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

Submission date	Recruitment status
11/08/2005	No longer recruiting
Registration date	**Overall study status**
01/09/2005	Completed
Last Edited	**Condition category**
31/05/2019	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Prevention

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(s)
Number of participants with at least one fall at 12 months.

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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

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	01/07/2009	31/05/2019	Yes	No
Protocol article	protocol	10/11/2005		Yes	No