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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Cluster-randomised controlled trial

## Study type(s)
Quality of life

## 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(s)
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.

### Key secondary outcome(s)
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).

### 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

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### 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)

**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

**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 | 23/05/2012 | | Yes | No |

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| Protocol article | protocol | 07/09/2009 | Yes | No |