The effects of a restraint minimisation education programme on physical restraints use, staff knowledge, attitudes and perceived job strain

Submission date 18/04/2008	Recruitment status No longer recruiting	Prospectively registered
		[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
12/06/2008	Completed	[_] Results
Last Edited	Condition category	Individual participant data
12/06/2008	Mental and Behavioural Disorders	[_] Record updated in last year

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

Study information

Scientific Title

Study objectives

It is hypothesised that an educational intervention in group dwellings for persons with dementia will increase staff knowledge about and change their attitudes towards the use of physical restraints. This will lead to a reduction in physical restraints use which in turn will have an positive effect on staffs' perceived job strain.

Ethics approval required Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Faculty of Umeå University. Date of approval: 12/03/2002 (ref: Section 92/02, dnr 02-105)

Study design Cluster randomised controlled trial.

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Use of physical restraints in group dwellings.

Interventions

The intervention consisted of an education programme for the nursing staff (registered nurses, licensed practical nurses and nurse aid). The content of the programme included dementia diseases, symptoms, treatment and related complications, fall prevention, prevention and treatment of delirium, interaction and communication in dementia care and negative effects of, alternatives to and legislation directing the use of physical restraints.

First, the head-nurse at each intervention unit selected one person who underwent the whole education programme compressed during two seminar days. Remaining staff received their education via 30-minute videotaped lectures. Three of the lectures also included a clinical

written vignettes forming the basis for group discussions. At each unit it was up to the staff to make arrangements for watching the films and if desired to arrange group discussions. Each unit was responsible for making arrangements for taking part of the lectures and if desired to arrange group discussions. The education programme ran alongside ordinary work at the units without further involvement of the researchers besides distribution of the video taped lectures and data collection. In the education programme the emphasis was on the importance of investigating the underlying causes instead of working in a symptom-oriented manner e.g. a resident that have sustained a fall accident should be investigated for the cause of the fall instead of just using physical restraints. The staff was encouraged to use physical restraints only as the last resort. The intervention/education programme was carried out over six months.

The control units did not receive any interventions during the study period; they did receive interventions after the study was completed.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Residents:

1. Physical restraints were recorded daily for each patient, for three weeks before interventions, and then until the end of interventions (6 months). The information recorded include type of physical restraints used, hours restrained and reasons for restraining.

Outcomes concerning staff, measured before interventions and at 6 months:

1. Staff knowledge about current legislation, measured by a seven-item index score ranging between 0-7 (higher values indicate higher knowledge)

2. Staff subjective knowledge relating to care of people with dementia, measured by a visual analogue scale (VAS)

Staff attitudes, measured by the 17-item Perceptions of Restraint Use Questionnaire (PRUQ)
Job strain, measured by three instruments:

4.1. The Job-Demand and Social Support Questionnaire

4.2. Stress of Conscience Questionnaire

4.3. Caring climate, measured by a VAS

Secondary outcome measures

Outcomes concerning residents:

1. Fall accidents, recorded during the whole study period (8 months [1 month prior to interventions, 6 months during interventions and 1 month after interventions)

2. Psychoactive drug use, assessed before interventions and at 6 months

3. Motor function, vision, hearing and speech, assessed by the Multi-Dimensional Dementia Assessment Scale (MDDAS) before interventions and at 6 months. MDDAS included the Activity of Daily Living (ADL) functions and behavioural and psychiatric symptoms questionnaire. Gottfries cognitive level questionnaire (subscale to the MDDAS) was used for the measurement of cognitive level.

Staff characteristics:

4. Demography

5. Education level

6. Years worked

7. Evaluation of the intervention, carried out within one week after the end of intervention

Overall study start date 01/02/2005

Completion date 01/06/2006

Eligibility

Key inclusion criteria

Residents (both men and women) living in group dwellings for persons with dementia, which have at least 20% of the residents restrained.

Participant type(s) Patient

Age group Senior

Sex Both

Target number of participants 320 residents

Key exclusion criteria

Units with less than 20% of the residents restrained.

Date of first enrolment 01/02/2005

Date of final enrolment 01/06/2006

Locations

Countries of recruitment Sweden

Study participating centre Umeå University Umeå Sweden SE-90187

Sponsor information

Organisation Umeå University (Sweden)

Sponsor details

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Sponsor type University/education

Website http://www.umu.se/umu/index_eng.html

ROR https://ror.org/05kb8h459

Funder(s)

Funder type Research organisation

Funder Name Lions Research Foundation for Age Related Diseases (Sweden)

Funder Name King Gustaf V's and Queen Victoria's Freemason Foundation (Sweden)

Funder Name The Field Research Centre for the Elderly in Västerbotten (Sweden)

Funder Name

The Swedisch Research Council (Grant ref: K2005-27-VX-15357-01A)(Sweden)

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