

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 | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 29/05/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 29/05/2012 | Condition category Other | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gabriele Meyer

Contact details
University of Witten/Herdecke
Faculty for Medicine
Institute of Nursing Science
Witten
Germany
58453
+49 (0)2302 926 317
Gabriele.Meyer@uni-wh.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Projektträger im DLR

Heinrich-Konen-Strasse 1

Bonn

Germany

53227

Diana.Klassen@dlr.de

Sponsor type

Government

Website

<http://www.bmbf.de>

ROR

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 |