

# REducing Falls in IN-patient Elderly

<b>Submission date</b> 17/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/10/2013	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## 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

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

Nottingham

United Kingdom

NG7 2UH

## **Sponsor information**

**Organisation**

Nottingham University Hospitals NHS Trust (UK)

**Sponsor details**

Queens Medical Centre

Derby Road

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England

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+44 (0)115 9249924

maria.koufali@nuh.nhs.uk

**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?
<a href="#">Protocol article</a>	protocol	10/09/2009		Yes	No
<a href="#">Results article</a>	results	01/03/2014		Yes	No