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A randomised controlled trial (RCT) of the cost-effectiveness of exercise in the over 65s

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/05/2011	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BP8

Study information

Scientific Title

Study objectives
The overall aim of the study was to quantify the cost-effectiveness of inviting a population of older adults to a community-based programme of exercise, whether or not the invitation was taken up, as an intervention to prevent or delay illness due to coronary heard disease (CHD), stroke, diabetes, mental illness or hip fracture, and to promote health and well-being.
The specific objectives of the study were:
1. To assess older adults' participation and adherence to a free and locally available exercise programme;
2. To evaluate the effect of such a programme on individual and population physical activity, quality of life, mortality, and use of health care;
3. To estimate the cost-effectiveness of the programme, if it proves to result in health gains.

Diseases areas: Cardiovascular diseases: Cerebrovascular disease; Cardiovascular diseases: Heart disease; Injury, occupational diseases, poisoning: Musculoskeletal injury; Mental and behavioural disorders: Depression, anxiety, neuroses; Nutritional, metabolic and endocrine diseases: Diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Cardiovascular diseases: Cerebrovascular disease; Cardiovascular diseases: Heart disease; Injury, occupational diseases, poisoning: Musculoskeletal injury; Mental and behavioural disorders: Depression, anxiety, neuroses; Nutritional, metabolic and endocrine diseases: Diabetes

Interventions
The intervention was defined pragmatically as invitation to a locally organised, free and regular programme of exercise classes. Each class was arranged to run weekly, at the same time and place each week, and usually led by the same exercise leader. In any week there would typically be four or five different classes available, run from two or three venues, and participants were encouraged to aim to attend at least two classes per week. Most classes were held in church halls, community centres and less frequently in residential homes. Control participants were not invited to partake in the exercise classes.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The major study outcomes were all-cause and exercise-related mortality, health service use, and health status. Mortality and health service use were assessed using routine NHS data. Health status was assessed by means of postal survey at baseline, 12 and 24 months using the SF-36 instrument. In addition an economic evaluation was undertaken of the cost-utility of the programme using a preference-based single index of health status derived from the SF-36.

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/1997

Eligibility

Key inclusion criteria
The subjects of the trial were the populations of 12 general practices in Sheffield, of which four were randomly selected as intervention populations, and eight as control populations. In each intervention population the least active four-fifths of those aged 65 and over were invited to attend free supervised exercise sessions in local community settings.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/1994

Date of final enrolment
31/12/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medical Care Research Unit
Sheffield
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Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Cardiovascular Disease and Stroke National Research and Development Programme (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/1997		Yes	No