Multifactorial day hospital intervention to reduce falls in high risk older people in primary care

Recruitment status No longer recruiting	Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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

Protocol number 6.5, R&D reference 04ME03

Study information

Scientific Title

Multifactorial day hospital intervention to reduce falls in high risk older people in primary care: a multi-centre randomised controlled trial

Study objectives

The main hypothesis to be tested is that a multidisciplinary falls assessment and intervention occurring at a Geriatric Day hospital can decrease the rate of falls over the course of one year, in older people identified in primary care as being at high risk of falling.

Secondary research questions:

- 1. Can the above intervention reduce the proportion of people with single or recurrent falls (greater than 1)?
- 2. Can the above intervention reduce fall-related injuries (including fractures)?
- 3. Can the above intervention reduce disability and improve quality of life?
- 4. Can the above intervention reduce institutionalisation and the need for the use of health services?
- 5. Is the intervention cost-effective and might it lead to overall cost-savings?
- 6. Can a screening questionnaire used in primary care reliably distinguish between low and high risk of falling?
- 7. Is there any difference in deaths between the two groups?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 08/09/2009: COREC approval has been obtained from the Nottingham main REC and the relevant local RECs (reference: 04/Q2404/93).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Interventions

Intervention arm:

Screening questionnaire, information leaflet, leaflet on falls prevention and invitation to attend the day hospital for assessment and any subsequent intervention.

Control arm:

Screening questionnaire, information leaflet, leaflet on falls prevention and usual care from primary care service until outcome data collected, then offer of day hospital intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The proportion of older people who fall over one year, identified in primary care as being at high risk of falling

Secondary outcome measures

Added 08/09/2009:

- 1. Proportion of people with single or recurrent falls (greater than 1)
- 2. Fall-related injuries: fracture, serious sprain requiring immobilisation in plaster, joint dislocations, head injury requiring hospitalisation, and lacerations requiring suturing
- 3. Disability: Nottingham Extended Activities of Daily Living Scale; Barthel Index of Daily Living; Quality of life: Falls Efficacy Scale and EuroQoL-5
- 4. Institutionalisation and use of health services: residency and diary information
- Cost analysis
- 6. Screening tool, defined by sensitivity/specificity as well as positive and negative predictive values
- 7. Deaths will be checked against PCT records and measured as proportions

Overall study start date

01/09/2004

Completion date

31/05/2006

Eligibility

Key inclusion criteria

The study population will comprise men and women aged 70 and over identified as being at high risk of falling by a postal screening questionnaire, registered with the participating general practices in Nottinghamshire and Derbyshire.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

400

Key exclusion criteria

- 1. Patients already attending one of the day hospitals
- 2. Patients under follow-up with an existing primary care based falls prevention scheme
- 3. Residents in nursing or residential homes
- 4. Patients with terminal illnesses
- 5. Those unwilling or unable to travel to the day hospital (using transport as provided)

Date of first enrolment

01/09/2004

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Rehabilitation and the Clinical Gerontology Research Unit

Nottingham United Kingdom NG5 1PB

Sponsor information

Organisation

Nottingham City Hospital (UK)

Sponsor details

Hucknall Road Nottingham United Kingdom NG5 1PB

Sponsor type

Industry

Website

http://www.nuh.nhs.uk/

ROR

https://ror.org/0022b3c04

Funder(s)

Funder type

Research organisation

Funder Name

Nottinghamshire, Derbyshire and Lincolnshire Research Alliance (UK)

Funder Name

Research into Ageing/British Geriatrics Society (UK) - Dhole fellowship (ref: DF/04)

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?
Protocol article	protocol	27/02/2006		Yes	No
Results article	results	01/11/2010		Yes	No