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The effectiveness of Iranian sheep-felt mattresses on pressure injuries prevention in moderate to high-risk hospitalized patients: a randomized controlled trial

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Abstract

Background Managing chronic wounds, particularly pressure injuries, poses a challenge for healthcare professionals. This study aimed to evaluate the effectiveness of Iranian sheep-felt mattresses in preventing pressure injuries among hospitalized patients.

Methods In this parallel, open-label randomized controlled trial, 55 patients at moderate to high risk of pressure injuries, admitted to the intensive care unit or the internal ward of Bohlol Hospital (Gonabad, Iran; 2022–2024), were randomly assigned to an experimental group ($n=28$) or a control group ($n=27$). Participants had no existing pressure injuries or uncontrolled diabetes upon admission. The control group received routine care with a standard wavy mattress, while the experimental group additionally received an Iranian sheep-felt mattress. Eligible patients were enrolled within 48 h of admission and followed for up to 30 days. Primary outcome was pressure injuries occurrence within 30 days; secondary outcomes included pressure injury-free days, pressure injury severity, and patient satisfaction. Data were collected via demographic/clinical questionnaires, the Braden Risk Scale, National Pressure Injury Advisory Panel classification, and the mattress satisfaction questionnaire, and analyzed using Chi-square, Mann–Whitney, exact tests, and survival analysis. Relative risk, absolute risk reduction, and number needed to treat were calculated.

Results Data from 50 patients (25 in each group) were analyzed. The incidence of pressure injuries was significantly lower in the experimental group compared to the control group (12.0% vs. 56.0%; $p < 0.001$), corresponding to a relative risk of 0.21, an absolute risk reduction of 44%, and a number needed to treat of 3, highlighting the clinical significance of using the Iranian sheep-felt mattress. A significant difference was also noted in the stage of pressure injuries ($p = 0.002$), with lower stages in the experimental group. The median survival time free of pressure injuries was 20.0 days (Interquartile range: 18.0–30.0) in the control group and 30.0 days (Interquartile range: 30.0–30.0) in the experimental group, with a significant difference between the groups ($p = 0.015$).

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Conclusions This study indicated that Iranian sheep-felt mattresses can reduce the incidence and severity of pressure injuries. Multi-center trials with larger sample sizes are necessary to confirm these results and evaluate long-term effects.

Clinical trial registration This research was registered (11/05/2022) at <https://irct.behdasht.gov.ir/> with registration number: IRCT20190622043968N3.

Keywords Pressure injuries/prevention & control, Sheep-felt mattresses, Support surfaces, Risk assessment, Controlled clinical trial, Intensive care units

Background

Chronic wound care, including the management of pressure injuries, poses a significant challenge for healthcare professionals and consumes a large portion of global healthcare resources [1]. Pressure injuries are localized areas of damage to the skin and the tissues beneath it, most commonly found over bony prominences or where medical devices apply pressure. These injuries result from prolonged or intense pressure, often combined with shear forces, and may be influenced by factors such as nutrition, blood flow, tissue condition, and other health problems. The severity of these injuries can vary from minor redness of the skin to deep damage involving fat, muscle, and bone [2]. They occur when soft tissue is compressed between bony prominences and external surfaces, resulting in tissue death due to restricted blood flow [3, 4]. Pressure injuries are a common source of patient injury [5] and are considered a key indicator of the quality of health care in medical facilities [6]. They can lead to prolonged hospital stays, increased workload for healthcare providers due to hospital-acquired infections and disruption of recovery processes, increased use of healthcare resources, reduced quality of life for patients, and increased mortality rate [3, 7].

Despite advances in medical technology and preventive programs, the global prevalence of pressure injuries during hospitalization continues to grow. According to a systematic review and meta-analysis, the worldwide prevalence of pressure injuries is 12.8%, with significant variations found in different geographic areas. For example, the prevalence is 14.5% in Europe, 13.6% in North America, 12.7% in South America, 3% in Asia, 12.6% in the Middle East, and 9% in Australia [8]. In the Eastern Mediterranean region, the prevalence of pressure injuries is between 7 and 44.4% [9]. In Iran, the prevalence of pressure injuries in general and specialized departments of hospitals is between 5 and 21% [10].

Various strategies are used to reduce pressure on bony prominences, including frequent repositioning and the use of support surfaces to distribute pressure evenly. Evidence shows that the use of pressure-redistributing support surfaces can significantly lower the incidence of pressure injuries [11, 12]. These surfaces include mattresses, overlays, bed systems, and other devices designed

to redistribute body pressure, minimize shear forces, and regulate microclimate conditions such as heat and humidity [12]. In recent years, there has been a growing interest in exploring alternative and complementary therapies for the prevention and treatment of pressure injuries. One approach is the use of protective surfaces made of sheep textiles. Findings from a systematic review of four trials on the effect of sheepskin on pressure injuries incidence suggest that sheepskin may have potential benefits in lowering the incidence of pressure injuries [11]. These findings are consistent with the recommendations of the latest international guideline on support surfaces, which highlights medical-grade sheepskin as an effective option for pressure redistribution and reduction of pressure injury incidence [13].

In Iran, felt (Namad) is a traditional wool-based fabric produced through pressure, moisture, and heat, commonly in regions such as Kermanshah, Mazandaran, Khorasan, Semnan, Chaharmahal, and Bakhtiari. Its main component, wool, gives felt physical properties that allow it to filter suspended particles in gases and liquids and to provide thermal insulation for walls, roofing, and other applications [14]. Beyond industrial uses, wool in felt also offers therapeutic benefits, including heat retention, enhanced blood circulation, and reduced muscle tension [14]. Clinical trials confirm that wool improves comfort and alleviates pain: in neuropathic pain, wool wristbands enhanced sympathetic skin responses and reduced pain [15], and in chronic nonspecific low back pain, woolen clothing and bedding significantly decreased pain and tender point counts [16].

To the best of our knowledge, there are currently no studies examining the effects of felt mattresses made from Iranian sheep wool for preventing and treating pressure injuries, highlighting the need for research in this area.

Aims & objectives

The primary aim of this trial was to evaluate the effect of Iranian sheep-felt mattresses on the prevention of pressure injuries within 30 days of hospital admission among patients admitted to the Intensive Care Unit (ICU) and the internal ward.

The secondary aims were to examine the effect of the intervention on (a) the time to occurrence of pressure injuries, and (b) the severity of pressure injuries.

Methods

A full version of the study protocol, detailing methodology and data collection procedures, has been included as Supplementary File 1.

Trial design

This study was a randomized, controlled, parallel-group clinical trial with a 1:1 allocation ratio and it was registered in the Iranian Registry of Clinical Trials under the code IRCT20190622043968N3, with the registration date of 11 May 2022. The report was developed in accordance with the CONSORT guidelines.

Study setting

Participants were selected using a convenience sampling technique from patients admitted to the ICU and the internal ward of Bohlol Hospital in Gonabad, Iran, between May 2022 and April 2024 who met the eligibility criteria.

Inclusion and/or exclusion criteria

The inclusion criteria for participation in the study were as follows: Being at moderate or high risk of developing pressure injuries based on the Braden Scale for Pressure Injury Risk Assessment (Scores of 14 or lower), providing informed consent of the patient or his significant others (relative or legal guardian) to participate in the research, not having any pressure injuries upon admission to the hospital, and not having uncontrolled diabetes (defined as HbA1c level $\geq 7\%$). Patients were excluded from the study if they had died or discharged within one week of starting the study, or if they had any sensitivity to the felt after the start of the intervention.

Sample size

The initial sample size for the study was set at 50 patients per group, calculated using G*Power 3.1.9.2, based on a type I error rate of 0.05, a power of 0.8, pressure injury rates from a similar study ($p_1 = 0.303$, $p_2 = 0.09$) [17], and an anticipated dropout rate of approximately 20%. During the implementation phase of the study, a high attrition rate was observed during participant screening, which prolonged the study's duration and made it impossible to maintain the original sample size. Consequently, the study was halted with 25 patients in each group. A post hoc power analysis was conducted to assess the study's statistical power with the reduced sample size. Given the significant difference in proportions ($p_1 = 0.56$ and $p_2 = 0.12$), a type I error rate of 0.05, and a sample size of 25, the study's power was deemed adequate at 0.9155.

Randomization and blinding

Participants were randomly assigned to either the experimental group (Iranian sheep-felt mattress) or the control group (Wavy mattress with cotton cover) using permutation blocks of size 4. The random allocation sequence was generated by the analyzer via the online platform (<https://www.sealedenvelope.com>) and kept confidential in sequentially numbered, opaque, sealed envelopes. These envelopes were opened, in order, only after participants had provided informed consent and enrolled in the study.

Blinding was specifically implemented for the analyzer. Treatments were coded as A and B in the dataset to maintain confidentiality and prevent bias during the analysis.

Study instruments

Demographic and clinical characteristics questionnaire

The questionnaire included several questions on age (in years), gender, marital status, educational level, occupation, weight (in kilograms), height (in centimeters), admission diagnosis, history of chronic diseases, substance abuse history, and history of pressure injuries. Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared (kg/m^2). BMI categories were defined according to World Health Organization criteria: underweight ($< 18.5 \text{ kg}/\text{m}^2$), normal weight ($18.5\text{--}24.9 \text{ kg}/\text{m}^2$), overweight ($25.0\text{--}29.9 \text{ kg}/\text{m}^2$), and obesity ($\geq 30 \text{ kg}/\text{m}^2$) [18].

Braden pressure injuries risk scale

The Braden scale, introduced in 1987 [19, 20], is globally recognized as one of the most commonly utilized methods for evaluating the risk of developing pressure injuries. It is a criterion consisting of six key criteria: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. Each criterion, except for abrasive force, is assessed on a scale of 1 to 4, while abrasive force is rated from 1 to 3. A score of 1 signifies the "worst possible condition", whereas a score of 4 indicates the "best possible condition". The total score is calculated by summing the six criteria scores, resulting in a range of 6 to 23. These scores are then categorized into low risk (15 to 18), moderate risk (13 to 14), high risk (10 to 12), and very high risk (9 or lower) categories [21]. The appropriateness of the Braden scale to assess the risk of pressure injuries in hospitalized patients was confirmed by other studies in Iran [10, 22].

National pressure injury advisory panel (NPIAP) classification system

The severity of pressure injuries was assessed using the NPIAP classification system. This system categorizes pressure injuries into Stages 1 to 4, unstageable, and deep tissue injury, based on the depth of skin and underlying

tissue involvement [23]. It has been used in various studies worldwide, including several conducted in Iran [24, 25].

Questionnaire of patients' satisfaction with felt mattresses

In this study, a researcher-developed questionnaire was used to assess patients' satisfaction with felt mattresses. Participants were asked to rate their experiences with the felt mattress in terms of comfort, sleep quality, pain relief, heat sensation, sweating, and unpleasant odor. Responses were collected using a three-point Likert scale (low, medium, high) to gauge the participants' experiences with the mattresses. The content validity of the questionnaire was assessed by a panel of experts in nursing and clinical care (Supplementary File 2).

Study procedure and interventions

After obtaining informed consent, demographic and clinical data for each participant were collected using a combination of medical record reviews and interviews with the patient or their legal guardian.

Interventions

Before the intervention, skin in areas prone to pressure injuries (e.g., sacrum, heels, elbows, scapulae) was assessed by trained nurses through visual inspection and palpation, consistent with international clinical guidelines [2], to detect early signs of pressure-related damage (e.g., erythema, induration, maceration). Mechanical factors (e.g., friction and shear) were evaluated based on patient positioning and observed skin changes. Chemical factors (e.g., moisture) were monitored by checking for incontinence or sweating, and preventive hygiene measures were applied when needed. Bacterial factors were evaluated clinically through inspection for any signs of local infection (e.g., odor, exudate, swelling, or inflammation).

Control group

Participants in the control group received a standard hospital mattress, a wavy mattress with a cotton cover. They were given routine care, which included regular skin assessments, maintaining skin hygiene, using gentle products for skin protection, and changing positions every two hours with the help of trained staff. Additionally, participants and their families were educated on skincare and pressure injuries prevention, emphasizing the importance of mobility and hydration. The mattresses and covers were regularly checked and replaced if soiled to ensure a clean and safe environment. The use of the other mattress, specially felt mattress in any form was prohibited for this group during the first 30 days after admission.

Experimental group

The experimental group received the same standard care as the control group, but with an added benefit. They were given a specialized pressure-reducing mattress, an Iranian felt mattress made by Devin Teb Pooya Co., placed on top of the standard mattress for the duration of their stay. The mattress complies with national quality and safety standards for medical textiles. Key specifications include:

Fiber diameter: 30–35 microns.

Fiber length: 100 mm.

Dimensions: 90 × 200 cm; thickness ≈ 8 cm; weight ≈ 4 kg.

Surface features: Square-shaped elevations (20 × 20 cm) with linear indentations (5 cm wide).

Cover material: 100% pure cotton fabric.

Applications: Designed to prevent pressure injuries, enhance relaxation and comfort during sleep, and effectively absorb perspiration.

Cleaning instructions: Cotton cover – machine washable; mattress body – hand wash or use hand-wash setting on washing machine.

The felt mattress was applied within 48 h of admission and remained in use for the entire hospital stay.

Both groups were monitored for 30 days after the intervention. Participants who stayed for less than one week (due to transfer, death, or discharge) were excluded from the study. During hospital stay, daily assessments of pressure injury-prone areas were conducted by trained nurses in all wards, including after transfer from the ICU, using the Braden Pressure Injury Risk Scale. If a pressure injury occurred, its severity was determined according to the NPIAP classification system.

After discharge, participants continued using their assigned mattress at home and were instructed to inspect pressure-prone areas daily and report any signs of skin damage to the research team. For reported cases, photographic documentation was obtained, when possible, for preliminary review. Staging of pressure injuries after discharge was determined through in-person assessment by a trained nurse.

Outcomes

The primary outcome of this study was the occurrence of pressure injuries within the initial 30 days after admission. Secondary outcomes included the number of days without pressure injuries and the severity of the pressure injuries. Additionally, the perceived comfort level with the Iranian felt mattresses in the experimental group was evaluated.

Statistical analyses

The study data was analyzed using SPSS software, version 21 (SPSS Inc., Chicago, IL). All participants included in the analysis had complete data, with no missing values.

The normality of quantitative variables was assessed with the Kolmogorov-Smirnov test. Descriptive statistics included mean and standard deviation for normally distributed quantitative variables, and median and inter-quartile range (IQR) for non-normal quantitative variables. Qualitative data were described using frequency and percentage. The Chi-square and exact/Fisher exact tests were employed to compare qualitative variables between groups. Normal and non-normal quantitative variables were compared between groups using the independent sample t-test and Mann-Whitney test, respectively. The primary outcome, focusing on the difference in pressure injuries incidence between the experimental and control groups, was evaluated using the Chi-square test. To compare the incidence of pressure injuries between groups, relative risk (RR), absolute risk reduction (ARR), and number needed to treat (NNT) were calculated along with their 95% confidence intervals.

The secondary outcomes included the survival time (in days) free of pressure injuries and the severity of pressure injuries. Survival curves for “time free of pressure injuries” were estimated using the Kaplan-Meier method, and differences between groups were assessed using the

log-rank test. For the survival analysis, time was measured from the start of mattress use until the occurrence of the first pressure injuries (event) or censoring. Participants who did not develop pressure injuries during the 30-day follow-up period were considered censored. The analysis assumed non-informative censoring and that the exact timing of events was accurately recorded. The severity of pressure injuries was compared using the exact test. A significance level of less than 0.05 was considered.

Results

Study flow

A total of 158 patients were screened, among whom 55 patients were enrolled in the trial. Of these, 27 (49%) were randomized to the control group and 28 (51%) to the experimental group based on the pre-determined randomization list. During the study, 3 patients from the experimental and 2 from the control group were died within one week of starting the study and excluded from the study. Finally, data from 25 participants in the experimental group and 25 participants in the control group were analyzed (Fig. 1).

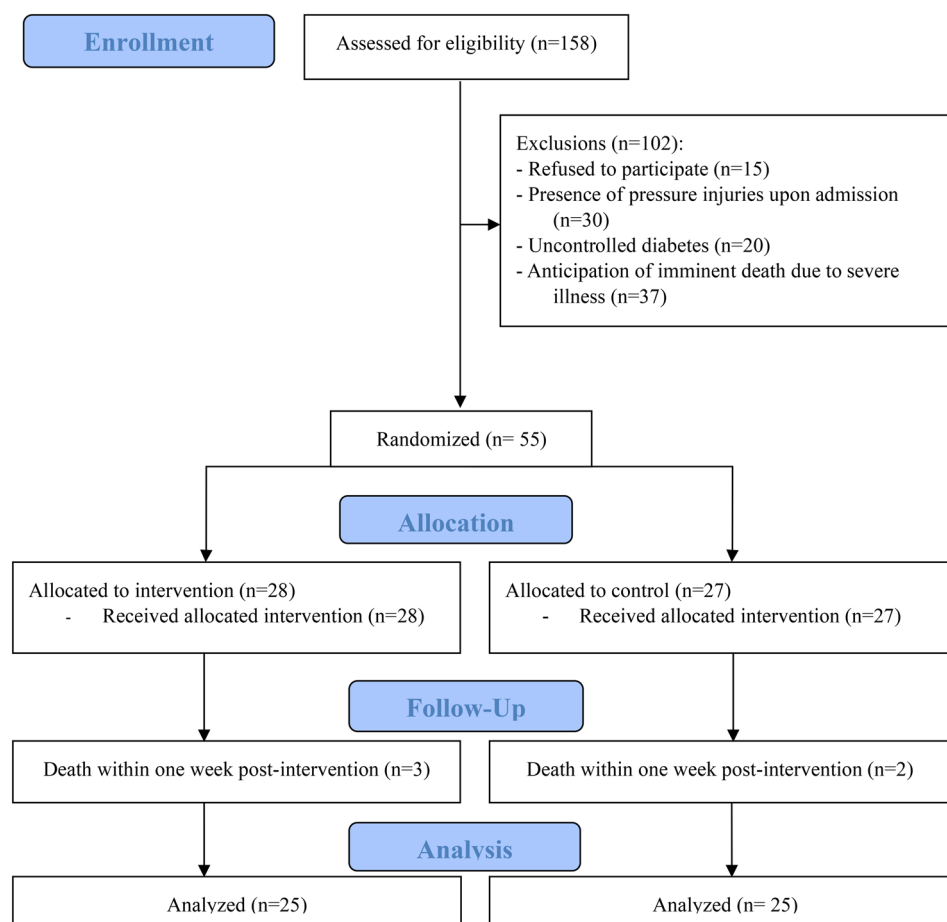


Fig. 1 The Consort flow diagram of the study

Baseline characteristics of the participants

The baseline characteristics of the participants are summarized in Table 1. The median age of the participants was 79.0 years (IQR: 67.0–87.0). Among the participants, 50% were female, 94% had a high school education or lower, and 80% were married. 48% were housewives, 32% were retired, 72% had a history of chronic diseases, and 14% had a history of substance abuse. The mean BMI of the participants was 22.9 (SD = 3.3). Most participants (66%) had a normal BMI, while 10% were classified as underweight, 11% as overweight, and 2% as obese. There were no statistically significant differences regarding age, sex, BMI, educational level, marital status, occupation, history of chronic diseases, history of substance use, and history of pressure injuries between the groups, except for admission diagnosis ($p = 0.016$). According to the Braden score, 24% (experimental group: 28% vs. control group: 20%) were at very high risk, while 72% (experimental group: 64% vs. control group: 80%) were at high risk of developing pressure injuries. In the experimental group, 8% had a prior history of pressure injuries, whereas no participants in the control group reported such a history.

Incidence of pressure injuries

In this randomized controlled trial, 3 of 25 participants (12.0%) in the experimental group and 14 of 25 participants (56.0%) in the control group developed pressure injuries, with a statistically significant difference between the groups ($p < 0.001$). In the experimental group, all 3 pressure injuries occurred in the sacral region, whereas in the control group, 12 cases were in the sacrum, 1 in the buttocks, and 1 in the shoulder (Table 2).

Clinical significance of the intervention

The RR for pressure injuries development with the intervention was 0.21 (95% CI, 0.07–0.65), indicating a 79% relative reduction in risk. The ARR was 44.0% (95% CI, 20.7%–67.3%), yielding an NNT of 3 (95% CI, 2–5), which means that, on average, one out of every three patients using the felt mattress would be prevented from developing pressure injuries.

Pressure injury severity

The majority of these injuries were classified as stage 1 (24%), followed by stage 2 (8%) and stage 3 (4%). Notably, two cases of stage 3 pressure injuries in the control group were observed during hospital stay in the internal ward, specifically in the sacral area. These patients were classified as high-risk due to very limited mobility, thin skin, and specific clinical conditions, which can allow rapid progression of pressure injuries. There was a statistically significant difference in pressure injury stages between

the two groups ($p = 0.002$), with lower stages observed in the experimental group (Table 2).

Group differences in time to first pressure injury event

The Kaplan–Meier survival analysis demonstrated a statistically significant difference in the time to the first occurrence of pressure injuries between the intervention and control groups (Log-rank test: $\chi^2 = 9.125$, $p = 0.002$). The median pressure injuries-free survival time was 30.0 days (IQR: 30.0–30.0) in the experimental group compared to 20.0 days (IQR: 18.0–30.0) in the control group. The survival curves for both groups are presented in Fig. 2.

Satisfaction levels with Iranian sheep-felt mattresses

Table 3 displays the level of perceived comfort with the Iranian sheep-felt mattress. 84% of participants rated the mattress as highly comfortable and soft. In terms of sleep quality, 48% described it as moderate, while 52% rated it as high. Additionally, 52% considered its effectiveness in relieving pain to be moderate, and 48% reported experiencing low and 48% moderate levels of warmth or coolness. Furthermore, 92% of respondents noted low levels of unpleasant odors coming from the mattress.

Discussion

The current study aimed to evaluate the effectiveness of sheep-felt mattresses in preventing pressure injuries among hospitalized patients at moderate to high risk, recruited from the intensive care unit, as well as internal and surgical wards. The results showed that the incidence rate of pressure injuries within 30 days of hospitalization was significantly lower in the group that used the sheep-felt mattress compared to the control group. Historically, sheepskin has been recognized as one of the oldest materials used for pressure injuries prevention [26]. Wool, the primary component of sheep felt, contains lanolin, a protein known for its moisture-absorbing properties. This makes it a potentially suitable material for hospital textiles, such as bed sheets and pillows, especially for patients at risk of developing pressure injuries [27].

Although no studies have specifically evaluated Iranian sheep-felt mattresses for pressure injury prevention, existing evidence supports the pressure-relieving properties of medical sheepskin products. Zhou et al. [28] found that sheepskin sitting pads increased contact surface area and reduced localized skin pressure in healthy young adults during sitting. In another study [29], it was demonstrated that sheepskin mattresses, with optimized fiber density and orientation, expanded the contact surface and enhanced airflow in adults lying in the supine position, thereby improving pressure relief. Raspovic et al. [30] measured contact pressure in patients with diabetic ulcers and observed that felt padding significantly

Table 1 Comparison of the demographic and clinical characteristics between the experimental (Iranian sheep-felt mattress) and the control (Wavy mattress with cotton cover) groups

Variable	Experimental group (n = 25)	Control group (n = 25)	p
Sex (Male), n (%)	11.0 (44.0)	14.0 (56.0)	0.396 *
Age (years), Median (1st quartile, 3rd quartile)	83.0 (67.5, 89.0)	78.0 (62.5, 84.0)	0.089 †
Weight (Kg), Mean (SD)	61.0 (10.3)	67.2 (12.9)	0.071 ††
Height (cm), Mean (SD)	165.7 (8.7)	167.9 (8.7)	0.367 ††
BMI** (kg/m²), Mean (SD)	22.1 (2.8)	23.8 (3.7)	0.086 ††
BMI categories (kg/m²), n (%)			0.156 ‡
Underweight (< 18.5)	2 (8.0)	3 (12.0)	
Normal (18.5–24.9)	20 (80.0)	13 (52.0)	
Overweight (25.0–29.9)	3 (12.0)	8 (32.0)	
Obese (≥ 30.0)	0 (0.0)	1 (4.0)	
Education level, n (%)			1.000 ‡‡
High school or lower	1 (4.0)	2 (8.0)	
Diploma or higher	24 (96.0)	23 (92.0)	
Marital status, n (%)			0.209
Married	21 (84.0)	19 (76.0)	
Single	0 (0.0)	1 (4.0)	
Divorced	2 (8.0)	0 (0.0)	
Widowed	2 (8.0)	5 (20.0)	
Occupation, n (%)			0.810
Housewife	13 (52.0)	11 (44.0)	
Employee	1 (4.0)	0 (0.0)	
Unemployed	3 (12.0)	11 (44.0)	
Self-employment	2 (8.0)	2 (8.0)	
Retired	6 (24.0)	10 (40.0)	
Admission diagnosis, n (%)			0.016
Decreased alertness and immobility	7 (28.0)	8 (32.0)	
cerebrovascular accident (CVA)	1 (4.0)	9 (36.0)	
traumatic brain injury (TBI)	5 (20.0)	2 (8.0)	
Respiratory disease	6 (24.0)	2 (8.0)	
Septicemia	4 (16.0)	0 (0.0)	
Cancer	1 (4.0)	2 (8.0)	
Other	1 (4.0)	2 (8.0)	
Admission unit, n (%)			0.529**
ICU	5 (25.0)	10 (33.3)	
Internal ward	20 (75.0)	15 (66.7)	
History of chronic disease, n (%)			0.208*
Yes	16 (64.0)	20 (80.0)	
No	9 (36.0)	5 (20.0)	
Substance abuse, n (%)			1.000
Yes	3 (12.0)	4 (16.0)	
No	22 (88.0)	21 (84.0)	
Assessed risk status at admission, n (%)			0.298
Moderate (scores 13–14)	2 (8.0)	0 (0.0)	
High (scores 10–12)	16 (64.0)	20 (80.0)	
Very high (score 9 or lower)	7 (28.0)	5 (20.0)	
History of pressure injuries, n (%)			0.490
Yes	2 (8.0)	0.0 (0.0)	
No	23 (92.0)	25 (100.0)	

ICU, Intensive Care Unit; BMI, Body Mass Index

*BMI was calculated as weight (kg) divided by height squared (m²). BMI categories were classified according to World Health Organization; ** The Chi-square test; † The Mann-Whitney test; †† The independent T-test; ‡ The exact test; ‡‡ The Fisher exact test

Table 2 Comparison of pressure injury incidence, staging, and pressure injury-free survival time between the experimental (Iranian sheep-felt mattress) and the control (Wavy mattress with cotton cover) groups

Variables	Experi- mental group	Con- trol group	<i>p</i>
Incidence of pressure injuries (yes), n (%)	3 (12.0)	14 (56.0)	< 0.001*
Pressure injury's location, n (%)			1.00 **
Shoulder	0 (0.0)	1 (7.1)	
Buttocks	0 (0.0)	1 (7.1)	
Sacrum	3 (100.0)	12 (85.8)	
Stage of pressure injuries (yes), n (%)			0.156††
Stage 1	2 (66.7)	9 (64.3)	
Stage 2	1 (33.3)	3 (21.4)	
Stage 3	0 (0.0)	2 (14.3)	
Survival time (days) free of pressure injuries, Median (1st quartile, 3rd quartile)	30.0 (30.0, 30.0)	20.0 (18.0, 30.0)	0.002 †

*The Chi-square test

**Chi-square test (exact method)

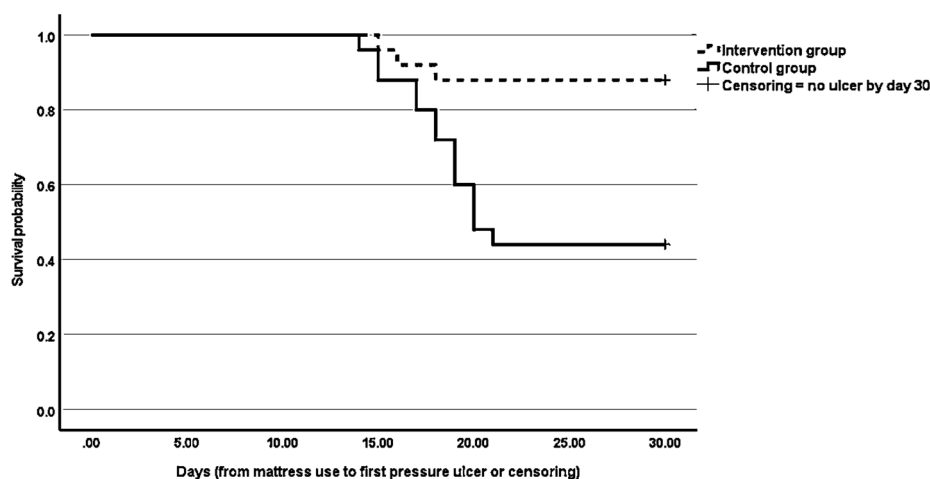
†The log-rank test

††The exact test

decreased pressure, suggesting potential benefits in preventing pressure injuries. Meneses et al. [31] also reported that felted foam provided the greatest reduction

in plantar pressure compared to conventional pressure-relief methods.

Clinical evidence further supports the effectiveness of medical sheepskin products in preventing pressure injuries. According to a systematic review and meta-analysis by McInnes et al. [11], Australian medical-grade sheepskins effectively prevent pressure injuries. Mistiaen et al. [32] reported a significant reduction in sacral pressure injuries among nursing home residents using Australian medical sheepskin overlays compared to standard care. Similarly, McGowan et al. [17] observed a 70% lower risk of hospital-acquired pressure injuries in elderly orthopedic patients who used sheepskin overlays. Jolley et al. [33] also observed a notably lower incidence of pressure injuries among low- to moderate-risk hospitalized patients when sheepskin overlays were used as mattress covers during hospitalization. In addition to sheepskin overlays, other offloading materials have also been evaluated for pressure reduction. For example, Fernando et al. [34], referencing Australian guidelines for offloading foot injuries, recommended combining felted foam with offloading devices to reduce plantar pressure. These consistent findings underscore the protective role of medical sheepskin and its relevance to the current study. The present study is consistent with these previous findings but extends them by investigating a mattress made from natural sheep-felt, highlighting its potential applicability



Group	Time (days)	0	5	10	15	20	25	30
Intervention group (Iranian sheep-felt mattress)	Number at risk	25	25	25	25	22	22	22
	Survival probability	1.00	1.00	1.00	1.00	0.88	0.88	0.88
Control group (Wavy mattress with cotton cover)	Number at risk	25	25	25	24	15	11	11
	Survival probability	1.00	1.00	1.00	0.96	0.60	0.44	0.44

Fig. 2 Kaplan–Meier survival curve of pressure injuries-free days by study groups. Kaplan–Meier curves showing time to first occurrence of pressure injuries over a 30-day follow-up in the experimental group (Iranian sheep-felt mattress, $n=25$) and control group (Wavy mattress with cotton cover, $n=25$). Censored observations represent participants who did not develop a pressure injury during the study period. The log-rank test was used to compare survival curves between groups ($p=0.002$)

Table 3 Participants' satisfaction levels with Iranian sheep-felt mattresses

Questions	Satisfaction level		
	Low	Moderate	High
How comfortable and soft did you find the felt mattress?	1 (4.0)	3 (12.0)	21 (84.0)
How would you rate your sleep quality on the felt mattress?	0 (0.0)	12 (48.0)	13 (52.0)
How effective was the felt mattress in relieving your pain?	4 (16.0)	13 (52.0)	8 (32.0)
How much heat did you feel while using mattress?	12 (48.0)	12 (48.0)	1 (4.0)
How much did you sweat while using the felt mattress?	21 (84.0)	4 (16.0)	0 (0.0)
How many unpleasant odors have you noticed coming from the mattress?	23 (92.0)	2 (8.0)	0 (0.0)

and its novel role in preventing pressure injuries among hospitalized patients.

Importantly, from a clinical perspective, an NNT of 3 (95% CI: 2–5) indicates that the use of the felt mattress can prevent one pressure injury for every three patients, highlighting its effectiveness in reducing the risk of pressure injury development. This is considered a clinically meaningful effect size, potentially leading to a reduction in nursing workload for repositioning and wound care, lower incidence of complications, and decreased treatment costs. These benefits align with evidence from previous studies highlighting the economic and safety impact of effective pressure injury prevention strategies [35, 36].

In the present study, most pressure injuries in the experimental group were stage 1, and both pressure injury severity and pressure injury-free survival time significantly favored the experimental group. These findings are partially consistent with McGowan et al. [17], who reported that patients using sheepskin experienced a longer pressure injury-free period and developed less severe injuries compared to controls. In contrast, Mistiaen et al. [32] found no significant differences in pressure injury severity (based on EPUAP grading) or pressure injury-free survival time, despite reporting a lower incidence of sacral pressure injuries with sheepskin use. These discrepancies may stem from differences in patient populations (ICU vs. nursing home residents), product type (Iranian sheep-felt vs. Australian medical sheepskin), or user compliance, as discomfort led some participants in their study to discontinue use.

Our results showed that most patients were satisfied with the sheep-felt mattress in terms of comfort, softness, sleep quality, pain relief, sweating, and odor. These findings align with Santos et al. [37], who reported that patients using wool felts in hospital settings appreciated their freshness, pain relief, reduced sweating, and minimal unpleasant odors. Similarly, McGowan et al. [17] and Mistiaen et al. [32] found that patients using sheepskin for pressure injury prevention were generally satisfied with comfort. However, both studies also noted that patients often experienced discomfort related to heat. In our study, patient opinions on mattress warmth varied, indicating mixed perceptions of thermal comfort

and highlighting an area for improvement. Although the sheep-felt mattress offers many benefits, addressing temperature regulation could further improve overall patient satisfaction. Based on the International Pressure Injury Guidelines, assessing temperature and moisture at the skin-surface interface and evaluating the individual's comfort is essential before using a medical grade sheepskin [2].

This study offers a significant contribution to nursing practice by introducing an intervention that is both clinically effective and culturally appropriate within the Iranian healthcare context. The use of sheep-felt mattresses, derived from local materials, can reduce the incidence and severity of pressure injuries among at-risk hospitalized patients, which in turn has the potential to lower overall treatment expenses, decrease complications such as infections, and shorten hospital stays. This reduction not only improves patient safety but also enhances quality of life by minimizing pain, discomfort, and mobility limitations associated with pressure injuries. Furthermore, tailoring pressure injuries prevention strategies to the geographical and cultural context can enhance patient acceptance and compliance, thereby improving the likelihood of successful implementation in clinical settings. Integrating this culturally sensitive method into routine care could also reduce the workload of healthcare providers by lowering the frequency of pressure injury-related complications and interventions.

From a health system perspective, widespread adoption of this intervention could lead to substantial cost savings and more efficient use of healthcare resources, particularly in high-risk units such as intensive care and long-term care wards. Moreover, this approach may serve as a model for other regions with similar cultural and economic contexts, contributing to global efforts to improve pressure injury prevention. Future research with larger sample sizes and longer follow-up periods is recommended to further confirm these benefits and evaluate long-term outcomes.

Strength and limitations

To the best of our knowledge, this is the first study to assess the preventive effects of sheep wool felt mattresses on pressure injury development—an area previously

unexplored in the literature. The randomized controlled trial design, widely regarded as the gold standard for interventional studies, enhances the internal validity and supports stronger inference regarding intervention effects. Moreover, using the well-established Braden Scale for Pressure Injury Risk Assessment added to the reliability and precision of the outcome measurements.

Nonetheless, several limitations should be acknowledged. First, the study was conducted at a single center in Iran, and most participants had a normal BMI, with only a small proportion being underweight or obese. Therefore, the generalizability of our findings to populations with different demographic and body composition characteristics may be limited. Second, the follow-up period was relatively short and may not have been sufficient to fully assess long-term outcomes. Third, because the intervention (use of felt mattresses) was clearly visible, neither patients nor nurses were blinded, and outcome assessors were also not blinded due to overlap between the care and assessment teams. This introduces the risk of performance and detection bias, including the possibility of a Hawthorne effect, as knowledge of mattress type could have influenced care practices, patient behavior, and outcome reporting. Fourth, although we aimed to standardize nursing care, unmeasured confounders—such as subtle differences in patient repositioning, skin hydration, mobility, and nutritional status—may have influenced the results. Fifth, cultural familiarity with sheep-felt mattresses could have affected participants' satisfaction ratings, independent of their physical properties, which should be considered when interpreting subjective outcomes. Sixth, there was an imbalance in certain baseline characteristics, particularly the proportion of participants with a history of cerebrovascular accident as a known risk factor for pressure injury. Given the relatively small sample size and unstable estimates, adjusted analyses to control for such variables were not feasible, which may have influenced the observed intervention effect. Therefore, future studies with larger sample size, more diverse populations across multiple centers, longer follow-up periods, and strategies to minimize bias, including blinded outcome assessment where feasible, are warranted.

Conclusions

The findings of this study indicate that Iranian sheep-felt mattresses could be a suitable option for enhancing patient care and comfort among hospitalized patients at moderate to high risk of pressure injuries, including those in the ICU and the internal ward. While the results indicate a potential role for these mattresses in pressure injuries prevention, future studies with larger sample sizes and multi-center designs are needed to confirm

these findings and to explore the long-term effects of sheep-felt mattresses on pressure injuries prevention.

Abbreviations

ICU	Intensive Care Unit
NPIAP	National Pressure Injury Advisory Panel
IQR	Interquartile Range
RR	Relative Risk
ARR	Absolute Risk Reduction
NNT	Number Need to Treat

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions

All authors contributed to the conceptualization and design of this project. Data collection and extraction were conducted by MAD, FK, RN, and MM. FM was responsible for the study methodology, data analysis, and interpretation. The manuscript was drafted by FM, with all authors participating in critical revisions and approving the final version.

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Data availability

The study's dataset is not publicly available due to privacy and ethical considerations. However, they are available from the corresponding author upon reasonable request. The material used in this study was the Iranian sheep-felt mattresses, which can be obtained from Devin Teb Pooya Co (Email Address: devintebpooyafeltco@gmail.com).

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of Gonabad University of Medical Sciences (Code: IR.GMU.REC.1400.184; Approval date: 24 January 2022). Before participation, all patients and their legal guardians were thoroughly informed about the study objectives and procedures. Written informed consent was obtained from each participant or their legally authorized representative. Participants were assured that they could withdraw from the study at any time without providing a reason and without any impact on their access to usual health services. Furthermore, participants incurred no costs related to the study interventions.

AI disclosure

This manuscript was prepared with the assistance of ChatGPT for language editing, grammar correction, and improving text clarity. All intellectual content, including the study design, data analysis, interpretation, and conclusions, was provided solely by the authors. The authors take full responsibility for the accuracy and integrity of the manuscript.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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