# Belt restraint reduction in nursing homes.

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1. Does a tailored multi-component intervention (EXBELT) result in the reduction of belts in nursing homes? 2. Does EXBELT prevent the use of belts in newly admitted residents? 3. Does EXBELT reduce the use of other types of physical restraints...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26766

**Bron**
Nationaal Trial Register

**Verkorte titel**
EXBELT

**Aandoening**

physical restraints use in the nursing home care of older people with dementia.
Het gebruik van vrijheidsbeperkende materialen in verpleeghuizen dementerende ouderen

### Ondersteuning

**Primaire sponsor:** Maastricht University
Faculty of Health, Medicine, and Life Sciences
School for Public Health and Primary Care (CAPHRI)
Post-office box 616
6200 MD Maastricht
**Overige ondersteuning:** This study is funded by ZonMw, the Netherlands organization for health research and development.

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary outcome measure of the effect evaluation is the use of belts.

# Toelichting onderzoek

### Achtergrond van het onderzoek

The use of physical restraints still is common practice in the nursing home care of older people with dementia. The prevalence of restraint use ranges from 41-64%. Recent prevalence measures in the Netherlands have shown that belts are used in10% of nursing home residents. In most cases physical restraints are used as safety measures; the main reason is the prevention of falls. However there is growing evidence that reducing the number of physical restraints does not lead to an increased number of falls or fall-related injuries. In addition, the use of physical restraints has negative physical, psychological and social consequences for the elderly. Knowing that the use of physical restraints has been shown to be an ineffective and sometimes even hazardous safety measure, emphasizes the need for reducing the use of physical restraints.

We developed an intervention programme, named “EXBELT”, aiming to reduce the use of belts in nursing homes. This intervention programme consists of an educational programme of nursing home staff and consultation of a nurse specialist in combination with a policy change (the use of belts will be prohibited by the nursing home management) and the availability of alternative interventions. It has been piloted in one nursing home ward. The results of this pilot study are very promising. However, it is of utmost importance to further develop and test “EXBELT” on wards in other Dutch nursing homes.

The main objective of the proposed study is to further develop and evaluate a tailored multi-component intervention programme aiming to safely reduce the use of belts from clinical practice in nursing homes. However, the reduction of belts should not result in an increase of other restrictive restraints (such as a chair with a table) or psychoactive drug use. Therefore, we also will investigate the effects on other restraint measures.
The outcome of the proposed study is an intervention programme which has shown promising results regarding the effectiveness in safely reducing the use of belts in Dutch nursing homes, and that has the potential, after further testing it in a randomized controlled trial, to be implemented on a large scale in Dutch nursing homes. It should be emphasized that “EXBELT” runs ahead of the proposed legislation “Zorg en dwang” by the Ministry of Health, Welfare and Sport. In this proposed new legislation both the minister and state

secretary of Health, Welfare, and Sport have the intention to prohibit the use of belts.

“EXBELT” will be tested in a sample of 24 psychogeriatric nursing homes wards, including a total of approximately 480 nursing home residents. Half of the wards will receive the “EXBELT” intervention, half continuous care as usual. The effect evaluation will focus on the reduction of belt use and other restraint measures, fall and fall related injures, and the use of alternative interventions. The process evaluation will be investigating the fidelity and dose of the intervention, and also includes a ‘creative session’ with nursing home staff and product developers aiming to stimulate the development of innovative interventions by discussing problem cases. Data regarding the effect evaluation will be measured at baseline and after five and eight months. Data regarding the process evaluation will be gathered in a period of eight months between baseline and the second posttest after the intervention. As the current study is not directly aimed at the residents residing on the participating psychogeriatric wards, but primarily aimed at the nursing home staff of the participating psychogeriatric wards, no adverse effects of the intervention programme are expected.

**Doel van het onderzoek**

1. Does a tailored multi-component intervention (EXBELT) result in the reduction of belts in nursing homes?

2. Does EXBELT prevent the use of belts in newly admitted residents?

3. Does EXBELT reduce the use of other types of physical restraints?

4. Does belt elimination result in an increase of falls and fall related injuries?

5. What patient centered alternative interventions are used in EXBELT?

6. What is the opinion of nursing home staff, management and residents’ relatives about EXBELT and the effectiveness of alternative interventions?

7. What are indicators for successful or unsuccessful implementation of EXBELT?

8. What improvements (related to content, organization and monitoring) are necessary to optimize the effect of EXBELT?

**Onderzoeksopzet**

In November 2008 the Medical Ethics Committee of the University Hospital Maastricht and Maastricht University has approved the study design and protocols. In December 2008 we started the selection of the nursing homes. The informed consent procedure began in February 2009. Representatives of the residents received written information and were asked to give written informed consent for the use of personal data on the residents in the study.

Data will be collected at baseline (T1), and four (T2) and eight (T3) months after baseline. Baseline measurements followed in February and March and the implementation of EXBELT was started in March and April. The last follow up measurements are planned for the end of 2009 (effect evaluation) and early 2010 (process evaluation). Analyses of the data and dissemination of results are planned for 2010.

**Onderzoeksproduct en/of interventie**

The four key components of EXBELT are:

1. Implementation of institutional policy change that prohibits belt restraint use including communication of the policy change to:

a. Nursing home staff;

b. Residents' relatives.

2. Intensive educational intervention program for nursing home staff (nursing home physicians, nurses, paramedical staff, psychologists and ward managers) that address changing staff attitudes. Key parts are:

a. Focus on safely reducing belts with the understanding that nursing homes never can guarantee no falls or related injuries;

b. Taught by a nurse specialist during three small-scale meetings, each lasting three hours, over a three week period;

c. Small-scale meetings attended by nursing home staff from different wards;

d. A 90-minute educational session directed toward all nursing home staff of each intervention ward after the three small-scale meetings were delivered;

e. One specific module focused on strategies for changing attitudes such as shifting perspectives.

3. Consultation:

a. The nurse specialist who delivered the educational program will provide on-site consultation to individual nurses on the the intervention wards regarding challenges in reducing restraints for specific resident cases [19];

b. A nursing home manager and the Dutch inspectorate for health care (IGZ) will be available as a consultant to nursing home managers and clinical staff for indivicual cases, as needed;

c. Representatives of the nursing staffs, product developers, and the research team will discuss problem cases in a creative session.

4. Development and availability of alternative interventions:

a. Directors of the involved nursing homes will provide resident centered alternative interventions available including hip protectors, infrared systems, balance training, exercise, special pillows and lower beds;

b. The nurse specialist stimulates en facilitates decision-making regarding alternative interventions by multidisciplinary team;

c. The nurse specialist encourages the use of alternative interventions.

# Contactpersonen

## Publiek

M.J.M. Gulpers
[default]
The Netherlands

## Wetenschappelijk

M.J.M. Gulpers
[default]
The Netherlands

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The management boards of the four participating nursing home associations agreed with the implementation of the EXBELT program. To participate, the prevalence of belt use on psychogeriatric nursing home wards had to be at least 10%.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Wards are excluded if the unit is dedicated to residents with Korsakoff’s, if far-reaching reorganizations and/or constructional renovations will be implemented, and if participating in

other studies and/or projects aimed at the reduction of restrain use.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |

**Controle:** Actieve controle groep

## Deelname

Nederland

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|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-10-2008 |
| Aantal proefpersonen: | 480 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 11-12-2009 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2023 |
| NTR-old | NTR2140 |
| Ander register | ZON-Mw : 8140.0006 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**

1. Hamers JP, Huizing AR: Why do we use physical restraints in the elderly? Z Gerontol Geriatr 2005, 38(1):19-25.<br>
2. Hamers JP, Gulpers MJ, Strik W: Use of physical restraints with cognitively impaired nursing home residents. J Adv Nurse 2004, 45(3):246-251.<br>
3. Huizing AR, Hamers JP, Gulpers MJ, Berger MP: Short-term effects of an educational intervention on physical restraint use: a cluster randomized trial. BMC Geriatr 2006, 6:17.<br>
3. Huizing AR, Hamers JP, Gulpers MJ, Berger MP: Preventing the use of physical restraints on residents newly admitted to psycho-geriatric nursing home wards: A cluster-randomized trial. Int J Nurs Stud 2008, 46:459-469.<br>
4. Hamers JP, Meyer G, Kopke S, Lindenmann R, Groven R, Huizing AR: Attitudes of Dutch, German and Swiss nursing staff towards physical restraint use in nursing home residents, a cross-sectional study. Int J Nurs Stud 2008, 46:248-255.<br>
5. Hamers JPH, Gulpers MJM. Reducing physical restraints in nursing homes: results of a pilot study. J Nutr Health Aging Suppl 2009; 13: S17.