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

Submission date	Recruitment status	[_] Prospectively registered
09/05/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2011	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Tahir Masud

Contact details
Department of Rehabilitation and the Clinical Gerontology Research Unit
Nottingham City Hospital NHS Trust
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 969 1169 ext. 47193
tm@nchhce.demon.co.uk

Additional identifiers

Protocol serial number
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).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Falls

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

Key secondary outcome(s)
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
5. 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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

Study participating centre
Department of Rehabilitation and the Clinical Gerontology Research Unit
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
Nottingham City Hospital (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

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