Predicting the Risk Of Falling - efficacy of a risk assessment tool compared to nurses' judgement: a cluster-randomised controlled trial

Submission date Recruitment status [X] Prospectively registered 11/08/2005 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 01/09/2005 Completed [X] Results [] Individual participant data Last Edited Condition category 31/05/2019 Injury, Occupational Diseases, Poisoning

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

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

01GT0306

Study information

Scientific Title

Predicting the Risk Of Falling - efficacy of a risk assessment tool compared to nurses' judgement: a cluster-randomised controlled trial

Acronym

PROF

Study objectives

To determine if the administration of a fall risk assessment tool reduces the number of fallers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Frail elderly

Interventions

Education session for all clusters to optimise standard care and to minimise centre effects. Intervention group: Optimised standard care, administration of a standard fall risk assessment tool (Downton Index) alongside nurses' clinical judgement Control group: Optimised standard care with nurses' clinical judgement alone

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Number of participants with at least one fall at 12 months.

Secondary outcome measures

- 1. Number of falls
- 2. Clinical consequences, i.e., fall and injury prevention measures applied
- 3. Side effects, i.e., use of restraints

Other:

- 1. Injuries and fractures related to falls
- 2. Hospital admissions and consultations with a physician due to falls
- 3. Costs

Overall study start date

01/09/2005

Completion date

31/03/2007

Eligibility

Key inclusion criteria

Cluster (nursing home by itself or an independently working ward of a large nursing home):

1. At least 30 residents

Residents:

- 2. 70 years or older
- 3. Not bedridden
- 4. Living in the nursing home for more than three months

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

1080

Total final enrolment

1125

Key exclusion criteria

Cluster:

1. Less than 30 residents

Residents:

- 2. 69 years or younger
- 3. Living in the nursing home for less than three months
- 4. Bedridden

Date of first enrolment

01/09/2005

Date of final enrolment

31/03/2007

Locations

Countries of recruitment

Germany

Study participating centre University of Hamburg

Hamburg Germany D-20146

Sponsor information

Organisation

University of Hamburg (Germany)

Sponsor details

Unit of Health Sciences and Education Martin-Luther-King-Platz 6 Hamburg Germany D-20146 +49 (0)4042 838 7230 gabriele.meyer@uni-hamburg.de

Sponsor type

University/education

Website

http://www.chemie.uni-hamburg.de/igtw/Gesundheit/gesundheit.htm

ROR

https://ror.org/04bs1pb34

Funder(s)

Funder type

Government

Funder Name

German Ministry of Education and Research (Germany) - within the Northern Germany Nursing Research Network

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?
<u>Protocol article</u>	protocol	10/11/2005		Yes	No
Results article	results	01/07/2009	31/05/2019	Yes	No