Randomised controlled trial of a home-based exercise programme to reduce fall frequency among people with Parkinson's disease (PD)

Submission date Recruitment status [] Prospectively registered 08/12/2003 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 05/01/2004 Completed [X] Results [] Individual participant data Last Edited Condition category Nervous System Diseases 21/01/2009

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AP0888

Study information

Scientific Title

Study objectives

To evaluate the effectiveness of a personalised home programme of exercises and strategies for repeat fallers with Parkinson's disease (PD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

East Dorset Local Research Ethics Committee gave approval in March 2001 (ref: 13/00/S)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Parkinson's disease

Interventions

Intervention:

A home-based exercise programme, supervised by a physiotherapist. Appropriate exercises will be chosen from a menu of:

- 1. Balance training exercises in sitting and standing
- 2. Stretches
- 3. A programme of walking and moderate intensity strengthening exercises for hip, knee and ankle
- 4. Control:

Usual care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Rates of falling at 8 weeks and 6 months.

Secondary outcome measures

- 1. Repeat fallen, nearly fallen or experienced injurious falls
- 2. Functional Reach
- 3. The Berg Balance Test
- 4. PD Self-assessment Scale
- 5. The Euro Quality of Life scale

Overall study start date

01/01/2004

Completion date

01/01/2007

Eligibility

Key inclusion criteria

- 1. Diagnosed with PD living in the community
- 2. Independently mobile
- 3. Have experienced two or more falls in the previous 12 months
- 4. Have passed a screen test for confusion
- 5. Aged 44 91 years, both sexes

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

140

Key exclusion criteria

- 1. Did not meet inclusion criteria
- 2. Unable to participate in assessments because of pain and acute medical condition
- 3. In receipt of, or soon to receive, treatment

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Health & Rehabilitation Research Unit,
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House Horsham West Sussex United Kingdom RH12 2DP

Sponsor type

Charity

Website

http://www.action.org.uk/

ROR

https://ror.org/01wcqa315

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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	01/07/2007		Yes	No