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Research Article

Prophylactic dressings to prevent sacral pressure injuries in adult patients admitted to intensive care units: A three-arm feasibility randomized controlled trial

Sharon Latimer [a,*], Rachel M. Walker [a,b], Wendy Chaboyer [a], Lukman Thalib [c], Fiona Coyer [d], Jodie L. Deakin [a,e,f], Brigid M. Gillespie [a,f]

[a] NHMRC Centre of Research Excellence in Wiser Wound Care, School of Nursing and Midwifery, Griffith University, Gold Coast, QLD, Australia
[b] Division of Surgery, Metro South Health, Princess Alexandra Hospital, Brisbane, QLD, Australia
[c] Department of Biostatistics, Faculty of Medicine, Istanbul Aydin University, Istanbul, Turkey
[d] School of Nursing, Midwifery and Social Work, The University of Queensland, St. Lucia, QLD, Australia
[e] School of Nursing and Midwifery, Griffith University, Gold Coast, QLD, Australia
[f] Nursing and Midwifery Education and Research Unit, Gold Coast Hospital and Health Service, Southport, QLD, Australia

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ABSTRACT

Background: Pressure injuries in intensive care patients are a safety issue. Specialized foam sacral prophylactic dressings prevent pressure injuries with several products available for clinicians to choose from.
Objectives: Assess the feasibility of conducting a multisite trial to test the effectiveness of two dressings versus usual care in preventing sacral pressure injuries in intensive care patients.
Methods: Using a three-arm pilot randomized trial design, adult intensive care unit patients at risk for pressure injuries were randomly allocated to the Mepilex® Sacrum dressing, the Allevyn™ Life Sacrum dressing or the control group. Daily pressure injury data were collected including a de-identified sacral photograph, which the blinded outcome assessor used to determine the study end point: a new sacral pressure injury. Pre-determined feasibility criteria were measured in terms of eligibility, recruitment, retention, intervention fidelity and missing data.
Results: From May-September 2021, we screened 602 intensive care unit adult patients for eligibility with 93 % (n = 558) excluded. Forty-four (7 %) were eligible, and all were recruited and randomized (100 %). After receipt of the intervention two participants withdrew from the study. Our final sample of 42 participants were randomly allocated to the Mepilex® (n = 12), Allevyn™ (n = 14) or control (n = 16) group. The interventions were delivered as intended and there were 11 (6 %) cases of missing outcome data. Five participants (12 %) developed a sacral pressure injury, four of whom received a sacral dressing.
Conclusions: A larger trial is feasible with minor refinement to the length of stay eligibility criterion.
Implications for practice: Prophylactic sacral dressings are recommended for pressure injury prevention. Determining the feasibility of a larger trial to test the effectiveness of two dressings versus usual care in preventing sacral pressure injuries in intensive care patients can provide evidence to aid clinicians, policy makers and managers make value-based care decisions.

Introduction

A pressure injury (PI) is local skin and underlying tissue damage often caused by unrelieved pressure and usually develops over bony prominences such as the sacrum and coccyx (European Pressure Ulcer Advisory Panel et al., 2019). PI are classified in stages I-IV, suspected deep tissue injuries and unstageable PI (European Pressure Ulcer Advisory Panel et al., 2019). Medical device-related PI are caused by pressure

* Corresponding author at: NMHRC CRE Wiser Wounds Care, School of Nursing and Midwifery, G01 2.05B Griffith University, Gold Coast campus, Parklands Dr, Southport QLD 4215, Australia.
E-mail addresses: s.latimer@griffith.edu.au (S. Latimer), r.walker@griffith.edu.au (R.M. Walker), w.chaboyer@griffith.edu.au (W. Chaboyer), Lukmanthalib@aydin.edu.tr (L. Thalib), f.coyer@uq.edu.au (F. Coyer), j.deakin@griffith.edu.au (J.L. Deakin), b.gillespie@griffith.edu.au (B.M. Gillespie).

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applied to the skin by healthcare equipment or furniture (European Pressure Ulcer Advisory Panel et al., 2019). Mucosal membrane PI are often equipment related and develop on moist membranes such as the respiratory (e.g. nasal passage) or urinary (e.g. indwelling catheter) tracts (European Pressure Ulcer Advisory Panel et al., 2019). Certain patient populations, such as those who are critically ill or have spinal cord injuries, are more vulnerable to PI development (Labeau et al., 2021; Levido et al., 2021). Several factors increase a patient's risk for PI development including age, incontinence, poor nutrition and immobility (European Pressure Ulcer Advisory Panel et al., 2019). Due to immobility, sedation, ventilation, and lifesaving medications (Lovegrove et al., 2022), intensive care unit (ICU) patients are almost four times more likely to acquire a PI during their stay compared to non-ICU patients (Coyer et al., 2022). ICU-acquired pressure injuries (ICU-PI) are preventable and can increase hospital length of stay (LOS), workloads and healthcare costs (Lovegrove et al., 2022). A 2018 point prevalence study of 13,254 patients in 1,117 ICUs found an ICU-PI prevalence rate of 16.2 % (95 % CI 15.6–16.8) with the sacrum (37 %) most often affected (Labeau et al., 2021).

PI prevention is a patient safety and healthcare quality priority (Australian Commission on Safety and Quality in Health Care, 2017; World Health Organization, 2021), with international clinical practice guidelines recommending PI prevention strategies including prophylactic sacral dressings (European Pressure Ulcer Advisory Panel et al., 2019; Levido et al., 2021) such as the Mepilex® Border Sacrum and Allevyn™ Life Sacrum (Mölnlycke, 2021; Smith + Nephew, 2021). The Mepilex® Border Sacrum is a five-layer foam dressing with Deep Defense Technology® (Mölnlycke, 2021) and the Allevyn™ Life Sacrum is a multi-layered hydrocellular foam dressing (Smith + Nephew, 2021). A *meta*-analysis of four superiority trials showed prophylactic sacral dressings were effective in preventing ICU-PI (Risk Ratio [RR] = 0.22; 95 % CI = 0.11–0.43; Z = 4.40; $p < 0.001$) (Lovegrove et al., 2022). However, evidence between these dressings is lacking (Sugrue et al., 2023); information that could inform clinical and value-based care decisions including any benefits and harms (Williams et al., 2016).

Methods

Objectives

The primary objective was to assess the feasibility of a larger trial to test the effectiveness of two prophylactic sacral dressings compared to standard care in preventing sacral ICU-PI in adult patients. The secondary objective was to determine the cumulative incidence rate of sacral ICU-PI.

Design

A single site three-arm pilot randomized controlled trial (RCT) was used to evaluate the study protocol regarding eligibility, recruitment, retention, intervention fidelity and missing data (Table 1). The Consolidated Standards of Reporting Trials (CONSORT) extension for pilot and feasibility trials guided the study reporting (Eldridge et al., 2016). The study was registered (ACTRN12620000875909p) and the Good Clinical Practice guidelines for clinical trials followed (National Health and Medical Research Council, 2020). A consumer representative contributed to the study protocol in relation to patient and relative communication. The study received human research ethics approvals (Gold Coast Hospital and Health Service [HREC/2020/QGC/64906]; Griffith University [2021/036]) and was conducted in compliance with relevant laws and institutional guidelines.

Table 1
Primary and secondary study outcomes.

Primary outcomes	Secondary outcomes
• Eligibility: ≥50% of screened patients are eligible for recruitment • Recruitment: ≥70% of eligible participants agree to participate • Intervention fidelity: ≥95% of participants receive their assigned intervention • Retention: <15% of participants are lost to follow up • Missing data: <10% of missing sacral outcome data	• Cumulative sacral ICU-PI incidence rate (any stage) • Incidence density: the number of participants who develop a sacral ICU-PI per 1000 patient days • Stage of sacral ICU-PI classified according to international guidelines (European Pressure Ulcer Advisory Panel et al., 2019)

Abbreviations: ICU: intensive care unit; PI: pressure injury.

Feasibility outcomes

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Setting and sample

The study was conducted in a 21-bed Australian adult ICU that admits approximately 2,100 patients each year, with a 3.5-day average LOS (Coyer et al., 2020). A consecutive sample of ICU patients meeting the study criteria were eligible for recruitment. The inclusion criteria were: ≥18 years of age; recruited within the first 24-hours of ICU admission; ICU LOS ≥ 48-hours following recruitment; informed consent; and high PI risk (Waterlow score ≥ 15, and a Braden score ≤ 12). We used the Waterlow (1985) and Braden (Bergstrom et al., 1987) tools because they are used extensively by clinicians. The exclusion criteria were: ≥12-hours of prone positioning; pre-existing sacral PI or skin condition; receiving droplet infection control precautions (e.g. COVID-19 infections); receiving end-of-life care; incontinence (urine or fecal); sacral creams (e.g. corticosteroids).

Recruitment and randomization

Pilot studies are not hypotheses driven or powered to detect an intervention effect and should not be used for future power calculation (Arnold et al., 2009; Leon et al., 2011). Rather, they test the study processes, such as recruitment and retention, and inform the feasibility of a larger trial (Leon et al., 2011). Using a pragmatic rule of thumb approach (Leon et al., 2011), which suggests a sample size per arm of between 10–30 participants (Machin et al., 2018), we planned to recruit 90 ICU participants (30 per arm); a sufficient sample to meet the study objectives. Screening and recruitment occurred 7-days a week from May-September 2021. Registered Nurses with ICU experience were recruited and trained as research assistants (RA) because their established networks and knowledge facilitated communication and data collection. Each day the RA screened all adult patients admitted to the ICU in the previous 24-hours. Eligible patients, or their authorized representatives, were approached by the ICU team leader and permission sought for the RA to approach them. For willing individuals, the RA provided a verbal study overview including potential benefits and risks. Participant anonymity, voluntary consent and study withdrawal process were described, and all questions answered. For eligible ventilated patients without an authorized representative present at recruitment, the approved local ethics committee's *'consent to continue'* process was implemented (National Health and Medical Research Council et al., 2007-updated 2018). This involved recruiting the patient to the study and then contacting their authorized representative as soon as reasonably possible for their *'consent to continue'*. For all recruited participants, baseline data were collected prior to randomization. Next, to minimize selection bias, the RA accessed a central online randomization service and generated a random participant allocation sequence to either study arm 1, 2, or 3 (control group) in varying block sizes of 3, 6 and 9. Participants were stratified as a medical or surgical ICU patient. Due to the nature of the interventions (dressing), blinding to group allocation was not possible for patients, RAs, or clinicians. However, the data analyst and the outcome assessor were blinded.

Interventions and control

Specialized foam sacral dressings such as Mepilex® and Allevyn™ are used in many ICUs to prevent PIs (Levido et al., 2021). Study arm 1 was the Mepilex® Sacrum (Fig. 1 A), study arm 2 was the Allevyn™ Life Sacrum (Fig. 1 B) and study arm 3 was the control (no dressing). Determined by the bedside clinician, usual PI prevention care as per the hospital ICU procedure, included daily skin assessment, second hourly repositioning, heel elevation, pressure relieving heel boots, continence management, nutritional support and active pressure redistributing mattresses.

Data collection

Each day over a four-hour period, the RA undertook screening, recruitment, randomization, allocation, data collection and sacral dressing monitoring (Supplementary file 1). We developed a standardized operating procedure manual to ensure intervention fidelity and protocol consistency. Using a password protected iPad, data were entered directly into the Research Electronic Data Capture (REDCap®) platform (Harris et al., 2019) hosted at Griffith University. Participant data were collected for a maximum of 14-days or until reaching a trial endpoint: a) developed a sacral ICU-PI (any stage); b) ICU discharge; c) death; d) commenced prone positioning; e) required droplet infection precautions; f) developed fecal/urinary incontinence that could not be effectively managed, – whichever occurred first.

During screening, the RA conducted a Waterlow (1985) and Braden (Bergstrom et al., 1987) assessment to confirm the patient's high PI risk status. If discrepancies occurred between the tools (i.e. one tool high PI risk and the other tool low PI risk) the RA consulted the ICU nurse leader, who used their clinical judgment to determine the patient's PI risk eligibility criteria. At baseline, demographic and clinical data (age, sex, comorbidities, diagnosis, ventilation and sedation status, APACHE II score (Knaus et al., 1985), current smoking status, PI risk assessment score, skin and nutrition assessment on ICU admission, existing PI (not sacral) and its management) were collected through direct observation and an electronic medical record audit. A sacral visual skin assessment was performed including skin blanching, where the fingertips were gently pressed into the skin for three seconds, then released and observed for reperfusion. All participants had a baseline sacral digital photograph taken. For intervention participants, the allocated dressing was applied, and a digital photograph taken of the dressing to inform the intervention fidelity analysis. PI prevention data (support surface, bed type, repositioning frequency and position, skin assessment, heel and elbow protectors, moisturizer, and device securement) were collected to determine the feasibility of its use as covariates in a larger trial.

Following the manufacturer's recommendations, each day the RA partially removed the sacral dressing to inspect the sacrum. Regardless of group allocation, a visual sacral skin assessment (erythema yes/no) and blanching test (blanchable/non-blanchable) were conducted, and a digital sacral photograph taken. The RA used the Adobe Photoshop Fix App® (version 2019) to edit intervention group photographs and "blur" any atraumatic skin markings made by the dressing (Fig. 2). For the control group, the same "blurred" marking was applied to their photographs. This process minimized dressing recognition by the blinded outcome assessor thus reducing detection bias related to group allocation (Walker et al., 2015). The sacral dressings were inspected and either re-applied or changed if the edges rolled, adhesion was lost, soiling, saturation or dislodgement occurred or as indicated by clinical practice (Mölnlycke, 2021, Smith + Nephew, 2021). PI prevention strategies implemented in the previous 24-hour were recorded including the number of sacral dressings used. Participant ICU and hospital LOS data were obtained.

Blinded outcome assessment

An outcome assessor, who was a registered nurse and PI expert, was recruited and trained. Each day they accessed the de-identified and "blurred" sacral photographs, the daily sacral visual skin (erythema present yes/no) and blanching (blanchable or non-blanchable) assessment. Using the international PI classification system (European Pressure Ulcer Advisory Panel et al., 2019), they determined the presence of a new sacral ICU-PI and its stage. During patient care, if the bedside ICU clinician determined the presence of a new sacral ICU-PI, the patient exited the trial and an adverse event recorded. A concurrent assessment was conducted by the blinded outcome assessor with disagreements in assessment noted in the study feasibility log. The blinded outcome assessor indicated the brand of sacral dressing, or none, applied to the participant's sacrum. Inter-rater reliability of the outcome assessor was established by evaluating the first 10 % (n = 9) of sacral photos with the aim of achieving a 0.8 Kappa (Nixon et al., 2005, Viera and Garrett, 2005).

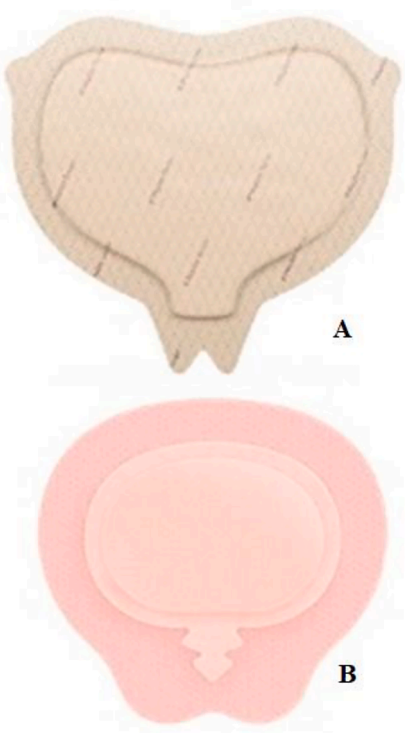

Fig. 1. Sacral prophylactic dressings. A:Mepilex® Sacrum; B:Allevyn™ Life Sacrum.

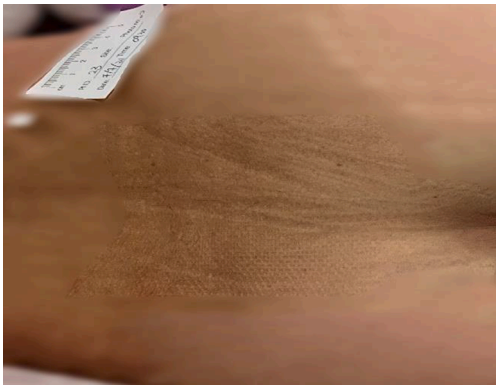

Fig. 2. Modified sacral photo.

Data analysis

De-identified data were imported into IBM SPSS Statistics (Version 29.0) (IBM Corp, 2022) then cleaned and verified for accuracy, outliers, distribution and missing values. The primary feasibility outcomes were calculated using frequencies and percentages. Baseline demographic and clinical characteristics for each group were descriptively analyzed. Continuous variables were reported using means, standard deviations, and 95 % confidence intervals (CI). Frequencies and percentages were calculated for categorical variables. Medians and interquartile range (IQR) were used for non-normally distributed variables. The focus of this study was to assess the feasibility of a larger trial and was under-powered to detect a treatment effect (Arnold et al., 2009). As such, group differences were not calculated because the results could be misleading and may not accurately inform the sample size estimate needed to see statistically significant group differences in a larger trial (Arnold et al., 2009).

Results

Over 16 weeks (May-September 2021), we screened 602 ICU patients for study eligibility with 93 % (n = 558) excluded mainly because their ICU LOS was less than 48-hours (n = 419; 75 %) (Fig. 3). Forty-four (7 %) patients were eligible, and all were recruited and randomized (100 %). Within 24-hours of recruitment, four (9 %) participants were lost to follow-up with no outcome assessment data collected. The reasons were ICU discharge (n = 1), requiring COVID-19 infection control precautions (n = 1) and study withdrawal (n = 2). Ethical approvals required any collected data from withdrawn participants were immediately destroyed and not analyzed. Hence, our final sample was 42. The participants were randomly allocated to the Mepilex® dressing (n = 12), the Allevyn™ Life dressing (n = 14) or the control group (n = 16). The inter-rater reliability for sacral ICU PI assessment using Cohen's kappa was $\kappa = 0.90$ ($p < 0.001$), indicating a high level of agreement between the assessors in classifying PI.

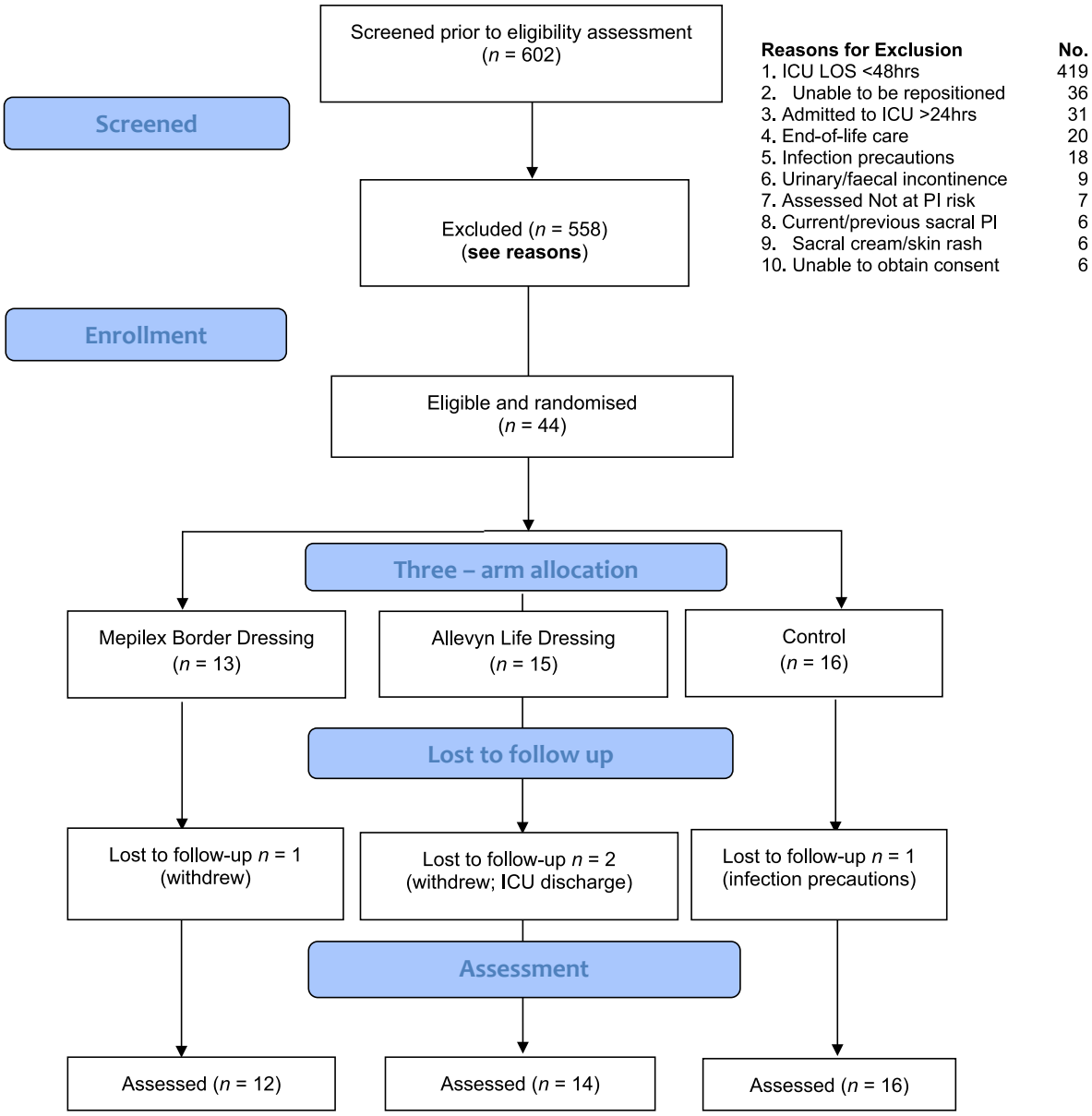

Fig. 3. CONSORT flow diagram of participants.

Table 2
Baseline sample characteristics (n = 42).

Characteristics	Mepilex® group (n = 12)		Allevyn™ group (n = 14)		Control group (n = 16)	
	Mean (SD)	95 % CI	Mean (SD)	95 % CI	Mean (SD)	95 % CI
Age (years)	54.3 (16.7)	43.6; 64.8	63.5 (17.9)	53.1; 73.8	57.8 (15.5)	49.6; 66.1
APACHE II score (0–71)	20.5 (8.4)	15.2; 25.8	20.8 (5.8)	17.5; 24.1	22.1 (8.0)	17.8; 26.4
BMI	25.4 (5.4)	21.9; 28.8	27.8 (4.3)[#]	25.2; 30.4[#]	30.8 (7.2)[^]	26.6; 34.9[^]
Waterlow score	17.7 (3.5)	15.5; 19.9	17.7 (2.8)	16.1; 19.3	17.8 (4.5)	15.5; 20.3
Braden score	10.1 (2.6)	8.5; 11.7	9.9 (2.4)	8.5; 11.3	10.1 (1.5)	9.3; 10.9
ICU LOS (days)	8.0 (5.6)	4.5; 11.6	5.7 (3.8)	3.5; 7.9	11.1 (11.2)	5.1; 17.0
Hospital LOS (days)	21.0 (11.7)	13.6; 28.4	13.5 (8.7)	8.5; 18.5	23.7 (17.6)	14.3; 33.1
	n (%)		**n (%)**		**n (%)**	
Sex (male)	6 (50 %)		10 (71 %)		13 (81 %)	
Admission specialty						
Medical	9 (75 %)		10 (71 %)		11 (69 %)	
Surgical	3 (25 %)		4 (29 %)		5 (31 %)	
Ventilation	7 (58 %)		11 (79 %)		13 (81 %)	
Sedation	7 (58 %)		12 (86 %)		14 (88 %)	
Vasopressors	8 (67 %)		11 (79 %)		11 (69 %)	
Current smoker	4 (33 %)		1 (7 %)		3 (19 %)	
Reason for admission						
Cardiac arrest	0 (0 %)		2 (14 %)		5 (31 %)	
Intracranial hemorrhage and stroke	3 (25 %)		3 (19 %)		1 (6 %)	
Seizure	3 (25 %)		2 (14 %)		2 (13 %)	
Post-operative critical care	0 (0 %)		1 (7 %)		4 (25 %)	
Hepatobiliary medical care	3 (25 %)		1 (7 %)		1 (6 %)	
Overdose	1 (8 %)		1 (7 %)		1 (6 %)	
Sepsis	0 (0 %)		1 (7 %)		1 (6 %)	
Trauma	1 (8 %)		1 (7 %)		0 (0 %)	
Cardiac failure	0 (0 %)		2 (14 %)		0 (0 %)	
Respiratory failure	1 (8 %)		0 (0 %)		1 (6 %)	
Comorbidities						
Cardiovascular disease	5 (42 %)		8 (57 %)		9 (56 %)	
Respiratory disease	4 (33 %)		2 (14 %)		4 (25 %)	
Cardiac failure	0 (0 %)		2 (14 %)		5 (31 %)	
Renal disease	2 (17 %)		1 (8 %)		3 (19 %)	
Cerebrovascular accident	2 (17 %)		0 (0 %)		3 (19 %)	
Diabetes mellitus	1 (8 %)		0 (0 %)		3 (19 %)	
Carcinoma	1 (8 %)		1 (6 %)		1 (6 %)	

*n = 3 missing data; ([#]n = 1 Allevyn™; [^] n = 2 Control). Abbreviations: BMI: body mass index; CI: confidence interval; ICU: intensive care unit; LOS: length of stay; SD: Standard deviation

Almost 70 % (n = 29) of the sample were male and the average age was 58.7 years (SD = 16.5) (Table 2). Most participants (n = 30; 71 %) were medical admissions due to cardiac arrest, intracranial hemorrhage, and seizures. Almost three-quarters (n = 31;74 %) were ventilated and the median APACHE II score was 21 (IQR;17:25). The average ICU and hospital LOS were 8.4 days (SD = 8.1) and 19.5 days (SD = 13.9) respectively.

Feasibility

We met every feasibility target except for eligibility (Table 3), with only 7 % (n = 44) of screened patients able to be approached. All eligible patients were recruited (n = 44;100 %) exceeding our recruitment target. Due to a lack of ongoing funding, we stopped the study before our target sample size of 90 participants (30 per arm) was achieved. Outcome assessment data (sacral photo) could not be collected on 11 (6 %) occasions involving 7 participants, with medical instability as the main reason (n = 9; 82 %). On most occasions, the blinded outcome assessor was unable to detect which dressing, or none, was applied (157/189; 83 %).

Table 3
Feasibility Results.

Criteria	Target	Result	Target achieved
Eligibility	≥50 % screened are eligible for recruitment	44/602 (7.3 %)	No
Recruitment	≥70 % of eligible patients are recruited	44/44 (100.0 %)	Yes
Retention	≥85 % retained to study endpoint	42/44 (95.5 %)	Yes
Intervention fidelity	≥95 % received allocated intervention	Baseline: 42/42 (100.0 %) Daily: 192/196 (97.9 %)	Yes Yes
Missing data	≤10 % of missing outcome data	11/189 (5.8 %)	Yes

Sacral ICU-acquired PI rates and stages

The sample cumulative incidence rate of sacral ICU-PI (any stage) was 12 % (n = 5/42) with most developing in the intervention groups (n = 4) (Table 4). The sacral ICU-PI incidence density (any stage) per 1000 patient days was 25.9. The sacral PIs were assessed as a stage I (n = 2; 40 %), II (n = 2; 40 %) or suspected deep tissue injury (n = 1; 20 %).

Table 4
Sacral ICU-acquired pressure injuries.

	Median (IQR)	Mepilex® group (n = 2)	Allevyn™ group (n = 2)	Control group (n = 1)	Total sample (n = 42)
Cumulative Sacral ICU-PI incidence (any stage)		2 (40 %)	2 (40 %)	1 (20 %)	5 (12 %)
Stage I PI		0 (0 %)	2 (40 %)	0 (0 %)	2 (5 %)
Stage II PI		1 (20 %)	0 (0 %)	1 (20 %)	2 (5 %)
Suspected deep tissue injury		1 (20 %)	0 (0 %)	0 (0 %)	1 (3 %)
Sex					
Male		0 (0 %)	1 (20 %)	1 (20 %)	2 (5 %)
Female		2 (40 %)	1 (20 %)	0 (0 %)	3 (7 %)
Age years	61.0 (45.0;73.3)				
≤ 60 years		0 (0 %)	1 (20 %)	1 (20 %)	2 (5 %)
> 60 years		2 (40 %)	1 (20 %)	0 (0 %)	3 (7 %)
APACHE II score	21.5 (16.7;23.0)				
1–22		0 (0 %)	1 (20 %)	0 (0 %)	1 (2 %)
23–71		2 (40 %)	1 (20 %)	1 (20 %)	4 (10 %)
BMI Median (IQR)	27.6 (25.0;31.0) *				
≤ 24.9 (under / healthy weight)		1 (20 %)	0 (0 %)	0 (0 %)	1 (2 %)
≥25 (overweight or obese)		1 (20 %)	2 (40 %)	1 (20 %)	4 (10 %)

[*] n = 3 missing data. Abbreviations: BMI: body mass index; ICU: intensive care unit; ICU-PI: intensive care unit acquired pressure injury; IQR: interquartile range; PI: pressure injury.

Participants developed a sacral ICU-PI between days 2 to 5 following study recruitment. Vasopressors were administered to all five participants, while 60 % (n = 3) were sedated and mechanically ventilated. For participants who developed a sacral ICU-PI, their mean ICU and hospital LOS were 14-days (SD = 13.8) and 35-days (SD = 18.3) respectively.

PI prevention strategies

ICU participants received a range of PI prevention strategies with active support mattresses (n = 40; 95 %) and repositioning (n = 38; 91 %) the most frequently implemented. In a 24-hour period, the median number of repositions was 9 (IQR; 8:10) or once every 2.6 h.

Discussion

Our primary aim was to evaluate our study protocol and determine the feasibility of a larger multi-site RCT. A lack of ongoing funding meant we did not recruit our target sample of 90 patients. Yet overall, our other pre-determined criteria were met indicating a larger study was feasible, although we would need to recruit several study sites because slow recruitment should be anticipated.

We developed the study criteria based on our previous observational and RCT research (Chaboyer et al., 2016; Latimer et al., 2015). Our pilot study did not met our ≥ 50 % eligibility target with only 7.3 % met this criterion; a problem faced in many ICU trails (Raven-Gregg et al., 2021; Queensland Government, 2020). We found the criterion 'ICU LOS of ≥ 48-hours' was the main reason for exclusion with many patients admitted to the ICU for 24-hours observation following complex surgery such as coronary artery bypass graft. In addition, a lack of funds to employ an RA for more than 4-hours per day resulted in the inability to follow-up patients who were receiving diagnostic care (i.e., CT scans) during the recruitment period. These factors impacted our recruitment rate, which was slower than expected; an issue reported in other ICU studies (Raven-Gregg et al., 2021; Queensland Government, 2020). Hence, in a future study we would refine the LOS criterion to 'ICU LOS > 24-hours' so that at least one outcome assessment (sacral photo) was collected and employ full-time RA per site to increase recruitment.

Lower than expected recruitment rates in critical care trials is a recognized issue (Raven-Gregg et al., 2021, Campbell et al., 2022), yet we achieved an exceptional 100 % recruitment rate. We suggest several factors contributed to this result including the advice of our consumer representative and training ICU registered nurses as RAs. As a previous ICU patient, our consumer representative advised that sensitive communication with patients and families was an important recruitment strategy, especially in the first few days of ICU admission. Hence, we developed a plain language recruitment script and training videos for the RAs, with sensitivity and script personalization a cornerstone of the training. Furthermore, the experience of our ICU data collectors in communicating with vulnerable and critically ill patients and family members meant they could authentically answer study questions as it related to the ICU context and felt comfortable to seek consent both face-to-face and via telephone. A 2021 systematic review of effective participant recruitment strategies (Raven-Gregg et al., 2021) confirmed the success of our strategies, with communication and the researcher's approach both key factors in building family trust and confidence in the research process which subsequently increased consent (Treweek et al., 2018).

Our participant retention rate exceeded our target of ≥85 %, with only four (9 %) participants lost to follow-up. This study was conducted during the second year of the COVID-19 pandemic when the vaccine was being rolled out and immunization coverage varied (Australian Government, 2021). Since then, increased vaccination rates of healthcare professionals and the general populations, including changes in organizational policy means the two participants that were lost to follow-up due to COVID-19 would be retained in a future trial. COVID-19 is one of many risks facing clinical research. So, developing a detailed risk management plan including risk reduction and mitigation strategies is required to ensure participant and staff safety and robust data collection processes (National Health and Medical Research Council, 2020).

Our study had high rates of intervention fidelity and limited missing outcome data (de-identified sacral photo) which we attribute to the established professional networks of our ICU data collectors and the strong research culture at the study site (Treweek et al., 2018, Raven-Gregg et al., 2021). Prior to data collection and throughout the study, we informed ICU staff about our study both verbally and via multimedia. Also, ICU data collectors were current clinicians in the ICU, which increased the opportunity for ad hoc staff discussions about the pilot study. Finally, the study site ICU has a strong research culture and is a member of the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG), with many of the staff involved in international RCTs. Employing ICU registered nurses as RA contributed to the strong research culture, by building research capacity and capability. Evidence suggests a strong research culture, research project promotion and open communication with staff contribute to the success of a study (Raven-Gregg et al., 2021). These strategies, especially training ICU registered nurses as RAs will be implemented in a future trial.

The collection and use of de-identified sacral photography in outcome assessment has been successfully implemented in another trial and deemed reliable (Walker et al., 2015). Our blinded outcome assessor experienced only a handful of technical issues accessing and assessing the photographs via the REDCap® database. These related to difficulties in opening a file due to formatting (e.g., JPG and HEIC formats) however, this was quickly resolved by deleting the file and re-uploading it. Modifying all de-identified sacral photographs, by "blurring" the edges of the sacral skin using the Adobe Photoshop Fix App®, was a successful strategy in reducing detection bias. The RAs reported the software was quick and simple to use and will be implemented in a future trial.

Our 12 % (5/42) cumulative sacral ICU-PI incidence rate, which developed in the first week of ICU admission. Our findings are consistent with the current available evidence (Coyer et al., 2022; Digesa et al., 2023; Labeau et al., 2021) and could be cautiously used in the sample size calculation of a future trial. We also found four of the five (80 %) sacral PI developed in the intervention groups with higher sacral ICU-PI stages in the Mepilex group. This must be cautiously interpreted within the pilot nature of the study and small sample size which were underpowered to detect any difference between the intervention and control group participants. This is particularly true when the number of events is also relatively small. In general, any relationship between interventions and events that may truly exist will not come to realization when the sample size is very small, and the number of events is few like in our case. For example, when we toss a coin only a few times the frequencies of the head and tail may not be equal. So, a future sufficiently powered larger trial is warranted to be certain of the relationship between the interventions and sacral ICU-PI incidents. This is particularly important given that current evidence shows sacral prophylactic dressings can reduce PI events in ICU patients compared to standard care (Lovegrove et al., 2022), contrary to our pilot findings. Following Good Clinical Practice, any future clinical trial would have an established data safety monitoring committee of independent experts to examine the interim data, sacral ICU-PI incidents, and adverse events at various intervals to ensure the interventions are not linked to increased PI events (National Health and Medical Research Council, 2020).

Limitations

Participant eligibility was impacted by our ICU LOS greater than 48-hour criterion. In a future trial, we anticipate reducing this to 24-hours will result in increased participant eligibility and subsequent recruitment.

Conclusions

Following rigorous protocol evaluation, a larger multisite RCT appears feasible with minor modifications to the exclusion criteria and the collecting data on PI prevention strategies. A major strength of this study was recruiting ICU clinicians and training them as RAs. Their local knowledge and expertise enabled them to seamlessly navigate the ICU context and contributed to building research capacity within the ICU and health service. Rigorous comparative effectiveness evidence on prophylactic sacral dressings is needed so clinicians, managers and policy makers can make informed practice decisions based on performance, preference, and cost-effectiveness.

Trial registration

Australian and New Zealand Clinical Trial Registration number: ACTRN12620000875909p and WHO Universal Trial number: U1111-1252-8897.

Ethical statement

The study received human research ethics approvals (Gold Coast Hospital and Health Service [HREC/2020/QGC/64906]; Griffith University [2021/036]) and was conducted in compliance with relevant laws and institutional guidelines.

CRediT authorship contribution statement

Sharon Latimer: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Rachel M. Walker:** Writing – review & editing, Methodology, Conceptualization. **Wendy Chaboyer:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Lukman Thalib:** Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Fiona Coyer:** Writing – review & editing, Methodology, Conceptualization. **Jodie L. Deakin:** Writing – review & editing, Methodology, Conceptualization. **Brigid M. Gillespie:** Writing – review & editing, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Professor Fiona Coyer holds an educational consultancy with Molnlycke Pty Ltd.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.iccn.2024.103746.

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