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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
11/08/2005

Recruitment status
No longer recruiting

Registration date
01/09/2005

Overall study status
Completed

Last Edited
31/05/2019

Condition category
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

Contact name
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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
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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?
Protocol article	protocol	10/11/2005		Yes	No
Results article	results	01/07/2009	31/05/2019	Yes	No