A randomised controlled trial (RCT) of the costeffectiveness of exercise in the over 65s

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1994

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

Age group

Senior

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre Medical Care Research Unit

Sheffield United Kingdom S1 4DA

Sponsor information

Organisation

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

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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