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An exploratory cluster randomized controlled trial of group exercise on mobility and depression in care home residents

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Objective: To investigate the feasibility, acceptability and potential efficacy of group exercise for residents in care homes.
Design: Exploratory cluster randomized controlled trial.
Setting: Five randomly selected care homes in South Birmingham, UK.
Participants: Fifty-six care home residents (mean age 84.5, 71% female), 39 (70%) with cognitive impairments.
Intervention: Two homes ($n = 28$) were randomized to group exercise held twice weekly for five weeks. The remaining three homes ($n = 28$) formed the control group and received usual care, with no person specifically responsible for exercise training.
Outcome measures: Assessments were conducted at zero (pre-intervention), three (post-intervention) and six months (follow-up) using the Rivermead Mobility Index and Hospital Anxiety and Depression Scale or Stroke Aphasic Depression Questionnaire (depending on cognitive impairment). Adherence to group exercise and retention to the study were also documented.
Results: No statistically significant improvements in mobility or depression were found in favour of group exercise. Retention to the study was high with 46 (82%) participants completing all assessments. Adherence to group exercise was somewhat lower with participants attending a mean of 3.61 out of 8.5 prescribed sessions (42.5%).
Conclusions: Group exercise can be delivered to care home residents with reduced mobility but it is not suitable for residents with severe cognitive impairment.
An estimated sample size of 240 participants would be required to detect a clinically significant difference in the Rivermead Mobility Index with 90% power.

Introduction

In 2004 there were approximately 410 000 older people living in care homes in the UK.[1] The projected rise in the proportion of the population over 65, from 16% in 2001 to 21% in 2026, will increase this number.[2]

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Both residents and care home staff regard mobility as pivotal to the resident's quality of life and well-being,[3] however the priority has to be basic care, feeding, washing and dressing. Consequently, staffing constraints may mean activity levels are unacceptably low. In a study of 30 care homes, Challis *et al.*[4] found the provision of therapy and activity services to be scarce and sometimes non-existent. An observational study from Oxfordshire found that residents, including those capable of independent ambulation, spent the majority of their time sitting doing nothing.[5] Prolonged insufficient physical activity can induce muscle atrophy, incontinence,[6] pressure sores,[7] depression[8] and psychological distress.[9] There is clearly a need to keep long-term care home residents as active as possible.

Changes in health status following placement into a care home is common. A retrospective cohort study of 205 residents from homes based in the health authority boundaries of Nottingham, UK found that 30% of residents showed higher dependency needs at follow-up after placement within a home.[10] The same study also reported that nearly a quarter of care home residents had severe cognitive impairment. The presence of cognitive impairment has been shown to correlate significantly with higher levels of depression[11] and low activity levels.[12] In a meta-analysis of antidepressants for the treatment of depression in dementia, Bains *et al.*[13] highlighted that due to serious side-effects, clinicians should prescribe antidepressants with due caution. A Cochrane review[14] of antidepressants in the elderly population similarly highlighted that the efficacy of such medication is compromised by negative side-effects and high withdrawal rates. Alternative strategies need to be investigated for managing depression.

Several reviews have been published on the effects of physical activity in non-institutionalized elders, however for reasons discussed earlier, this population differs significantly from that belonging to a long-term care facility. We have found only one systematic review focusing on institutionalized elders.[15] This provides strong evidence for a positive effect of physical training on muscle strength and mobility; moderate evidence for a positive effect on range of motion; and contradictory evidence for a positive effect on gait, activities of daily living, balance and endurance. The authors highlight a need for greater focus on clinically relevant outcomes such as activities of daily living and quality of life.

The aim of this study was to investigate the feasibility and efficacy of a seated exercise programme on mobility and depression in care home residents, including those with reduced self-care independence and cognitive impairment.

Method

The study was designed as an exploratory randomized controlled trial with cluster randomization, at the level of care home, to group exercise or usual care.

Study population

The Guide to Care Homes for Birmingham City Council[16] was used to identify a sample of 70 nursing and residential homes with more than five beds that would include residents aged 65 year and older with self-care dependency needs. Five homes were identified randomly. The managers or senior nurses of these homes were approached, and agreed to take part in the study. Randomization was performed by an independent principal statistician from Birmingham Clinical Trials Unit, using computer-generated random numbers. Two homes formed the intervention group and the remaining three homes formed the control group. Allocation was concealed from the independent assessors and the statistician performing the analysis.

Residents were invited to participate in the study if they (a) were expected to survive for more than nine months, and (b) had reduced mobility, indicated by a Barthel Activities of Daily Living Index score[17] less than or equal to 16.

Staff from each home obtained consent (as per ethical committee recommendations) either directly with the resident or with the resident and their next of kin. The names of those consenting to participate were passed to the research team and an assessment was carried out with each resident.

This involved an initial screening of cognitive impairment, using the Mini Mental State Exam,[18] to determine whether self-completion or proxy-completion of outcome measures was required.

The Oxfordshire Research Ethics Committee approved the study on 5 September 2003 (REC reference no. A02.072). Site-specific ethical approval was then given on 4 February 2005 from South Birmingham Primary Care Trust by South Birmingham Local Research Ethics Committee.

Group exercise intervention

An interactive group exercise class lasting 40–60 minutes was held twice weekly for five weeks. The exercise sessions took place in the lounge area of each home and were conducted by the same two physiotherapists throughout. To minimize confusion and maximize individual gain one physiotherapist led the sessions while the second offered individual support to less able participants. The physiotherapists were also involved in the design of the exercise programme.

Most residents were non-ambulatory therefore the main intervention consisted of seated exercises. Informed by current recommendations for prescribing exercise in the elderly,[19–22] the following elements were incorporated into each session:

- Warm-up and cool-down period
- Flexibility – range of movement and stretching
- Sitting balance – postures that progressively reduce the base of support and dynamic movements such as reaching and throwing that perturb the body's centre of gravity
- Posture – education and practice of good posture during exercises
- Coordination – reaching targets and dual-tasking
- Strengthening of the clinically major muscle groups – hip extensors, knee extensors, ankle plantar flexors and dorsiflexors, biceps, triceps, shoulders, back extensors and abdominal muscles
- Cardiovascular, e.g. marching on the spot (in sitting or standing).

Repetition rates, frequency and progression were left to the discretion of the physiotherapists, based on individual and group performance. Residents were encouraged to work within a pain-free range of movement at low to moderate intensity, as suggested for arthritic elders.[23] In order to make the sessions enjoyable and meaningful, the exercises were made as dynamic and task-oriented as possible. Fixed end-points and targets such as boxes were used during reaching exercises to provide feedback that participants had accomplished the exercise goal. Other equipment included balls, balloons and beanbags, all of which were inexpensive and easy to transport.

Short, clear explanations were given together with visual demonstrations and tactile feedback to allow residents with communication difficulties, such as impaired hearing, cognitive problems and language barriers, to benefit from the sessions. With the aim of enhancing group cohesiveness participants were arranged in a circle. This allowed the lead instructor to be seen by all. It also facilitated interaction between residents, encouraging peer reinforcement[24] and promoting the social aspect of group intervention, which has been identified as important for older residents to sustain exercise participation.[25]

Control intervention

Residents in the control group received usual care. In the UK, regular exercise therapy and physiotherapy are not routinely available to nursing home residents.[26,27] The homes identified in our study were consistent with this, with no provision of regular physiotherapy or exercise training.

Assessments

Assessments were conducted at zero months (pre-intervention), three months (post-intervention) and six months (follow-up), by one of two research staff trained in the use of the measurement tools and masked to group allocation. The primary outcome measures consisted of the Rivermead Mobility Index,[28] the depression subscore of the Hospital Anxiety and Depression Scale,[29] and the Stroke Aphasic Depression Questionnaire.[30] All outcome measures were

interview administered by the assessor, either with the resident or main carer, depending on Mini Mental State Exam scale. Participants with a Mini Mental State Exam score of less than 21 received proxy completion of the questionnaires, however participants with a borderline score were given the option of self-completing the questionnaires. For participants allocated to group exercise, attendance to each session was documented.

The Rivermead Mobility Index[28] was used as a self- and proxy-measure of mobility. The measure is scored out of 15 where higher scores indicate higher levels of mobility. Individuals scoring three or less are unable to stand, those scoring between four and six inclusively can transfer and those scoring seven or more are able to ambulate. The Rivermead Mobility Index has been shown to be a valid, reliable[28,31] outcome measure that is sensitive to change in stroke survivors.[32]

The Hospital Anxiety and Depression Scale – depression score[29] was used to screen cognitive participants for signs of depression. Scores greater than seven out of a possible 21 were considered indicative of depressed mood.

The Stroke Aphasic Depression Questionnaire[30] was used as a proxy for identifying depressed mood in aphasic and cognitively impaired individuals. Scores greater than or equal to 14 out of a possible 30 were considered indicative of depressed mood.[33] The Stroke Aphasic Depression Questionnaire has been validated against the Hospital Anxiety and Depression Scale in community stroke survivors[30] and in a care home setting.[33]

SAS version 9.1 was used to analyse the data and calculate summary statistics for the Rivermead Mobility Index, the Hospital Anxiety and Depression Scale – depression score, the Stroke Aphasic Depression Questionnaire and participant demographics. Mean changes from baseline at three and six months, with 95% confidence intervals, were also calculated for the Rivermead Mobility Index, the Hospital Anxiety and Depression Scale – depression score and the Stroke Aphasic Depression Questionnaire. The analysis was performed on an intention-to-treat basis, taking into account clustering effects.

Results

From the five care homes included in the study, 56 residents formed the study group. The flow of participants through the trial is demonstrated in Figure 1. Two homes (one residential home and one nursing home) comprising 28 participants were randomized to the group exercise intervention, and the remaining three homes (two residential homes and one nursing home), comprising 28 participants, formed the control group. A between-group comparison of baseline characteristics is given in Table 1. Both groups were well matched. Age was the only characteristic showing a statistically significant difference between groups (87 in the exercise group versus 82 in the control group).

Mean scores and the mean change in scores for the Rivermead Mobility Index, the Hospital Anxiety and Depression Scale – depression score and the Stroke Aphasic Depression Questionnaire are shown in Tables 2 and 3 respectively. No significant improvements were found in favour of group exercise, however the study was not adequately powered for us to make reliable judgements on efficacy.

Retention to the study was high, with 23 (82%) participants in each arm completing all assessments. As the questionnaires were interviewer-administered there were very few missing data.

Due to conflicting schedules between care homes and physiotherapists, nine sessions of group exercise were provided at one home and eight sessions were provided at the other. Participants in the exercise arm attended a mean of 3.61 out of 8.5 prescribed sessions (43%). Five (18%) residents attended all of the sessions. Reasons for non-attendance included illness/death ($n=2$), moving home ($n=1$) and conflicting schedules such as chiropody/hair appointments, outings with friends and family and organized social activities ($n=7$). Six participants were unable to engage in the exercise sessions due to severe cognitive impairment and three participants demonstrated socially disruptive behaviour, again due to severe cognitive impairment.

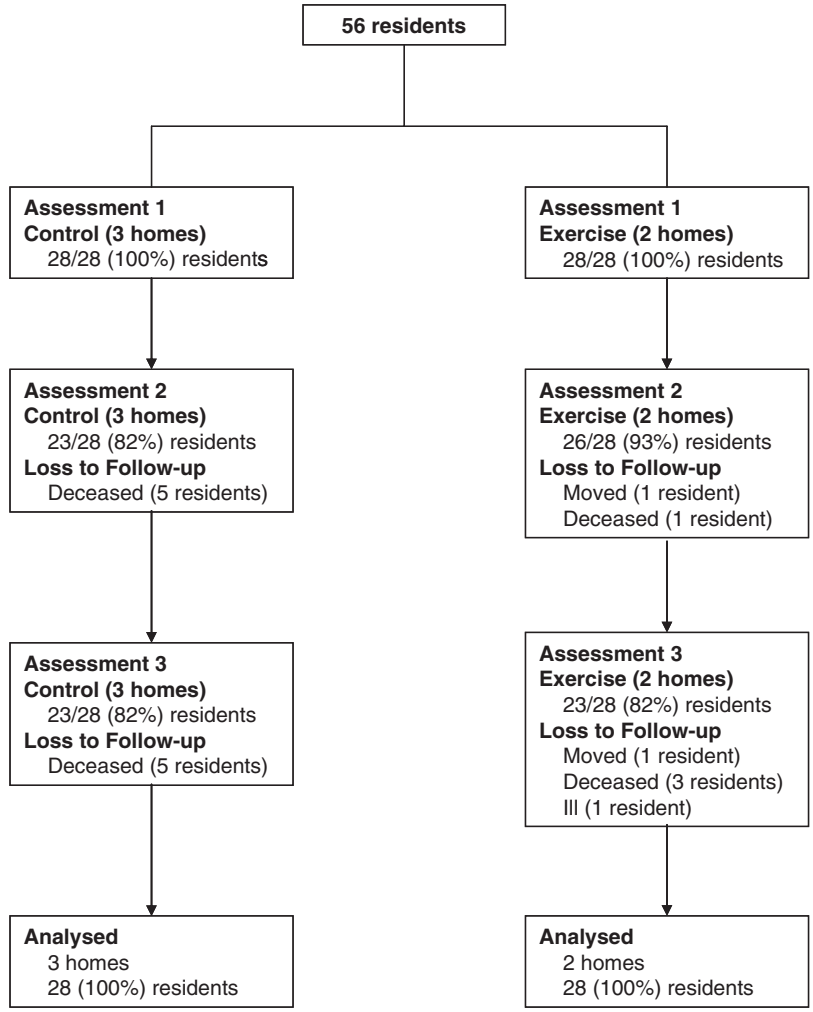

Figure 1 Flowchart of events.

Discussion

No significant improvements in the Rivermead Mobility Index, the Hospital Anxiety and Depression Scale nor the Stroke Aphasic Depression Questionnaire were found in favour of group exercise. Retention to the study was high but adherence to the exercise programme was somewhat lacking. Anecdotal evidence from participants and exercise conductors suggests that the content of the group exercise sessions was aimed at an acceptable level. The exercises were well received by most attendees, however those with severe cognitive impairment struggled to follow instructions and some exhibited disruptive behaviour. It is clear that the exercise programme was not suitable for these residents. This is an important finding in the context of the care home setting where a large proportion of the population are cognitively impaired. Many previous studies of exercise in care homes have excluded cognitively impaired residents.

Table 1 Baseline characteristics

Characteristics	Control ($n=28$)	Exercise ($n=28$)	*P*-value
Age (years): Mean (SD)	82 (9.98)	87 (6.99)	0.04
Female: *n* (%)	18 (64)	22 (79)	0.2
At least one confirmed stroke: *n* (%)	6 (21)	7 (25)	0.6
BI: mean (SD)	11.0 (4.19)	11.1 (4.20)	0.9
RMI: mean (SD)	7.5 (4.22)	6.1 (3.69)	0.2
MMSE: *n* (%)			
<21	20 (71)	19 (68)	0.9
21–23	4 (14.5)	5 (18)	
>24	4 (14.5)	4 (14)	
HADS-D: *n* (%)			
≤7	7 (25)	7 (25)	0.6
>7	3 (11)	1 (4)	
SADQ: *n* (%)			
<14	8 (28)	13 (46)	0.4
≥14	10 (36)	7 (25)	
Missing: *n* (%)			
Not completed HADS and SADQ	0 (–)	0 (–)	–

BI, Barthel Index; RMI, Rivermead Mobility Index; MMSE, Mini Mental State Exam; HADS-D, Hospital Anxiety and Depression Scale – depression subscore; SADQ, Stroke Aphasic Depression Questionnaire. Residents who scored in the borderline ranges of the MMSE (20–23) were given the option of completing the HADS (hence $n=10$ and $n=8$ HADS completers in group 1 and 2 respectively).

Table 2 Outcome data at zero, three and six months

Item	Assessment	Exercise ($n=28$)		Control ($n=28$)	
		n	Mean (SD)	*n*	Mean (SD)
RMI	1	28	6.1 (3.7)	28	7.5 (4.2)
	2	26	5.7 (3.7)	23	7.0 (3.7)
	3	23	5.1 (3.2)	23	6.9 (3.6)
HADS-D	1	8	3.9 (2.9)	10	5.7 (3.9)
	2	11	3.4 (2.2)	10	5.4 (3.3)
	3	10	3.6 (2.0)	11	6.0 (4.3)
SADQ	1	20	11.7 (5.4)	18	14.3 (4.1)
	2	15	13.5 (5.0)	13	17.2 (3.3)
	3	13	14.7 (5.0)	12	15.2 (6.4)

RMI, Rivermead Mobility Index; HADS-D, Hospital Anxiety and Depression Scale – depression subscore; SADQ, Stroke Aphasic Depression Questionnaire.

The main weaknesses of this study include a small sample size and obvious inability to blind participants to their assigned group. Strengths of the study include randomization, concealment of allocation, blinding of outcome assessors and analysis by intention to treat.

Due to the small sample size this study lacks the statistical power to draw any conclusions about whether or not group exercise is a significant mediator of mobility and depression in care home residents. Using the Rivermead Mobility Index as the primary outcome measure, data from this study were used to estimate the sample size needed in future clustered randomized controlled trials of group exercise in this population. To identify a clinically significant two-point change in mean score for the Rivermead Mobility Index (assuming a standard deviation of 4.41) at the 0.05% level of significance, with an ICC of 0.37 and 90% power, a total sample size of approximately 200 residents

Table 3 Mean change in scores over six months

Item	Epoch	Exercise ($n=28$)		Control ($n=28$)	
		Mean change	95% CI	Mean change	95% CI
RMI	A1–A2	−0.8	−1.5 to −0.1	−1.4	−2.5 to −0.4
	A1–A3	−1.4	−2.3 to −0.4	−1.5	−2.5 to −0.5
HADS-D	A1–A2	−0.3	−1.4 to 0.9	−1.1	−4.8 to −2.5
	A1–A3	0.5	−1.5 to 2.5	−0.8	−3.0 to 1.5
SADQ	A1–A2	1.0	−1.5 to 3.5	3.2	−0.2 to 6.6
	A1–A3	2.9	0.1 to 5.8	1.0	−3.6 to 5.5

RMI, Rivermead Mobility Index; HADS-D, Hospital Anxiety and Depression Scale – depression subscore; SADQ, Stroke Aphasic Depression Questionnaire.

would be required. As the trial would be a cluster, randomized design, 10 homes of 10 residents would be needed in each intervention arm. Assuming a drop-out and death rate of 18%, 12 homes of 10 residents would be required in each intervention arm (240 residents in total).

Comparison with former studies is made difficult by the heterogeneity across the literature in terms of exercise type, exercise dose, outcome measures used and populations studied. Our results are consistent with four out of twelve studies, reported in the systematic review on exercise in institutionalized elders,[15] which found contradictory evidence for the effect of physical training on mobility. Our results are also consistent with a recent randomized controlled trial that found neither strength nor functional training to improve depression in older people living in long-term care facilities.[34] In the systematic review by Rydwik *et al.*,[15] studies showing a positive effect on mobility involved a higher frequency of exercise sessions over a longer duration of time compared with our study. Similarly, a meta-analysis revealing a positive exercise effect on exercise for elderly people (80 ± 6.1 years) with cognitive impairment[35] reported a mean frequency of 3.6 exercise sessions per week for a mean duration of 23 weeks compared with our exercise programme that consisted of two sessions per week for five weeks. Heyn *et al.*[35] concluded that older people attending a higher number of sessions per week show greater potential to benefit from exercise. This suggests that two exercise sessions per week for five weeks' duration may not be enough to induce change in elderly residents. Future studies should take this into account when designing exercise interventions for this population.

Rydwik *et al.*[15] highlight the importance of training specificity. Consideration should therefore be given towards the appropriateness of the Rivermead Mobility Index to assess change. Some of the items assessed by the Rivermead Mobility Index were trained during the exercise intervention, such as sitting balance and marching, all be it on the spot. However many of the other exercise components, particularly those aimed at a functional level, such as range of movement and strengthening, were not directly assessed. Future studies may wish to include outcome measures targeting function as well as activity. As a decline in health status is normal in vulnerable populations, preventing a decline in health would be seen as a positive outcome in care home residents. Data on hospital admissions, visits from general practitioners and changes in medication are useful indicators of decline and should be considered as secondary outcome measures in future trials.

In our study adherence to group exercise was disappointingly low, with participants attending a mean of 3.61 out of 8.5 prescribed sessions. It is not unusual for adherence rates to be lower than retention rates in elderly populations. In a retirement village, group-based intervention, 92% of participants returned for follow-up testing but they had only attended an average of 42% of the sessions delivered.[36] Nevertheless, instructor-led group exercise programmes still appear to be more effective than individual, home-based programmes in terms of longer term retention and adherence.[37] Future studies should consider ways

to promote and facilitate adherence to exercise sessions. This may involve educating residents and staff about the benefits of exercise, and better timetabling the sessions. Very few residents in this study were independently mobile, therefore demand on staff for escorting residents to and from the sessions was high. Better integration of exercise sessions into care home schedules may improve efficiency of sessions and ease staff workload.

The group exercise programme required input from two physiotherapists. This raises concerns of the practicality and generalizability of this programme across multiple sites. Future studies should look into the possibility of training care home staff to deliver group exercise. As well as increasing likelihood of long-term sustainability of the programme, this would also allow more economical replication of the study on a larger scale. As previously mentioned, care home staff tend to deliver assistance to residents, often to save time, and the residents become accustomed to this. Training staff about the importance of exercise may help to change this habitual behaviour.

To conclude, larger randomized controlled trials of group exercise in care homes are needed. Careful consideration should be given to the social environment of the home and sustainability of the exercise programme. Better adherence may be achieved by educating staff, residents and relatives about the benefits of exercise and negotiating allocated times and dates for the exercise classes.

Clinical messages

- Seated group exercise sessions can be delivered to care home residents with reduced mobility.
- Residents with severe cognitive impairments struggle to comply with group exercises.
- Adherence is compromised by conflicting activities in the home. Better understanding of how to influence social environment in the home may enhance adherence.

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