

# Cost-effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home clients

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To assess the effects and costs of the use of the Australian Medical Sheepskin and usual care with regard to the prevention of sacral pressure ulcers in somatic nursing home clients, versus usual care only.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30419

### Source

ToetsingOnline

### Brief title

Cost-effectiveness of the Australian Medical Sheepskin

### Condition

- Other condition

### Synonym

decubitus, pressure ulcers

### Health condition

decubitus

### Research involving

Human

## Sponsors and support

**Primary sponsor:** NIVEL

**Source(s) of monetary or material Support:** ZonMW-doelmatigheidsprogramma

## Intervention

**Keyword:** Cost-effectiveness, Nursing home, Pressure ulcers, Sheepskin

## Outcome measures

### Primary outcome

-incidence and prevalence of pressure ulcers on the sacrum in the first month

after admission

- costs

### Secondary outcome

- sacrum pressure ulcer free days

- adverse events

- comfort / ease of use

## Study description

### Background summary

Pressure ulcers are a very common problem in nursing home patients and have a high burden. Earlier research demonstrated a preventive effect of the Australian Medical sheepskin in hospital patients. Probably there will be the same preventive effect of the sheepskin in nursing home patients.

### Study objective

To assess the effects and costs of the use of the Australian Medical Sheepskin and usual care with regard to the prevention of sacral pressure ulcers in somatic nursing home clients, versus usual care only.

## Study design

Multicenter randomised controlled trial

## Intervention

The experimental condition is use of the Australian Medical Sheepskin as an overlay on the mattress in combination with usual care. The control condition is the usual care. In both conditions usual nursing co-interventions (e.g. mobilisation and repositioning schemes) may be applied. It is also allowed to apply other pressure-relieving equipment (e.g. foam mattresses), as normally used in that nursing home, as soon as pressure ulcers occur or are expected. For both conditions there will be a concise registration of all care and devices applied.

## Study burden and risks

As far as we know there are only minimal burden or risks with the application of the Australian Medical Sheepskin. The research burden consist of daily skin inspection of 2 minutes during thirty days and responding to a short questionnaire about comfort and ease of use of the sheepskins.

## Contacts

### Public

NIVEL

Postbus 1568  
3500 BN Utrecht  
Nederland

### Scientific

NIVEL

Postbus 1568  
3500 BN Utrecht  
Nederland

## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

adult, admitted for a somatic reason, free of sacral pressure ulcer, not having a darkly pigmented skin (because of difficulty to diagnose stage 1 ulcer) and having an expected stay of more than one week.

### Exclusion criteria

Admitted for a primarily psycho-geriatric reason, having sacral pressure ulcers at admission

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2007
Enrollment:	750

Type: Actual

## Medical products/devices used

Generic name: Australian Medical Sheepskin

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 02-01-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

CCMO

**ID**

NL14075.041.06