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REducing Falls in IN-patient Elderly

Submission date 17/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 19/08/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 23/10/2013	**Condition category** Signs and Symptoms	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UKCRN 4527

Study information

Scientific Title
REducing Falls in IN-patient Elderly: a randomised controlled trial

Acronym
REFINE

Study objectives
The use of a pressure sensor alert system, incorporating a radio-paging alerting mode to alert staff to patients rising from their bed or chair, can decrease the number of bedside falls, in older people hospitalised in an acute care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 1 approved on the 23rd May 2008 (ref: 07HC006; MREC No.: 08/H0403/40)

Study design
Interventional single centre parallel-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Fall prevention

Interventions
Subjects are randomised either to receive bed and chair sensor equipment, or standard care (control arm). Subjects are allocated to the sensor or control arm using the web based randomisation service provided by the Clinical Trials Support Unit, University of Nottingham. The intervention is for the duration of the patient's ward admission, and the follow-up assessment is carried out one day prior, or on the day of, discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of bedside in-patient falls per 1,000 bed days from time of randomisation until the participant is discharged from the ward. A bedside fall is defined as an unexpected event in which the participant comes to rest on the ground, floor or lower level in the area around the bedside, with the bedside being defined as the area encompassed by the curtained area surrounding the bed. Outcomes are measured one day prior, or on the day of, discharge.

Secondary outcome measures
Outcomes are measured one day prior, or on the day of, discharge:
1. Number of injurious in-patient falls per 1,000 bed days, defined as falls resulting in abrasion, bruise, swelling, cut, laceration, dislocation, fracture or muscle sprain or strain
2. Length of hospital stay
3. Residential status on discharge
4. Transfer/mobility score and activities of daily living, measured using the Barthel Index
5. Fear of falling, measured using the Modified Falls Efficacy Scale (mFES) to ascertain any differential fear of falling in the two participant groups due to an increased awareness of a potential for a fall, or a greater sense of safety arising from sensor use
6. Health related quality of life, measured using the EUROQOL EQ-5D

Overall study start date
28/10/2008

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. In-patients
2. Male and female
3. Elderly, i.e., aged 65 years and over

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1800

Key exclusion criteria
1. Permanently bed bound prior to admission
2. Moribund/unconscious

3. Receiving end of life care on admission
4. Previously been included in the study in an earlier admission

Date of first enrolment
28/10/2008

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor in Orthogeriatric Medicine & Consultant Physician
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.qmc.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) (ref: PB-PG-0107-11112)

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	10/09/2009		Yes	No
Results article	results	01/03/2014		Yes	No