

# Is lowering of shear and friction (cost)effective for prevention of pressure ulcers? A multicenter, prospective, controlled randomized clinical trial in Dutch nursing homes.

Published: 02-09-2014

Last updated: 21-04-2024

Analyze whether application of a theoretical reasoned and tested system with test subjects is preventive and costs effective.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Skin and subcutaneous tissue disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON42278

### Source

ToetsingOnline

### Brief title

Lowering shear/ friction forces is effective for pressure ulcer prevention?

### Condition

- Skin and subcutaneous tissue disorders NEC

### Synonym

Bedsores, Decubitus, Pressure Ulcer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Sense Textile BV

**Source(s) of monetary or material Support:** Sense Textile B.V., Sense Textile BV

## Intervention

**Keyword:** Costs, Pressure ulcer, Prevention, Shear and friction force

## Outcome measures

### Primary outcome

Reduction of pressure ulcers on the Bedcare Plus system with 30%.

### Secondary outcome

Reduction of superficial pressure ulcers related to transfers, reduction of total cost prevention.

## Study description

### Background summary

Patients in Dutch nursing homes are suffering often with pressure ulcers.

### Study objective

Analyze whether application of a theoretical reasoned and tested system with test subjects is preventive and costs effective.

### Study design

Prospective, randomized controlled study with 220 patient.

### Intervention

About half the population will receive a visco-elastic foam mattress and the other part the same type of mattress with the Bedcare Plus system on top of it.

### Study burden and risks

There will be an inspection of the skin only once a week.

## Contacts

### Public

Sense Textile BV

Hertog Hendriklaan 6  
Oisterwijk 5062 CJ  
NL

### Scientific

Sense Textile BV

Hertog Hendriklaan 6  
Oisterwijk 5062 CJ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Both genders, age  $\geq 60$  years, mentally competent or incompetent
2. Life expectation  $>3$  month
3. Chronic patient in nursing home
4. No pressure ulcer in last 3 months
5. Braden score 6-15
6. Patient or his legal representative has read and signed Informed consent form before treatment

### Exclusion criteria

1. Patient is participating in another wound study.

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2. Patient has any condition(s) like need of hospital care, cancer, sepsis that seriously compromises the patient's ability to complete this study according to the judgment of the MD

## Study design

### Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2015
Enrollment:	220
Type:	Actual

### Medical products/devices used

Generic name:	Bedcare Plus
Registration:	No

## Ethics review

Approved WMO	
Date:	02-09-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	17-12-2014
Application type:	Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	11-05-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	02-09-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
Other	Aanvraag loopt
CCMO	NL48831.028.14