionalized PWDs. **J Am Geriatr Soc 2017.**

Key words: older adults; long-term care facilities; exercise; social activity; dementia

People with dementia (PWDs) living in nursing homes (NHs) have high levels of disability, multimorbidity, and polypharmacy[1] (in particular antipsychotic drugs).[2,3] The number of older adults living in NHs is growing,[4] and dementia is a prevalent[5] disabling condition.[6] Therefore, nonpharmacological interventions aiming to slow the progression of the disabling cascade in PWDs in NHs is a public health priority.

Exercise, a structured, repetitive and purposeful subset of physical activity, is a powerful intervention to improve or maintain functional status in institutionalized older adults.[7,8] Although exercise may improve dementia care by addressing other health problems (e.g., depression, sarcopenia),[9,10] evidence of the benefits of exercise for the functional status of PWDs is inconsistent.[11] Randomized controlled trials (RCTs) of exercise for institutionalized PWDs have had methodological limitations, such as lack of cluster randomization (to avoid contamination between study arms) and short intervention length (<16 weeks for most). Furthermore, the control comparator group in most cases consisted of usual care or unstructured social activities (e.g., casual conversations). Although structured activities specifically designed for PWDs have the potential to improve health outcomes, they were rarely operationalized as an active comparator group.

This was a 24-week pilot cluster-RCT study to compare the effects of group-based exercise with those of well-structured group-based social activities on the ability of PWDs living in NHs to perform activities of daily living (ADLs) (Effects of a Long-term Exercise Program on Functional Ability in People with Dementia Living in Nursing Homes: A Cluster Randomised Controlled Trial (LEDEN

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Study)). It was hypothesized that exercise would slow the progression of functional loss more than social activities.

METHODS

The methods and procedures of LEDEN have been published in detail elsewhere[12] and will be briefly described hereafter. The ethics committee approved the study protocol (CPP SOOM III), which was registered in a clinical trial registry (registration NCT02444078). Participants (if applicable), next of kin, and legal representatives signed an informed consent form, as appropriate, before baseline assessments.

Participants

Inclusion criteria were a diagnosis of Alzheimer's disease or vascular or mixed dementia according to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV); a Mini-Mental State Examination (MMSE) score of 20 or less; age 65 and older; living in the NH for at least 1 month; ability to walk 4 m without human assistance; and ability to rise from a chair with minimal human assistance. Exclusion criteria were terminal illness (life expectancy <6 months), Parkinson's disease or dementia with Lewy bodies, unstable condition precluding participation in exercise, planned transfer from the NH during intervention period, and participation in another exercise program for two times per week or more in the last 2 months. Sample selection bias was avoided by inviting all NH residents meeting eligibility criteria to participate.

Randomization and Masking

LEDEN is a two-arm pilot cluster-RCT with NHs as the unit of randomization. NHs were randomized to a 24-week exercise or social activities intervention in a 1:1 ratio. A statistician blinded to NH identity and not involved in any other aspect of LEDEN performed randomization. Group allocation was stratified according to the median value of dementia prevalence in the NHs and was performed using random permuted block sizes of two within each of the two strata. Group allocation concealment was guaranteed by using opaque, sealed envelopes until group assignment was revealed to the NHs.

Study Design and Procedures

LEDEN is a pragmatic pilot study. Intervention length was 6 months. Feasibility was an important aspect of LEDEN, and thus, the study partly relied on the direct participation of NH staff. Randomization occurred before baseline assessments to avoid too long an interval between participant assessment and the beginning of the interventions. NH staff were responsible for identifying and selecting interventionists, particularly for the social activities. NH staff assessed and recorded outcome measures and data on adverse health events (unblinded to group assignment); in practice, outcome assessors were mainly NH nurses, nurses' aides, and coordinating physicians. The research team conducted in-person trainings for NH staff on all study procedures.

Interventions

Exercise

Exercise instructors (3-year university diploma in physical activity) had experience working with institutionalized PWDs. Group-based exercise interventions took place in the NHs twice per week for 60 minutes per session for 24 weeks. The exercise was a multicomponent training: 10 minutes of warm-up (e.g., range of motion), 10 minutes of coordination and balance exercises (e.g., short walks with direction changes), 10–15 minutes of muscle strengthening (e.g., weight lifting), 20 minutes of aerobic exercise (mostly walking), and 5–10 minutes of cool-down. Exercise intensity was targeted to be moderate. Instructors endeavored to establish progression individually; visual cues were used, and participants were regularly encouraged to improve their performance in the absence of pain or breathlessness. When a subject had improved the execution of an exercise, a progression was proposed by increasing exercise difficulty, the number of repetitions to be performed, or exercise load.

Social Activity Group

Social activity interventionists had experience in working with institutionalized PWDs. Group-based activities took place in the NHs twice per week for 60 minutes per session for 24 weeks. The selected interventions were new activities for the residents. No predefined model of social activity was established because the same intervention was not always feasible or available at all participating NHs. According to availability of interventions near the NHs and NH staff choice, NHs randomized to social activity received one of therapeutic music mediation (e.g., relaxation with music, playing percussion instruments, singing, light dancing) or arts and crafts (e.g., painting and drawing alone and in pairs, clay modelling).

Outcomes

The prespecified main outcome measure of LEDEN was functional status, as measured using the Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory for Severe Alzheimer's Disease (ADCS-ADL-sev) scale,[13] an assessment tool specifically validated for people with moderate or severe dementia. This is a 19-item scale (range 0–54, with higher scores indicating better function) measuring ability to perform basic ADLs (6 items, e.g., bathing, toileting) and instrumental ADLs (IADLs, 13 items, e.g., turning faucet or lights on and off) in the last 4 weeks. Participants' ADL function was assessed three times during the 6-month intervention period (baseline, 3 and 6 months).

The prespecified secondary outcomes were assessed twice (baseline, 6 months) and were 4-m usual gait speed (m/s), cognitive function as measured according to MMSE score (range 0–30, higher is better),[14] lower limb function as measured using the Short Physical Performance Battery (SPPB,[15] a validated tool composed of three timed subtasks (usual gait speed, chair stand, balance tests),

range 0 (worst performers) to 12 (best performers), neuropsychiatric symptoms (Neuropsychiatric Inventory,[16] range 0–120, higher is worse), pain (Algoplus scale,[17] range 0–5, higher is worse), nutritional status (Mini-Nutritional Assessment,[18] range 0–30, higher is better). The effects of the interventions on function-related outcomes (ADCS-ADL-sev, gait speed, SPPB, MMSE) were examined.

Adverse Events

All adverse events (including mortality, fractures, emergency department (ED) visits, nonscheduled hospitalizations (hospital stay ≥24 hours), noninjurious and injurious falls[19]) were recorded throughout the 6-month intervention period.

Statistical Analysis

No formal sample size calculation was performed. Descriptive statistics are presented as means±standard deviations (SDs), median with interquartile ranges (IQRs), and percentages, as appropriate. Baseline differences and differences in adverse events and dropouts between groups were checked using the chi-square test, Fisher exact test, Student *t*-test, and Wilcoxon rank sum test, as appropriate. Intracluster correlation (ICC) for baseline and 3 and 6 months were obtained using analysis of variance. Efficacy analyses were performed, as prespecified in the protocol, using a modified intention-to-treat approach including all participants with at least one postbaseline assessment for the ADCS-ADL-sev. Multilevel analyses were performed on ADCS-ADL-sev using a three-level (with random effects at the levels of NH and participants (participants nested within NHs) and a random slope on time) regression model with group, time, and group-by-time interaction as fixed effects. Models were adjusted (fixed effect) for the variable used to stratify the randomization (prevalence of dementia in the NH) and for potential confounders that differed between groups at baseline. Analysis of MMSE scores, gait speed, and SPPB scores used similar three-level regression models. Adjusted means for each group were obtained from the models, and adjusted mean differences were calculated. Statistical significance was determined as $P < .05$. In the case of statistical significance for secondary outcomes, multiplicity was taken into account using the false discovery rate.[20] Analyses were performed using Stata version 14.0 (Stata Corp. College Station, TX).

Sensitivity Analysis

Post hoc exploratory sensitivity analyses of ADCS-ADL-sev were performed by adding intervention adherence (continuous, in %) to the mixed-effect regression, removing people who participated less than once per week in the intervention (adherence <50%), removing "fast decliners" (people who declined 2 SDs or more on the ADCS-ADL-sev between baseline and postintervention because fast decliners may affect associations through a phenomenon known as the "horse-racing effect"[21]), and performing the analysis separately for ADLs and IADLs.

RESULTS

Figure 1 displays the flowchart of the study. Ninety-seven volunteers from seven NHs (cluster sizes: 8, 9, 12, 13, 17, 18, 20) met eligibility criteria and underwent baseline assessments. The six dropouts (three in each group) with no follow-up assessments did not differ ($P > .05$) from the remaining 91 participants in sociodemographic characteristics or outcome measures. The number and reasons for dropping out did not differ between groups. Table 1 shows baseline characteristics of the 91 participants included in the analyses. Groups differed in terms of sex, neuropsychiatric symptoms, and nutritional status.

Forty-eight hours of exercise or social activities was provided. Median adherence was 74% (IQR 42–88%) in the exercise group and 83% (50–91%) in the social activities group ($P = .41$). ICCs are presented in Table S1.

Multilevel models adjusted for prevalence of dementia in NHs, sex, neuropsychiatric symptoms, and nutritional status are shown in Table 2 and Figure S1. The interaction between group and time was not significantly associated with any of the studied outcomes, indicating that the effects of exercise did not differ from the effects of social activities. Exercise group participants declined more than social activity group participants on the ADSC-ADL-sev and MMSE, whereas social activity group participants declined more than exercise group participants on usual gait speed and SPPB (Figure S2), but none of those differences were statistically significant.

All sensitivity analyses (Table S2, Figure S3) on the global ADCS-ADL-sev score provided unchanged results. Analysis of the 13-item IADL subscale showed that exercise group participants declined more than social activity group participants (B-coefficient = −0.40, 95% CI = −0.75 to −0.05, $P = .02$), with significant between-group adjusted mean differences at 3- (−3.9, $P < .001$) and 6-month (−2.3, $P = .03$) follow-up visits.

Sample size calculations using the SD and intraclass correlation coefficients indicated a 53% power to detect a significant effect if the true difference was the observed 1.9-point difference between groups in the adjusted-change score of the ADCS-ADL-sev at 6 months; to detect this difference with 90% power, a sample size of 228 subjects (n = 114 per study arm) would have been needed.

Adverse Events

No differences were found between groups in death, fractures, ED visits, or hospitalizations (Table S4). There were significantly more falls ($P = .04$) and participants falling ($P = .04$) in the social activity group than in the exercise group. No differences were found regarding injurious falls.

DISCUSSION

This pilot cluster-RCT found no differences between the effects of an exercise intervention and those of a social intervention on ADL performance or physical or cognitive function in PWDs living in NHs. Study groups had similar adherence rates and did not differ in adverse health events, except that social activity group participants fell more than exercise group participants.

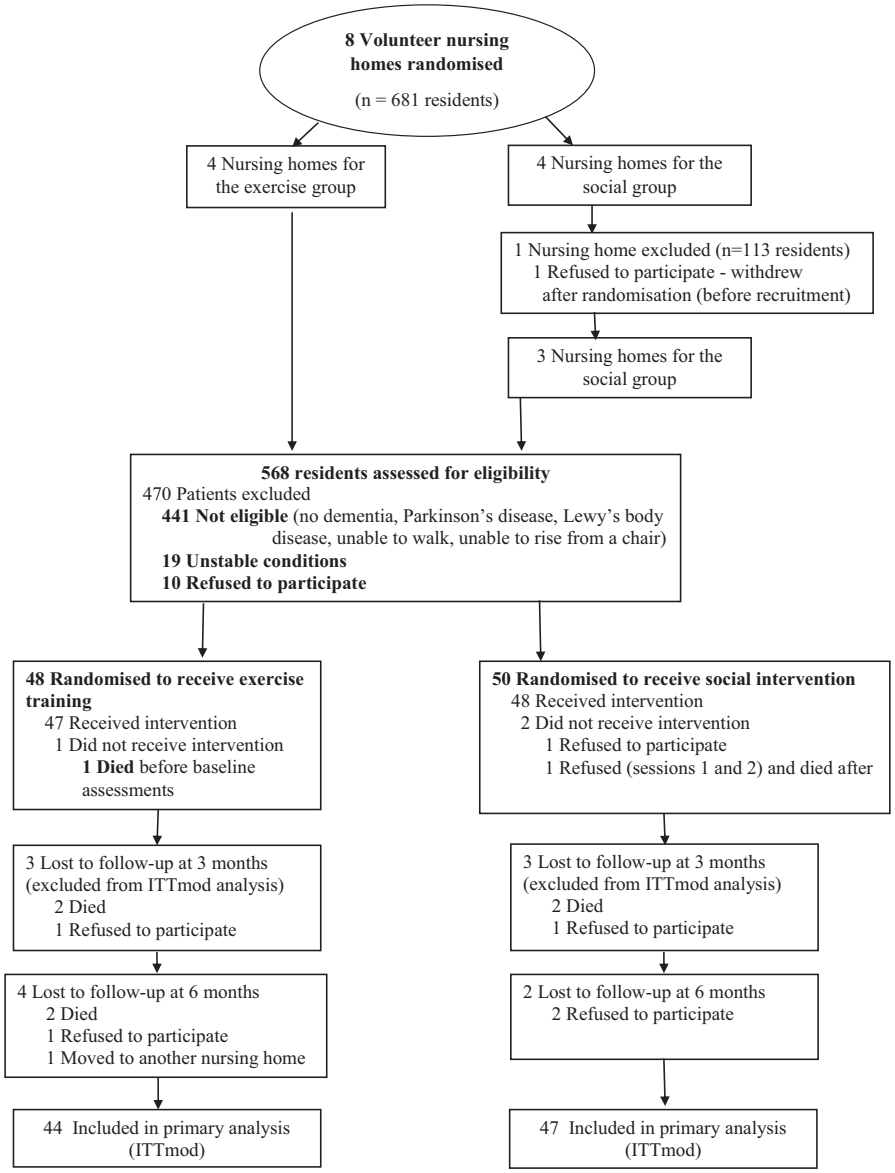

Figure 1. Flowchart of nursing homes and study subjects.

It has been demonstrated that exercise has positive effects on ADL performance in institutionalized PWDs,[22–24] although the results have been mixed for trials comparing exercise with structured social activities in this population. Similar to the current findings, two other RCTs[25,26] found no differences on ADL performance and gait speed[26] between exercisers and controls who participated in structured social activities. In a 3-month RCT in NHs,[27] subgroup analysis restricted to PWDs (n = 95) found a positive effect of exercise on ADL performance. The current study adds information to the sparse literature showing that a medium-term (6 months) cluster-RCT comparing exercise with structured social activities for institutionalized PWDs showed no effect on functional status or motor or cognitive function, although exercise led to fewer falls than social intervention, which is an interesting finding because the effects of exercise in reducing falls in institutionalized elderly adults has not been established.[7,28] No differences between groups in injurious falls were found in the current study.

Although not statistically significant, differences may be considered clinically meaningful for the ADCS-ADL-sev[29] (1.9 points), SPPB (0.6 points), and gait speed[30] (0.05 m/s). Because exercise group participants declined less in physical performance but more in ADL function, the social activities may have slowed declines in ADLs through a mechanism independent of motor skills, for example, by delaying decline in tasks requiring greater cognitive than motor effort. Although data were not available on specific cognitive functions (e.g., executive function, attention) to examine this hypothesis, the results of the exploratory analysis on the IADL subscale points in this direction (exercise group participants declined more than social activity group participants). The hypothesis that structured social activities would improve ADL performance through improved cognitive function or another unknown mechanism (e.g., enhanced motivation) requires further investigation. Furthermore, improvements in ADL performance of exercisers did not follow the nonsignificant improvements in physical performance (SPPB, gait speed);

Table 1. Baseline Characteristics and Between-Group Differences

Variable	Exercise, n = 44	Social Activity, n = 47	*P*-Value
Age, mean ± SD	88.3 ± 5.1	86.9 ± 5.8	.23
Sex, n (%)			
Female	41 (93.2)	36 (76.6)	.03
Male	3 (6.8)	11 (23.4)	
Education			
No diploma	11 (25.0)	11 (23.4)	.48
Secondary education (no high school diploma)	27 (61.4)	25 (53.2)	
High-school diploma or higher	6 (13.6)	11 (23.4)	
Number of diseases, median (IQR)[a]	1.5 (1–2)	2 (0–3)	.81
Body mass index, kg/m^2 median (IQR)	23.5 (20.4–27.4)	22.9 (21.4–25.8)	.80
Mini-nutritional assessment score, median (IQR) (range 0–30)	22 (19.7–23.7)	21.5 (18.5–22.5)	.03
Neuropsychiatric inventory 10-item score, median (IQR) (range 0–120)	18.5 (10.5–39)	14.0 (4.0–21.0)	.03
Pain (Algoplus score, median (IQR)) (range 0–5)	0 (0–1)	0 (0–1)	.33
Alzheimer's disease cooperative study activities of daily living inventory for severe Alzheimer's disease scale, mean ± SD (range 0–54)	21.0 ± 11.0	20.3 ± 10.3	.75
Mini-mental state examination score, mean ± SD (range 0–30)	11.4 ± 6.2	10.8 ± 5.5	.60
Short physical performance battery score, mean ± SD (range 0–12)	4.4 ± 2.4	4.5 ± 2.3	.74
Usual gait speed, m/s, mean ± SD	0.48 ± 0.23	0.48 ± 0.18	.97

SD=standard deviation; IQR=interquartile range.
[a]Dementia was not included in the calculation of number of diseases.

Table 2. Effects of the Effects of a Long-term Exercise Program on Functional Ability in People with Dementia Living in Nursing Homes: A Cluster Randomised Controlled Trial Interventions on Functional Ability, Cognition, and Physical Function Outcomes

Outcome	Exercise Group	Social Control Group	Between-Group Adjusted Mean Difference (95% CI)[a]	*P*-Value	β-Coefficient for Time-by-Treatment Interaction (95% CI)[b]	*P*-Value
	Within Group Adjusted Mean Difference (Standard Error)					
Alzheimer's disease cooperative study activities of daily living inventory for severe Alzheimer's disease scale						
3-month	−3.1 (0.98)	1.8 (0.95)	−4.9 (−7.6 to −2.3)	<.001	−0.35 (−0.87 to 0.17)	.19
6-month	−3.9 (1.2)	−2.0 (1.1)	−1.9 (−5.1 to 1.2)	.23		
Mini-mental state examination	−1.0 (0.51)	−0.5 (0.47)	−0.55 (−1.9 to 0.8)	.43	−0.09 (−0.32 to 0.14)	.43
Short physical performance battery	−0.2 (0.36)	−0.8 (0.34)	0.6 (−0.4 to 1.6)	.22	0.10 (−0.06 to 0.26)	.22
Usual gait speed	0.07 (0.03)	0.03 (0.03)	0.05 (−0.04 to 0.14)	.30	0.01 (−0.01 to 0.02)	.30

Forty-four exercise group participants and 47 social control group participants were entered into the regression models for all analyses except gait speed, in which there was one missing value in each study group (n = 43 for exercisers, n = 46 for social controls).
CI=confidence interval.
[a]Negative values indicates greater declines in the exercise group than the social group; positive values indicate greater declines in the social group than in the exercise group.
[b]The social control group was the reference group.

previous RCTs in NH residents have shown that feasible[31] exercise programs improved several physical parameters (e.g., total distance walked, walking speed, chair rise)[32,33] in this population but not overall ADL performance.[33]

The positive points of this study were that the findings will inform a larger, well-dimensioned RCT; the intervention was longer than those of most RCTs of exercise for institutionalized PWDs; and the exercise regimen adhered to several aspects of recent evidence-based guidelines of exercise for NH residents.[10] The most-important lessons from this pilot study were that 6-month exercise and social interventions are feasible in PWDs living in NHs, although recruitment rates should be conservatively estimated (10–15 people per NH) and that involvement of NH staff must be carefully considered to avoid lack of motivation and time. Because of regulatory and ethics approval delays, the interval between first contact with NH staff and participant recruitment was longer than 8 months, which led one NH to withdraw. The high adherence and low attrition (6.2% dropout at 3 months and 12.4% at 6 months) rates suggest that keeping residents motivated throughout the intervention (e.g., providing positive feedback, systematically proposing residents who missed sessions to reintegrate the intervention) may be helpful in this population. Several limitations are worth mentioning. The sample size was small; calculations using data from the current work suggest that 114 subjects per group would provide 90% power to detect a 1.9-point difference between groups on the ADCS-ADL-sev. NH staff were the outcome assessors and were therefore unblinded to group assignment.

Participating NHs were private for-profit institutions belonging to the same company.

In sum, the effects on ADL performance and physical and cognitive function of a 6-month exercise intervention for PWDs living in NHs did not differ from those of well-structured social activity. A larger, longer, cluster-RCT is needed to determine whether exercise has any additional health benefit over social activity for institutionalized PWDs.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Table S1. Intracluster Correlation Coefficients

Table S2. Sensitivity Analyses of the Effects of a Long-term Exercise Program on Functional Ability in

People with Dementia Living in Nursing Homes: A Cluster Randomised Controlled Trial (Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory for Severe Alzheimer's Disease Scale)

Table S3. Adverse Events According to Study Group During 6-Month Intervention Period

Figure S1. Effects of exercise and social activity on functional status, cognitive function, and performance-based tests of physical function.

Figure S2. Score change of outcome measures over the 6-month intervention period.

Figure S3. Activity of daily living (ADL) and instrumental activity of daily living (IADL) score change over the 6-month intervention period.

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