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Evaluation of an evidence-based guidance on the reduction of physical restraints in nursing homes

Submission date 29/04/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/05/2009	**Overall study status** Completed	
Last Edited 29/05/2012	**Condition category** Other	

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

Sponsor ref: 01GT0605

Study information

Scientific Title
Evaluation of an evidence-based guidance on the reduction of physical restraints in nursing homes: a cluster-randomised controlled trial

Acronym
EBAGRAP

Study objectives
The purpose of this study is to evaluate the clinical efficacy and safety of an intervention programme based on an evidence-based guidance on the reduction of physical restraints in nursing homes. We are specifically interested in whether the intervention can reduce the number of residents with at least one physical restraint at six months of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Hamburg Chamber of Physicians approved on the 8th April 2009 (ref: PV3165)
2. Ethics Committee of the University of Witten/Herdecke approved on the 24th April 2009

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Physical restraints in nursing homes

Interventions
The intervention is based on an evidence-based guidance on the reduction of physical restraints in nursing homes, comprising 24 statements on relevant interventions to avoid physical

restraints. The intervention consists of a structured single information session of approximately 90 minutes for all nursing staff, provision of written information material for nurses, legal guardians and residents' relatives and a one-day training workshop for nominated nurses of each cluster, who will be responsible for all issues concerning physical restraints. Nurses in charge of the control group receive personal and written brief standard information on legal and scientific evidence on physical restraints and alternatives aimed to avoid measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of residents with at least one physical restraint after six months of follow-up. Physical restraints are defined as any device, material or equipment attached to or near a person's body, which cannot be controlled easily or removed by the person and which deliberately prevents or is deliberately intended to prevent a person's free body movement to a position of choice. Prevalence data of physical restraints will be obtained by direct observation on three occasions on one day (morning, noon, evening) by trained external investigators, who are blinded to allocation of nursing homes. Data will be collected before randomisation, after three and after six months using a proven data collection instrument of a previous epidemiological study.

Secondary outcome measures
The number of falls and fall-related fractures. Nursing staff will document fall events within their in-house documentation system throughout the whole study period. If no documentation sheet for fall events exists it will be provided by the researchers. Data will be collected throughout the study period (6 months).

Overall study start date
15/04/2009

Completion date
31/05/2009

Eligibility

Key inclusion criteria
Nursing homes in the city of Hamburg and in surrounding cities of Witten/Herdecke with at least 20% of residents with physical restraints and at least 60 residents. All residents will be included.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
36 nursing homes (approximately 3,000 residents)

Key exclusion criteria
Nursing homes with less than 20% of residents with physical restraints and less than 60 residents.

Date of first enrolment
15/04/2009

Date of final enrolment
31/05/2009

Locations

Countries of recruitment
Germany

Study participating centre
University of Witten/Herdecke
Witten
Germany
58453

Sponsor information

Organisation
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

Sponsor details
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Sponsor type
Government

Website
http://www.bmbf.de

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

Funder Name
Northern Germany Nursing Research Network (Germany) (ref: University of Hamburg: 01GT0605, University of Witten/Herdecke: 01GT0808)

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	07/09/2009		Yes	No
Results article	results	23/05/2012		Yes	No