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The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients: A prospective multicenter randomized-controlled trial (ISRCTN17553857)

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ABSTRACT

A multicenter prospective randomized clinical trial was undertaken to investigate the effectiveness of the Australian Medical Sheepskin (AMS) in the prevention of sacral pressure ulcers in somatic nursing home patients. Patients were randomized at admission and were then followed daily for 30 days. The experimental group received usual care plus an AMS as a layer on the mattress within ultimately 48 hours after admission; the control group received usual care only. Usual care was all the care that nursing wards normally applied for pressure ulcer prevention without any further standardization for this study. A total of 588 patients were randomized (293 control and 295 experimental group) and the data of 543 patients could be analyzed (272 from the control and 271 from the experimental group). The incidence of sacral pressure ulcers grade 1 or higher was significantly lower in the experimental group than in the control group (8.9% vs. 14.7%). In a multilevel analysis on the incidence of pressure ulcers adjusted for Braden risk score, age, and gender, it shows an odds ratio of 0.53 (95% confidence interval: 0.29–0.95), meaning a significant protective effect of the AMS. These results are in line with the results of two earlier trials on the AMS in hospital patients. The majority of patients in our trial that used an AMS rated it positively, but one-third found the sheepskin too warm. We conclude that the AMS is an effective aid in the prevention of sacral pressure ulcers in nursing home patients.

Pressure ulcers are highly prevalent, especially among elderly residing in nursing homes.¹⁻⁴ Pressure ulcers are not only a very common problem but they also represent a major burden and reduce quality of life for patients and their caregivers; pressure ulcers cause prolonged contact with the health care system, pain, discomfort, and inconvenience.⁵⁻¹⁰ Moreover, the prevention and therapy of pressure ulcers are very costly.^{7,11-15}

Pressure ulcers develop when capillary circulation is obstructed by prolonged pressure. Also, shear and friction are contributing factors for the development of pressure ulcers. Therefore, many interventions are in use to minimize pressure on bony prominences, such as repositioning and different kinds of pressure-reducing devices.^{13,16,17} Sheepskin is one such pressure-reducing device. According to a literature review of the Australian Commonwealth Scientific and Industrial Research Organization (CSIRO),¹⁸ citing studies from as early as the 1930s, it is known that sheepskins have pressure-reducing properties. Besides this, sheepskins have good moisture-absorbing capacities. Therefore, sheepskins have long been in use to prevent pressure ulcers. However, the old natural sheepskins could not retain their pressure-reducing capacities after frequent washing; hygienic problems also arose because they could not withstand washing above 40°C. Later, many attempts were made to produce artificial sheepskins, but none had the same pressure-reducing or moisture-absorbing properties. Hence, the use of sheepskins, both genuine and artificial, was almost completely discontinued and came to be regarded as ineffective.¹⁹ Currently, none of the guidelines known to us on pressure ulcer prevention and treatment encourage the application of any form of sheepskin. However, in the 1990s, interest in genuine sheepskin was renewed. Marchand and Lidowski²⁰ found promising results, which prompted the Australian Commonwealth Scientific and Industrial Research Organization, CSIRO, to develop new methods for producing new genuine medical sheepskins with high pressure-reducing capacities but without the disadvantages of the old-style sheepskins. The Australian Medical Sheepskin (AMS) is a real genuine sheepskin, coming from the Australian Merino sheep. The sheepskin has a wool pile length of 30 mm, and a high density of wool piles. The sheepskin is tanned and processed in such a way that it has an increased resistance to urine and can withstand up to 60 washes at 80 °C to achieve high-level thermal disinfection, without losing its moisture-absorbing and pressure-reducing properties.²¹

This new AMS has been tested extensively on pressure-reducing characteristics, laundry procedures, disinfection, wear-and-tear, patient comfort, and other aspects²¹ (<http://www.csiro.gov.au>). The necessary qualities for a sheepskin to be called an AMS are described in the National Australian Standard AS 4480.1.²² The effectiveness of the AMS in the prevention of pressure ulcers was first tested clinically in a randomized-controlled trial in 297 elderly orthopedic hospitalized patients with good results: the incidence rate of pressure ulcers was 9.6% in the intervention vs. 30% in the control group.²³ These results were confirmed in another randomized trial with 441 adults patients from different hospital wards.²⁴ Both studies were well designed, the latter receiving an award for the best research article published in the Medical Journal of Australia of 2004. These previous studies established that the application of Australian Medical Sheepskins was easy for nursing personnel and for patients^{23,24} and there were no problems with washing the skins.²⁵ These trial results led to positive comments and recommendations in four recent systematic reviews.^{16,17,26,27}

However, the question arises as to whether these results in acute hospital patients can be replicated in nursing home patients, who are generally considered to be at higher risk for developing pressure ulcers.

In this study, we therefore tested the hypothesis that the incidence of sacral pressure ulcers in newly admitted somatic nursing home patients that are given an AMS in conjunction with usual care will be lower than the incidence in a group that receives usual care only.

MATERIALS AND METHODS

Ethical considerations

Patients were informed by the admitting nurse verbally and in written format about the research project before they were asked to participate and before they signed the informed consent form. At all times, patients were free to withdraw from the study without having to give a reason for doing so.

The study protocol was approved by the certified Medical Ethics Review Board of the University Medical Centre of Utrecht (protocol number 06/287), on behalf of all the participating nursing homes.

The Board of Directors of each participating nursing home signed a form in which they stated that they have read and understood the research protocol and that there were no obstacles at all to conduct the research in their organizations.

The scientific merits of the study protocol have been reviewed in the consecutive phases of the research funding process by independent reviewers of the funding organization ZonMw, the Netherlands Organization for Health Research and Development (<http://www.zonmw.nl/en>; ZonMw grant number 945-07-513).

Besides this, the research protocol, and more specifically the washing procedure of the sheepskins, have also been evaluated by the Dutch Working Party on Infection Prevention (<http://www.wip.nl/UK/>) and approved as safe.

The protocol is registered in the Controlled Trial Register as ISRCTN17553857 and has been published earlier.²⁸

DESIGN

The study concerned a prospective multicenter randomized-controlled trial with one experimental and one control group.

The study population consists of patients newly admitted for a primarily physical impairment, e.g., after a cerebrovascular accident or after a hospital admission for a hip fracture, to one of eight participating nursing homes. Inclusion criteria are: admitted for a primarily somatic reason, adult (aged 18 years and older), expected stay >1 week, free of pressure ulcers on the sacrum at admission, not having darkly pigmented skin (because of difficulty in diagnosing grade 1 pressure ulcer), and no known allergy to wool. Inclusion criteria were checked at admission by the admitting ward nurse.

Patients that were admitted for a primarily psycho-geriatric reason were excluded.

Patients that fulfilled these criteria were given verbal and written information by the admitting nurse about the research and were asked for consent. In case a patient was cognitively impaired, informed consent was obtained from the family.

Randomization and start of the intervention occurred mostly on the admission day and ultimately within 48 hours after admission.

The selection of the eight participating nursing homes (involving 23 nursing wards) was made on the basis of the customer list of the laundry company that we selected, which was able to do the washing and drying of the sheepskin according to the Australian Standard.²²

The patient inclusion process started on May 1, 2007 and ended on January 31, 2009. The patient inclusion flow is shown in Figure 1.

[FIGURE 1].

As discussed in the study protocol,²⁸ a power calculation was performed beforehand and learned that 750 patients (2×375) were needed to find a 10% difference between groups with a power of at least 80% and a two-sided α of 0.05.

To ensure concealment of allocation, a randomization scheme was created in SPSS by assigning the intervention to a random sample of circa 50% in a list of 1,500 numbers and assigning the control group to the rest. This allocation of the group (sheepskin, usual care) was then blinded on a paper list numbered 1 through 1,500 by a secretary not further involved in the project. Each time a patient was admitted, the admitting nurse called the principal investigator who then disclosed the allocation from that blinded list to the nurse and she, in turn, to the patient.

Because it is impossible to blind health professionals or patients to whether someone is in the experimental group or not, only the patient allocation itself was blinded to all parties involved.

The allocated condition had to be marked with green/red stickers in the patient records and had to be filled out daily on the observation checklist. Furthermore, an overview of the allocated conditions was communicated weekly from the principal investigator to the research contact persons in each institution so they could check if the intervention/control was applied as allocated. Finally, the principal investigator checked bimonthly if the allocated intervention was correctly applied.

INTERVENTION

The experimental condition consisted of all usual care and the application of the AMS (type: Hi-temp, Urine Resistant, size XXL, bought from Yellow Earth, Laverton, Australia) as an overlay on top of the standard mattress in the area of the buttocks. An extra AMS at the bottom of the bed and in the (wheel)chair was also permitted. The application of the AMS started no later than 48 hours after admission. The AMS was then applied during the first 30 days after admission or until a patient died or was discharged, whichever came first. If patients wished so, they could continue to use the AMS after these initial 30 days (frequency of this has not been recorded). In addition, patients were free to quit using the AMS whenever they wanted, but in these cases the daily skin observations continued until day 30 after admission, according to the intention-to-treat principle. The period of 30 days was chosen because most pressure ulcers develop in the first weeks after admission.^{2,29-31}

Besides the use of the Australian Medical Sheepskin, all other usual pressure ulcer preventive interventions such as mobilization and repositioning could be added as cointerventions, in so far as they concerned usual care in the participating nursing homes. All other nursing care could be continued as usual (including incontinence materials).

The control group received usual care only, including all the pressure-reducing interventions and other preventive actions, normally taken in the participating nursing homes. The application, in any form, of the AMS was forbidden in this group during the first 30 days after admission; patients from this control group were free to ask for an AMS after the observation period of 30 days was ended (the frequency of this has not been recorded).

In both groups, the regular/usual mattresses were applied. Trademarks and types differed from institution to institution and even from ward to ward. Most common mattresses in use were Deron-Deqpress, Doove-Economica, Ubica-Salvia, Aquarius-combi, HillRomm-cliniplot, and Bos-Europur.

Wound care specialists from the institutions were allowed to start with a special pressure-reducing mattress for a patient during the observation period when they considered this necessary. In this case, it was required to note this on the daily observation form.

Outcomes

The primary outcome for this study was the incidence of sacral pressure ulcers in the first 30 days after admission. It was decided to focus on sacral pressure ulcers, because these are the most frequent in Dutch nursing homes.¹ Secondary outcomes were the presence of pressure ulcers on other places, duration of pressure ulcers, onset day of pressure ulcers, quality of life, comfort of the sheepskin as experienced by the patients, and ease of use of the sheepskin as experienced by the care personnel.

Measurement instruments

At admission, data on general characteristics (age, gender, medical diagnosis category) were gathered as well as information on possible influencing factors such as surgery in the previous month, presence of pressure ulcers at admission on other places than the sacrum, incontinence status, nutritional status (including body mass index [BMI]), the risk on developing pressure ulcers with the Braden scale,³² and the functional status with the Barthel index.³³ These measures were assessed again at day 30 after admission.

With regard to the Braden scale, two cut-off points as being at risk for PU were chosen: the first at ≤ 20 , because this cut-off point is used in the annual Dutch national prevalence study of care problems^{1,34-36} and the second at ≤ 18 as proposed by the latest publication of Braden herself.³⁷

The primary outcome—incidence of sacral pressure ulcers—was assessed daily by the nurse caring for that patient that day. The nurse reported her assessment on a form specially designed for this study. On this “daily observation checklist,” it was also noted whether there were pressure ulcers on other locations than the sacrum, whether a sheepskin was applied in bed and/or chair, whether a repositioning scheme was applied, whether other pressure-reducing devices were used in the bed and/or chair, and whether the patient used some kind of incontinence material during the day and/or night.

The presence and severity of pressure ulcers were recorded confirming the EPUAP grading system (<http://www.epuap.org>). A photographic series of the various pressure ulcer grades was available on each ward as well as transparent disks that nurses pressed against erythema by hand to see whether the area blanched under pressure.

In order to obtain valid and reliable results, the ward nurses were instructed to call a specialized nurse, experienced in observing pressure ulcers, when they felt uncertain about their observations (it has not been

recorded how many times this had occurred during the trial). Also, the ward nurses were obliged to report all cases of pressure ulcers to an assigned wound care specialist, who then could check the observation, give care instructions, and monitor the progress of the ulcer. Finally, the daily skin observations by nurses during routine care were also checked bimonthly by the principal investigator (P.M.) from the central research office (34% of the included patients were checked by the primary investigator with 99.1% agreement concerning the presence/absence of sheepskin and 98.1 agreement concerning the presence of a sacral pressure ulcer at that day).

Quality of life was measured at day 30 by a visual analog scale with two anchors: 0=the worst health status ever and 100=the best health status that could be imagined.

Furthermore, the patients in the experimental group were asked at the end of the research period (or earlier if they no longer wanted to use the sheepskin) to rate the (dis)comfort of the sheepskin. For this purpose, a self-developed seven-item questionnaire with a five-point rating answer structure was developed. Items concerned softness, itching, smell, warmth, tickling, comfort, and if they would recommend an AMS to other patients; additional comments could be written on the form.

Ease of use of the sheepskin for caregivers was measured by group interviews with the ward nurses that were held on three occasions during the research period.

Data analysis

Statistical testing of the primary outcome, the difference in incidence between experimental and control group was conducted by multilevel binary logistic regression analysis,^{38,39} with three levels: patients nested within wards and these nested within institutions. Hereto, the software MLwiN Version 2.02⁴⁰ was used and the estimation procedure PQL with second order was applied. The independent variable was the allocated intervention and the dependent the incidence of sacral pressure ulcer during the observed period. The multilevel analysis was controlled for age, gender, the number of observed days, and the pressure ulcer risk at admission, as determined by the Braden scale.

According to the intention-to-treat principle, all patients were analyzed in the groups they were randomized to. Thus, where a patient discontinued the use of the AMS, the daily observations continued and this patient was kept in the experimental group for the analysis.

In addition, the difference in proportion of pressure ulcer-free days and in the mean number of pressure ulcer days was tested by a two-sided Student's *t* test.

RESULTS

Patient characteristics In the research period, there were 1546 new admissions, of which 1066 patients fulfilled the inclusion criteria. These 1066 patients were given information and were asked to participate. Of these, 588 patients gave consent and were randomized (293 to the control and 295 to the experimental group). The number of randomized patients per participating nursing home varied from 11 to 244. No significant differences existed between nursing homes in the proportion of patients that were randomized to the intervention or control group.

Outcome data were received from 543 patients (272 from the control and 271 from the experimental group). The group of 45 patients from which no outcome data were received, was equally divided over the two groups and did not differ from the final group with regard to age, gender, pressure ulcer risk, or functional status (Table 1). The main reason for not obtaining outcome data was primarily nurses that forgot to send the forms or the forms were mistakenly discarded when a patient died or was discharged home or transferred to another institution or the forms were lost somewhere in the mail process.

[TABLE 1]

Experimental and control group did not differ from each other at baseline with respect to gender, age, Braden score, Barthel score, and BMI (Table 2). Also, no differences between groups existed in relation to medical diagnosis groups: 40.5% of all patients had an admitting diagnosis related to a cardiovascular disease (mainly a cerebrovascular accident) and a further 38% of patients had a bone-related admitting diagnosis (mainly a hip fracture). Forty-two percent of the patients underwent surgery in the month before admission to the nursing home with a similar amount in both groups. By and large, the patients were admitted to the nursing home for the purpose of rehabilitation.

[TABLE 2]

The total number of observable days was 7563 days in the control vs. 7721 in the intervention group; the mean number of observable days was 27.8 days in the control and 28.4 days in the intervention. Neither total nor mean differed statistically between groups.

Intervention

In the experimental group, the AMS was present in bed during 70% of all observation days in the 30-day period for the sheepskin group, according to the daily observation record. One-third of the patients in the sheepskin group discontinued the use of the AMS, mostly within the first week and mainly because they found it too warm. The sheepskin was almost never applied under the heels or in the chair.

In the control group, 1.7% of the observable days was spent with an AMS; this occurred in the beginning of the study period, because it was then not entirely clear to the nurses when they were allowed to give an AMS to the patients.

According to the intention-to-treat principle, patients from the experimental group who discontinued the AMS or control patients who received an AMS remained for the analyses in the groups they were randomized to.

There were no significant differences between groups concerning the “usual care” component, e.g., regarding the use of repositioning schemes or regarding the use of incontinence material during day or night time or regarding the type of mattress (Table 3).

[TABLE 3]

With regard to the application of preventive special pressure-reducing mattresses, it looks like more patients from the control group switched from the basic mattress to a special pressure-reducing mattress somewhere during the observation than patients from the intervention group, although not reaching the statistical significance point. However, these mattresses were mostly (63%) started after a patient already developed a pressure ulcer.

Incidence of sacral pressure ulcers

Overall, 64 patients developed a sacral pressure ulcer in the first 30 days after admission. The majority of sacral pressure ulcers were grade 1 (50 patients with a pressure ulcer of maximal grade 1, 12 patients with a pressure ulcer of maximal grade 2, and two patients with a pressure ulcer of maximal grade 3). The incidence of sacral pressure ulcers in the first 30 days after admission was significantly lower in the experimental group with the AMS than in the control group (24 (8.9%) vs. 40 (14.7%); two-sided χ^2 , $p=0.035$).

The mean onset day of pressure ulcers in the control group was the ninth day after admission and the 12th day in the experimental group. Figure 2 shows the decline over time in percentage of patients who are free of sacral pressure ulcer by group.

[FIGURE 2.]

For the patients with a sacral pressure ulcer incident, the mean number of days with a sacral pressure ulcer in the first 30 days after admission showed no statistically significant difference (10.7 days in the control group vs. 9.2 in the intervention group; t test, $p=0.46$).

Patients from the intervention group had in total 97% pressure ulcer-free days vs. 94% in the control ($p<0.001$).

No differences between intervention groups were found in pressure ulcer severity, expressed as EPUAP grades.

When the multilevel analysis on the incidence of pressure ulcers is adjusted for Braden risk score, age, and gender, it shows an odds ratio of 0.53 (95% confidence interval: 0.29–0.95), meaning a significant protective effect of the AMS. No statistically significant ward or institutional effect was found in the multilevel analysis.

Incidence of new pressure ulcers elsewhere than sacral was not statistically different across groups (15.1% in the control vs. 16.4% in the intervention group; χ^2 , $p=0.69$). The most frequent location of pressure ulcers elsewhere were the heels, that occurred in 11% of all patients.

In the total group, 133 patients (24.5%) developed a pressure ulcer on one or more body locations (60 (22.1%) in the intervention group vs. 73 (26.8%) in the control group).

No statistically significant difference between groups was found in mean quality of life for the patients (mean 62.1 in experimental group vs. 61.3 in control group; Student's t test $p=0.71$). However, it is worth noting that the mean quality of life for patients without sacral pressure ulcers was 63 and significantly higher than the mean of 53 found in the patients with a sacral pressure ulcer (Student's t test, $p=0.003$).

With regard to perceived comfort of the AMS, 209 (71%) patients from the intervention group filled out the comfort questionnaire. They judged in majority positively about the AMS on all aspects. But one-third of the patients considered the AMS too warm, what was often (for two-thirds of these patients) a reason to quit using the AMS. Fifty-two percent of the patients would recommend the AMS to other patients, 26% had no judgment, and 22% would not recommend the AMS to others (Figure 3).

[FIGURE 3]

The 29% nonresponse was equally divided between patients that used the AMS until the end of the observation period and patients that quit using it in that period. Hence, there are no indications that only patients that were in favor of the AMS filled out the questionnaire. Main reasons for nonresponse were either that the patient died during the trial or was discharged and nurses had forgotten to give the comfort questionnaire in time, or the patient was not cognitively able to fill out the questionnaire.

Finally, nurses did not encounter difficulties in using the AMS in daily practice. But it was remarked that the AMS made it slightly more difficult to change bed linen in bedridden patients. Also, the fact that the dirty sheepskins needed separate linen bags caused some inconvenience.

DISCUSSION

This study found that the AMS is an effective intervention in the prevention of sacral pressure ulcers in somatic nursing home patients. Our results in nursing home patients are completely in line with the results of the two earlier trials^{23,24} in hospital patients.

A discussion point may be the fact that pressure ulcers grade 1 were included in the outcome measurement. In many prevalence studies grade 1 is omitted due to the fact it is difficult to detect and this may distort the figures. However, this trial was an incidence study, and for each patient, consecutive daily observations were performed and we could see that an observation of grade 1 pressure ulcer was, in 92% of the cases, not a single day observation only, but rested a few days. Of the 57 patients who developed a pressure ulcer that initially was a grade 1, seven cases deteriorated into a more severe grade ulcer. Moreover, this trial was on prevention of pressure ulcers and in our opinion it is important to measure pressure ulcers as soon as they appear, although the first signs may not be very serious to patients. Halfens et al.⁴¹ demonstrated that grade 1 ulcers can deteriorate and they conclude that grade 1 can be interpreted as an important warning sign for nurses and patients to act. Nevertheless, the clinical significance of grade 1 pressure ulcers has not yet fully been demonstrated.

In our study, a limited observation time of 30 days after admission was used and hence it is unknown what occurred after those initial 30 days. It would be very interesting to follow the course of pressure ulcers that still were present at day 30, for instance, to see if the AMS is also capable of preventing pressure ulcers from turning from grade 1 into grade 2, or if the AMS is helpful in reducing the length of pressure ulcer existence. For this purpose, future trials are needed with a much larger time frame.

The incidence of pressure ulcers in both groups was lower than we had expected beforehand based on the scant literature available. This may be explained by the possibility that only nursing homes agreed to participate in the study that are already quite advanced in pressure ulcer prevention. Also, the lower incidence could be due to the attention the study brought to pressure ulcer prevention. Furthermore, there are indications^{1,42} that, in general, the incidence and prevalence of pressure ulcers in nursing homes have decreased through the years and are now indeed lower than the figures we used at the time of the study design.

A weakness of the study is the fact the outcome measurement was not blinded. However, several nurses were involved during the observation period of 30 days for a single patient and hence where each other control and nurses were clearly instructed to call a senior nurse or wound care specialist when they felt uncertain or suspected a pressure ulcers and, finally, the primary investigator did bimonthly checks on the observations. Furthermore, as far there had been influence from the nonblinded assessment, there is a great chance it would be in the direction against the AMS, because we faced many nurses during the trial who were very suspicious and had prejudices about the use of sheepskins. They were taught at school that sheepskins were not allowed and the guidelines discourage these. Blinded outcome assessment by the use of photographs has been considered and discussed by the scientific team, but we expected too many difficulties to obtain this kind of measurement implemented in a standardized way in daily practice, and we feared that many patients would refuse that daily pictures of their buttocks be taken. Moreover, photographs are not suitable to detect if erythema is blanching or not.

Another limitation of the study relates to the intervention dose: although the AMS was recorded as present in bed in 70% of all observable days in the intervention group, it is not known what amount of time patients actually spent in bed and laid on the sheepskin.

The same remark is to be made concerning the application of repositioning: on the daily observation form, it was only checked if such a scheme was applied, but we were not able to check if this scheme was also actually correctly applied.

A remarkable finding in this study is that one-third of the patients found the AMS too warm. This is much more than the 3.6% of patients that found the AMS too warm or uncomfortable as reported in the Australian trial of Jolley et al.²⁴ It is difficult to establish what the cause of this difference might be. Is it culturally induced: are Australian people much more used to sheepskin? Or are there differences in institutional climates between Europe and Australia? A recent Dutch study⁴³ indicated that a majority of nursing home patients found the inside temperature of nursing homes too warm. Or are there differences between hospital and nursing home patients? Future research is needed to answer such questions. In addition, no data were collected about the experienced comfort of the bed in the control group. It could be the case that patients from the control group also found their bed and linen too warm.

A further question still to be addressed is whether the AMS is less, equally or more (cost)effective than other pressure-reducing materials or methods.

This study, together with the two other Australian trials, clearly provides evidence that the AMS is an effective aid for preventing pressure ulcers. Therefore, we recommend that guidelines on pressure ulcer prevention revise their statements in relation to the use of genuine sheepskins.

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Competing interests: The authors declare that they have no competing interests.

The sheepskins were purchased, after having requested trade offers from three different companies, at regular market prices from Yellow Earth, Laverton North, Australia. The washing procedures of the sheepskins were carried out at regular market prices by Lips Textile Services, Schiedam, the Netherlands.

These two companies did not contribute in any way to the funding of this study, and none of the authors have commercial or financial interests with these companies.

Authors' contributions: All authors contributed substantially to the development of the study protocol and to the drafting of this paper. All authors read and approved the final manuscript.

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TABLES AND FIGURES

Figure 1. Patient inclusion flow chart.

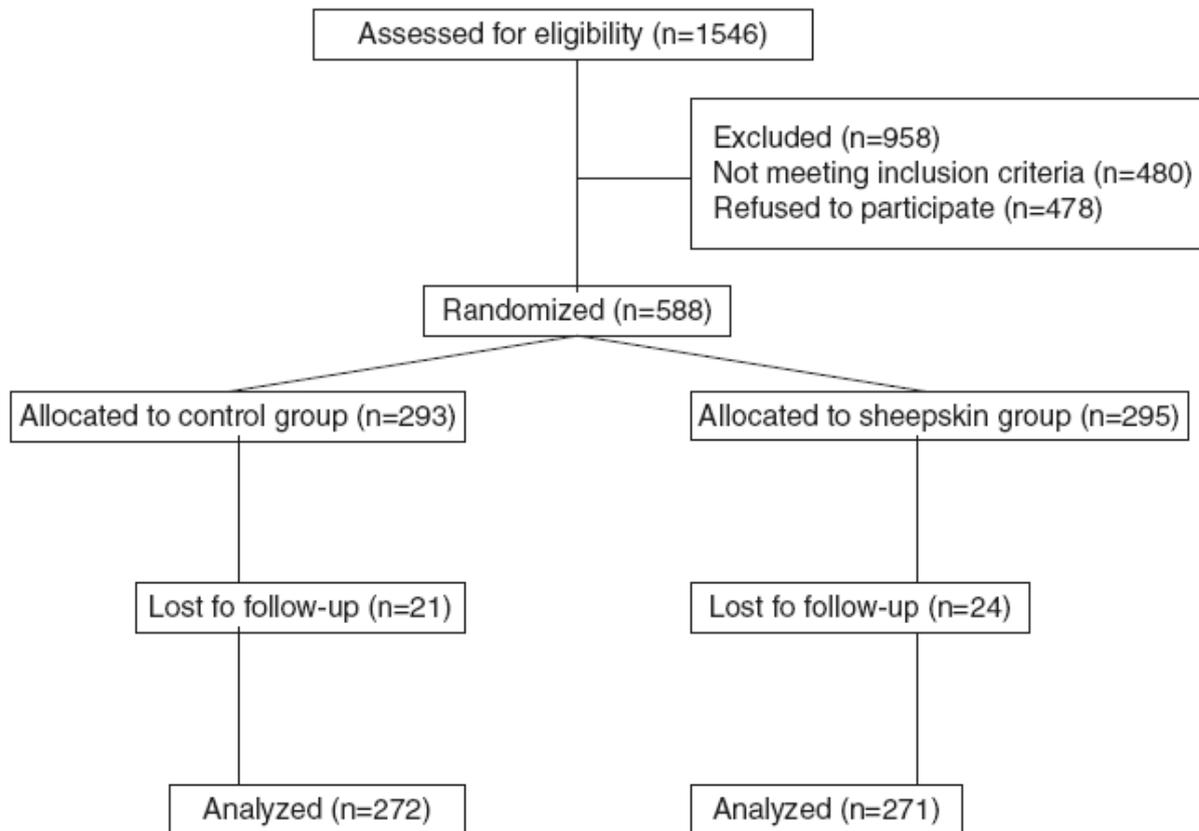


Table 1. Characteristics of lost to follow-up patients vs. analyzed patients

	Lost to follow-up		Analyzed patients (n=543)	-p-value difference control vs. intervention in lost to follow-up patients	p-value difference lost to follow-up vs. analyzed patients
	Intervention (n=24)	Control (n=21)			
Female (%)	63	71	68	0.53	0.72
Age (mean)	78	75	78	0.51	0.23
Barthel score (mean)	10.5	10.5	9.6	0.98	0.41
Braden (mean)	18.4	18.6	18.2	0.88	0.70
BMI (mean)	23.7	25.4	25.1	0.37	0.81

BMI, body mass index.

Table 2. Baseline patient characteristics by randomized group

	Intervention (n=295)	Control (n=293)	<i>p</i>
Female (%)	71	67	0.26
Age mean (min–max)	78 (26–97)	78 (27–98)	0.71
Barthel score mean	9.9	9.4	0.18
Patients with risk on pressure ulcer % (Braden score ≤ 20)	70	71	0.79
Patients with risk on pressure ulcer % (Braden score ≤ 18)	47	47	0.84
Body mass index mean	24.6	25.6	0.36

Table 3. Usual care components by intervention group

Expressed as % of patients	Intervention (n=271)	Control (n=272)	<i>p</i>
Repositioning scheme	16.4	15.9	0.87
Basic mattress			0.78
Aquarius	50	50	
Deron	38	62	
Doove	62	38	
Hill-Rom	48	52	
Ubica	50	50	
Bos	55	45	
ComfortCare	50	50	
Special pressure-reducing mattress (not standard mattress)	9.7	15.1	0.06
Special pressure-reducing seat	15.4	15.8	0.87
Incontinence material in day time	49.8	55.1	0.21
Incontinence material in night time	50.9	55.9	0.25

Figure 2. Decline over time in % of patients free of sacral pressure ulcer by group.

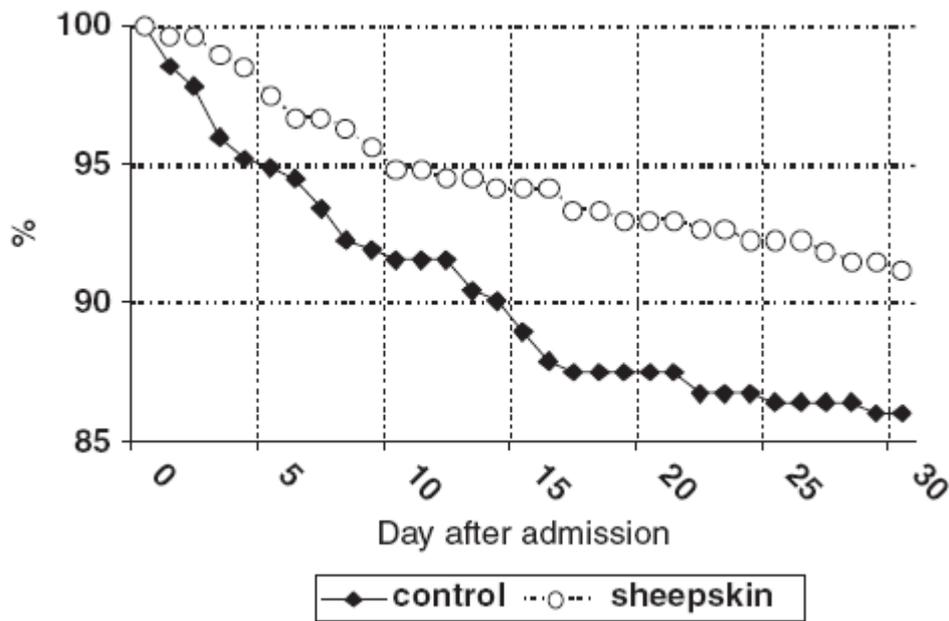
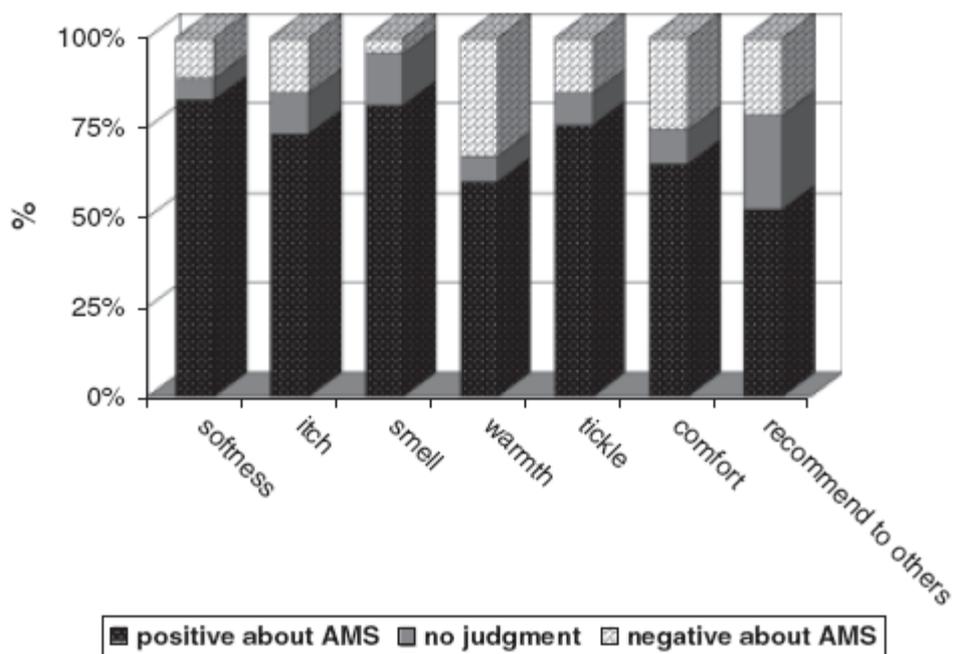


Figure 3. Patients' judgment about the Australian Medical Sheepskin.



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