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Randomised Controlled Trial of Exercise in the Elderly

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Abstract
Eighty-seven healthy volunteers aged 60–81 years were randomly allocated to either an aerobic exercise class or a health education group. Only 6 subjects dropped out during the 32-week study, and the average compliance with the interventions was 83% for exercise (on average 83/100 individual exercise sessions were attended) and 71% for health education. The health education group showed improvements from the baseline in physical activity levels, pulse rate, blood pressure and self-rating of mood. The exercise group improved from baseline in knee and spine flexibility, leg and back strength, pulse rate, blood pressure, maximum physical exertion levels, self-rating of mood and perceived health status. Between group comparison at the end of the study showed the exercise group significantly better than the health education group in terms of spine flexion ($p < 0.0001$), perceived health status ($p < 0.05$), life satisfaction ($p = 0.05$) and maximal physical exertion ($p = 0.01$). This study has demonstrated the acceptability and effectiveness of an aerobic exercise class for the elderly, and the effectiveness of health education for this age group.

Introduction

Although the benefits of exercise in the elderly on cardiovascular risk [1], lipid profile [2], aerobic power [3], osteoporosis [4], cerebral function [5] and constipation [6] are well established, levels of customary physical activity in the old are low [7]. Facilities and specific advice on exercise for the elderly are scant, and as much of the age-associated decline in muscle strength is now thought to be inactivity related, it seemed prudent to explore means of making exercise more accessible to the elderly.

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There are considerable methodological difficulties in conducting evaluations of exercise programmes, including adequate description of the exercise programme, detailed reporting of outcomes, blind outcome assessment, details of exercise compliance, drop-outs, sample size calculation and randomisation [8]. Several randomised controlled trials of exercise in the elderly have been performed in the United States [9–14], but all have concentrated on cardiovascular outcomes. Of equal importance is the potential for regular exercise to preserve function and prolong not just life expectancy, but active life expectancy [15]. Health practices that offer the possibility of slowing age-related decline are increasingly attractive to an ageing society. If exercise is to be of sustained benefit, then participation must be long term. Our randomised controlled study was designed to evaluate (1) the physical and psychological effects of attendance at an exercise class for the elderly; (2) the acceptability of an exercise class to the elderly, and (3) the effectiveness of health education in the elderly.

Subjects and Methods

Subjects and Recruitment

The subjects were recruited by an advertisement inviting enquiries from those in good general health, aged 60 years and over who were interested in joining a health and fitness project. 350 enquiries were received, from which 100 were selected at random. Subjects with a history of arrhythmias and those receiving β-blocker therapy (n = 5) were excluded. General practitioners were contacted and given the opportunity to exclude their patients from the study, and 8 subjects were excluded in this way because of severe ischaemic heart disease (n = 5) and psychiatric illness (n = 3). Eighty-seven eligible volunteers aged 60–81 years were recruited to the study.

The study was approved by the Tayside Committee on Medical Ethics, and written informed consent was obtained from the subjects.

Randomisation

Eighty-seven subjects were randomly assigned to one of two groups: exercise (n = 44) and health education (n = 43). Randomisation was by opening sealed envelopes supplied in sequence by the coordinator of the study (M.E.T.M.) and prepared from random number tables.

Measurements

The following measurements were made by the same observer (L.B.) at the same time of day in both groups at baseline, and at 1, 2, 4 and 8 months. At follow-up, all variables were assessed without reference to baseline values.

Primary Outcome Variables

The primary outcome variables of interest were flexibility and strength. Knee flexibility was measured resting supine in relaxed extension, and the subject instructed to maximally flex the knee. Flexion angle was measured with a goniometer to the nearest 1°. Spine flexibility was measured from an erect standing posture to full flexion. A tape measure was placed from C7 to S1, and the increase in length on full flexion recorded to the nearest 0.5 cm [16].

Grip strength was measured on the dominant side using a hand-grip dynamometer (Takei), and the best of three efforts recorded. Leg and back strength was measured using a back and leg dynamometer (Takei). The subject stood on the base plate and pulled maximally on the chain hooked to the dynamometer. The best of three efforts was recorded in kilograms of force.

Secondary Outcome Variables

Height and weight were measured with the subjects wearing outdoor clothes, but without shoes, using Krups portable scales, and a wall-mounted Seca scale.

Pulse rate and blood pressure were measured using a digital blood pressure and pulse monitor (Omron model HEM 400C) in the standing position and in the supine position after 2 min rest. Two readings were taken, and the mean value recorded.

Sway was measured using a Wright's [17] ataxiameter. Subjects stood with their feet comfortably apart and arms by their sides. They were asked to look at a distant object and to stand as still as they could for 30 s. A further measurement was made over the same period with the eyes shut.

Psychological assessments were made using a self-rating scale for depression (Geriatric Depression Scale [18], the Life Satisfaction Index [19] and a 3-point perceived health status questionnaire (above average = 1, average = 2, below average = 3).

Life-style assessment was made with questions concerning physical activity levels using a daily diary method [7]. Time spent in the exercise classes was omitted in this calculation. Physical exertion levels [20] and alcohol and tobacco consumption were noted.

Exercise Protocol

The exercise intervention required attendance 3 times per week at the University of Dundee Department of Physical Education's Over 60's Exercise Classes. Each session lasted for 45 min and comprised exercise to music. There was a warm-up period of 5–10 min at the start, and a cool-down period of similar duration at the end of each session. The format of the exercise classes contained elements of endurance, low-resistance muscle strengthening and suppleness. Most exercises were performed whilst weight bearing.

Health Education Protocol

Six health education sessions were held at regular intervals throughout the 8-month study, covering the following topics in order; the ageing process; the benefits of exercise; the importance of diet; the dangers of smoking tobacco and how to stop; osteoporosis, and stress management.

Sample Size and Statistical Analysis

Sample size calculation indicated that a sample size of 90 would give a 90% probability of detecting a 10% increase in flexibility and an 80% probability of detecting a 15% increase in back and leg strength at the 0.05 significance level.

Changes in normally distributed outcome variables were analysed using paired t tests. Between group comparisons were made using unpaired t tests. Outcome variables which were not normally distributed (perceived health status and depression score) were analysed using the Wilcoxon rank test. The study group was not subdivided for sex in the analysis, as it was assumed that men and women would respond to the interventions in a uniform fashion.

Results

Compliance and Follow-Up

Of the 87 subjects assigned to the study groups, 81 (93%) completed the study at 8 months. Three subjects dropped out of the exercise group: 1 because of lack of enjoyment; 1 because of a chronic 'back' condition, and 1 because of sciatica. Three subjects dropped out of the health education group; 1 because of gaining full-time employment; 1 because of lack of time, and 1 because of lack of interest. The average (range) of attendance at the exercise sessions was 83% (54–100%) and at the health education sessions 71% (50–89%).

Table 1. Physical characteristics of subjects at entry to study (mean ± SD)

Characteristic	Health education group (n = 43)	Exercise group (n = 44)
Age, years	64.5 ± 3.3	66.1 ± 5.1
Height, cm	157 ± 82	160 ± 86
Weight, kg	68.2 ± 11.4	68.6 ± 11.0
Body mass index, kg/m^2	28 ± 4	27 ± 4
Female:male	1.3:1	1.4:1

Alcohol and Tobacco Consumption

Only 11/87 (12.6%) of the subjects smoked at baseline, 5 in the exercise group and 6 in the health education group, and only 1 subject (in the health education group) had given up smoking tobacco by the end of the study. The average (range) cigarette consumption fell in both groups from 17.6 (1–30) to 14.2 (1–25) in the exercise group and from 16.2 (1–25) to 10.4 (0–20) in the health education group. The average alcohol consumption was 2.3 units per week in both groups, and this did not alter significantly by the end of the study.

Baseline and Follow-Up Study

There were no differences between the groups at baseline (table 1). Baseline and 8-month follow-up data for primary and secondary outcome variables showing a significant change are presented in table 2. Signifi-

Table 2. Primary and secondary outcome variables with significant differences at baseline and 8 months (means ± SD or medians and ranges are given)

Variable	Exercise			Health education		
	baseline	8 months	p value	baseline	8 months	p value
Knee flexion, °	130 ± 8	137 ± 7	< 0.001	132 ± 7	134 ± 11	NS
Spine flexion, cm	6.8 ± 2.3	9.8 ± 1.6	< 0.001	7.3 ± 2.0	7.5 ± 1.7	NS
Leg back strength, kg	88.4 ± 39.0	104.4 ± 48.0	< 0.001	87.0 ± 26.9	86.5 ± 42.5	NS
Mean pulse rate	82 ± 12	68 ± 9	< 0.001	79 ± 13	69 ± 10	< 0.001
Mean standing blood pressure, mm Hg						
Systolic	143.1 ± 18.0	140.2 ± 18.6	NS	136.8 ± 15.9	132.8 ± 20.8	NS
Diastolic	88.6 ± 11.7	85.0 ± 11.3	0.01	87.4 ± 10.6	83.6 ± 14.1	0.05
Life satisfaction	13.8 ± 3.9	15.9 ± 4.0	< 0.001	13.5 ± 3.5	14.1 ± 4.1	NS
Maximum physical exertion level	4.6 ± 1.4	5.4 ± 1.7	< 0.05	4.7 ± 1.9	4.5 ± 1.7	NS
Depression score	4 (0–30)	2 (0–27)	< 0.005	6 (0–15)	3 (0–17)	< 0.05
Perveived health status	1.4 (1–2)	1.2 (1–2)	0.01	1.5 (1–2)	1.6 (1–3)	NS

cant improvements in knee flexion ($p < 0.001$) and spine flexion ($p < 0.001$) occurred in the exercise group, but not in the health education group. Leg and back strength improved only in the exercise group ($p < 0.001$), but grip strength did not improve in either.

Sway did not improve significantly in either group, which may be due in part to a very wide inter-individual variation in values.

Mean pulse rate fell in both the exercise group ($p < 0.001$) and the health education group ($p < 0.001$). Both groups also showed a fall in standing diastolic blood pressure, more marked in the exercise group ($p = 0.01$) than the health education group ($p = 0.05$). These changes may reflect either a genuine effect of cardiovascular training or more likely merely a familiarisation with the digital measurements of pulse and blood pressure and a lessening of anxiety.

Both groups rated themselves as significantly less depressed at the end of the study ($p < 0.005$ in the exercise group, and $p < 0.05$ in the other group). One subject in the exercise group scored 30/30 on her baseline Geriatric Depression Scale rating and subsequently was treated by a psychiatrist. Both life satisfaction ($p < 0.001$) and perceived health status ($p = 0.01$) improved significantly in the exercise group only.

Physical activity levels increased by the end of the study in the health education group, but this failed to attain statistical significance. Maximum physical exertion scores, in contrast, increased in the exercise group ($p < 0.05$), but did not alter significantly in the health education group.

Follow-Up Study Comparison between the Two Groups

At 8 months, the exercise group was significantly improved over the health education group in terms of spine flexion ($p < 0.0005$), perceived health status ($p < 0.05$), life satisfaction ($p = 0.05$) and maximal physical exertion level ($p = 0.01$). The superiority in leg and back strength in the exercise group just failed to achieve statistical significance (table 3).

Table 3. Significant differences between groups at 8 months (means ± SD and medians and ranges are given)

Variable	Exercise	Health education	p value
Spine flexion, cm	9.8 ± 1.6	7.5 ± 1.7	< 0.0005
Maximum exertion level	5.4 ± 1.7	4.4 ± 1.7	0.01
Life satisfaction	15.9 ± 4.0	14.1 ± 4.1	0.05
Perceived health status	1.2 (1–2)	1.6 (1–3)	< 0.05

Discussion

This study has shown that adults aged 60 years and over participating in a 32-week health education programme made significant improvements from baseline in pulse rate, blood pressure and score on a depression scale. Although at baseline few of this group smoked, the average tobacco consumption did fall to a greater extent than in the exercise group. Inevitably, subjects who volunteer for such a study are already health conscious and may leave less potential for improvement [21]. However, information on health promotion tailored to this active subgroup of the elderly population is singularly lacking, and this study has demonstrated that provision of information and encouragement are sufficient to result in life-style changes and measurable physical benefit.

The ideal exercise regime for older people has not been established. It varies for different persons and especially among the elderly in whom variation is greater. Exercise should be dynamic, interesting, fun, varied [22], easily accessible and safe [23]. One subject dropped out of the exercise group with sciatica at 24 weeks. It is possible, but by no means certain, that the onset of this problem was related to participation in the exercise classes. No other adverse effects occurred.

Maintaining compliance is crucial to any long-term exercise programme, and as many as 50% of participants may defect over the first 6 months [24]. The strikingly good compliance of 83% in this 32-week study indicates that this exercise protocol was acceptable and enjoyable. Most other trials of physical activity in older people have devised an exercise regime which is used exclusively for the research project, and then discontinued. If exercise is to be widely adopted among the elderly then it must not require expensive specialised equipment or an unreasonable expectation of what an average pensioner should have to do to attain benefit. Exercise classes will not appeal to everyone, but the inherent social aspects may provide additional benefits in overcoming social isolation [25]. This study has evaluated an existing facility which has run in Dundee since 1977 and shown clear evidence of efficacy in terms of gains in flexibility, life satisfaction, perceived health status and maximum physical exertion levels.

The relationship between falls in the elderly and postural sway is well established [26], and the morbidity and mortality associated with falls is widely recognised [27]. Movement of the body trunk in the antero-posterior direction may be measured using a Wright [17] ataxiameter while a force platform yields information on the locus of resultant ground force reaction. The two methods have been correlated [28]. Several previous studies have examined the effect of exercise on postural sway, some of which have noted a favourable effect [29], but in others no improvement in balance has followed from par-

ticipation in an exercise programme [30, 31]. No effect was noted in our study, but a very wide inter-individual variation in sway readings was noted.

It has been shown elsewhere that hand-grip correlates with muscle mass in older subjects [32], but no improvements in grip strength were found in this study, despite gains in leg and back strength.

It is acknowledged that the subjects who volunteered for this project were likely to represent only a subgroup of the elderly population. It is well recognised that those who participate in an intervention study are very different from non-volunteers in many ways [20]. Volunteerism is associated with sex, age, socioeconomic status, education and other less-well-defined correlates of health consciousness. This does not affect the validity of the results, but may affect the generalisability of the results to the elderly population as a whole. Nonetheless, of the 81 subjects completing the study, 78% (35/41 in the exercise group and 28/40 in the health education group) have enrolled to continue taking part in exercise classes.

This study has demonstrated the acceptability and efficacy of an exercise class for the elderly. All old people should be encouraged to be physically active, and the development of specialist exercise classes may be a realistic means of achieving this. In addition, a health education intervention for the elderly resulted in beneficial life-style modification, and further study of health promotion in older people is indicated.

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